Association of New Zealand Advertisers (ANZA)

29 Customs Street West, Auckland Central, PO Box 9348 Newmarket.
Executive Director, Jeremy Irwin Tel: 09 300 5932, 021 775 083,
anza@anza.co.nz

Direct to consumer advertising of prescription medicines - part of a well functioning democracy and economy

July 9, 2004

Introduction

The Association of New Zealand Advertisers (ANZA) and the Researched Medicines Industry members want to retain the current regulatory advertising regime for Direct to Consumer Advertising (DTCA), which is effectively supplemented by industry self-regulation.

The Health Minister wants to ban DTCA of branded prescription medicines and adopt the Australian policy of generic advertising, which permits Disease State Awareness (DSA) advertising. The legislative vehicle may be the Bill to create the Trans Tasman Therapeutic Agency.

The Case for DTCA

1. DTCA is part of the rich fabric of a well functioning democracy and market economy, where consumers and business are free to talk with each other through the mass media. Under the Bill of Rights Act 1990, New Zealanders are free to communicate and receive messages about products, services and other matters, provided any communication does not breach a law such as defamation, or is otherwise banned for compelling public interest reasons. In the case of DTCA, no such reasons have been advanced.

2. Consumers therefore have a right to know what medicines are available to them and not to rely solely on their GPs to tell them. This is a consumer rights issue. Health options are too important to be left to the politicians and health professionals alone.

3. DTCA is beneficial because it results in some people seeing their GPs about medical problems they would not otherwise raise, and thereby

improving their health prospects. Research by the US Federal Drug Administration and Massey University academics Dr Lynne Eagle and Associate Professor Janet Hoek, shows that people typically ask their GPs about DTCA products while making a regular visit.

The 2003 Janet Hoek survey of 418 consumers found that: 56% said it "makes people more aware of options"; and 51% said "leads to more informed discussions". The same survey found 76% supported retaining DTCA, with 59% wanting tighter self-regulation. Only 21% supported a total ban on DTCA and replacement with a Government funded independent health service.

4. DTCA involves the promotion of Government approved as well as unfunded medicines that help people live longer and improve the quality of their lives. Why would a Government want to deny an opportunity to make consumers aware of products they may not know even exist?

5. Global circulation of publications and the internet make controls over information increasingly less practical. Knowledgeable consumers can use the web to find out about medicines or services that might help them regardless of what any Government does. A concern is that web-based information from unreliable sources may actually misinform the public on the proper or effective use of medicines. A ban on traditional New Zealand media carrying DTCA would be an attack on only one form of communication.

6. DTCA is particularly helpful to those people who have less access to the relevant publications and the web, which are usually the less advantaged. A ban on DTCA would be a form of discrimination against these people.

7. Claims that an advertisement does not provide all the information some individuals see as desirable is no reason to ban that advertisement or that type of advertising. It is common knowledge that advertisements are not, and were never intended to be, comprehensive information resources about a product or service. That is not their role.

8. Some people want to deny consumers knowledge about products that might help them, because they think "doctor knows best", which may not always be the case. DTCA is only a threat to doctors who want to control the information flow to patients, thereby limiting discussion of all options.

9. If those promoting a ban on DTCA are successful, where will they and the government stop? What about banning news items on new medicines, or speeches by representatives of pharmaceutical companies or even public lectures by academics associated with them? Some of these suggestions have been made by advocates.

10. It is totally illogical for instance to ban medicine advertising for obesity when advertisements for weight reduction programmes can be advertised. Health professionals and companies can advertise other treatment and products, including pharmacy only products and complementary health products, that purport to help consumers improve their health and well being.

11. Contrary to misleading claims by some, there is no negative impact on the Government's budget. Firstly, most of the medicines advertised are not subsidised; secondly, GPs do not generally issue prescriptions where they are unnecessary, and third, Pharmac is adamant that it has never acquiesced to public pressure to fund any specific medicine(s).

12. DTCA is regulated by the Government and the industry in a way that ensures consumers are given accurate information and appropriate warnings about warnings and side effects and, where appropriate, that there will be a cost.

13. The Government wants to foster the development of a New Zealand-based biotech industry for which pharmaceutical companies play a vital partnering role. As Pharmac rarely makes new medicines widely available to the public, and countries such as Australia provide higher subsidy levels per capita, it is necessary for the pharmaceutical companies to be able to market medicines directly.

    Banning DTCA would send a message that the Government is hostile to the pharmaceutical sector as a whole, including any biotech development. Although the Government may see the biotech industry and medicine policy as separate matters, pharmaceutical companies take all factors into account when making investment decisions. Continuing with DTCA would help create a more positive attitude towards investment by pharmaceutical companies in New Zealand's biotech industry and research.

NZ situation – how Government and self regulation actually works

In New Zealand DTCA is permitted by the Medicines Act. The Act and Regulations set out the mandatory information, which must be included in all DTCA advertisements. In addition, the Advertising Standards Authority (ASA) Code for Therapeutic Advertising requires a high standard of social responsibility as well as mandatory information. In interpreting its Codes, the Advertising Standards Complaints Board (ASCB) requires "serious adverse effects information be obvious to the reader, viewer or listener"

To ensure compliance with the ASA's Codes, the Therapeutic Advertising Pre-vetting System (TAPS) prevets all advertisements prior to publication or broadcast. It is significant that only one DTCA complaint was upheld in 2003 by the ASCB.

The Researched Medicines Industry (RMI) Code of Practice also regulates the pharmaceutical industry and its promotional and marketing activities. The RMI Code is consistent with the ASA Code but also imposes additional requirements and limitations. The RMI Code was revised mid-2003, and the rules relating to DTCA were reviewed and expanded to reinforce requirements for social responsibility and balance. If RMI members breach the industry code, they can be fined up to $80,000 for serious breaches. The TAPS adjudicators also ensure compliance with this Code.

All advertisements for pharmaceutical products are required to be reviewed by the Therapeutic Advertising Prevetting System's (TAPS) independent adjudicators. Their responsibility is to advise advertisers on advertising content and use best endeavours to provide compliance assurance to the media. Media will not accept advertisements unless they have been reviewed by TAPS.

Any member of the public, Government agencies or competitors can complain to the ASCB about any advertisement in any media. If a complaint is upheld, the parties are requested to remove the advertisement. There is 100% adherence to this request.

Public health campaigns, such as immunisation against rubella, must also meet all of the requirements and are subject to complaint.

Australian situation

In Australia DTCA is prohibited, but remains under review. Prescription medicine advertisements are only allowed to be directed to health professionals. As a consequence, Disease State Awareness (DSA) advertising has evolved for consumers, which will incorporate many of the New Zealand features, including TAPS and Delegated Authorities prevetting.

There are three kinds of DSA advertising in Australia.

Disease awareness campaigns, which have the objective of raising awareness regarding specific diseases, including public health campaigns. An immunisation campaign for rubella is an example.

Unbranded advertising which promotes the use or supply of a medicine by inviting the consumer to seek further information about their condition and its treatment from a doctor.

Generic advertising, which promotes the benefits of a particular category of medicine but is not related to any particular branded product.

The Therapeutic Goods Advertising Code does not have jurisdiction over DSA advertising of prescription products. Therefore, they are not subject to an advertising code although the general law may apply, but this is a grey and untested legal area. There is no right of complaint to the Complaints Resolution Panel (CRP), which is the New Zealand equivalent of the ASCB.

In short DSA advertising is virtually unregulated and is not subject to advertising codes or complaint. In addition, unbranded or generic advertising fails to raise awareness of potential risks associated with use of these medicines, an issue that has been continually raised in New Zealand-based consumer research on DTCA (see Massey University research).

Australian expenditure on medicines compared with New Zealand

The Australian government agency PBS, spent A$4,892 million on prescription medicines for the year ended March 31, 2004. This compares with Pharmac's June 2004 year budget of NZ$566 million for prescription medicines. This means, having regard for the population difference (20 million versus 4 million), the Australia Government is spending nearly twice as much per capita on medicines as does the New Zealand Government. It is hardly surprising that many New Zealanders are buying unsubsidised prescribed medicines, some of which are advertised to consumers.

Therapeutic Advertising Harmonisation

Work has been underway for two years on harmonising the Therapeutic Advertising Rules in Australia and New Zealand. In 2002, Mike Codd carried out a Review and made recommendations for a harmonised system, suggesting that the New Zealand system be used as the model. But as the Codd report noted: "The policy issue of whether prescription medicines should or should not be advertised directly to consumers is specifically excluded from the Reviews terms of reference."

In 2003, an Interim Advertising Council (IAC) was established chaired by Mike Codd. There has been substantial progress. The IAC originally had 14 members, which is now expanded to 18 members. A Joint Code is near completion. The New Zealand complaints system and TAPS system will remain intact and integrated into the new harmonised system. Australia will establish new systems, which incorporate many of the New Zealand features.

The IAC has worked on the basis the two countries would retain different policies regarding DTCA, but sought otherwise to harmonise regulation of advertising rules.

Jeremy Irwin, who administers ANZA's prevetting system (TAPS), Glen Wiggs (ASA), Susan Martindale (MOH) and Lesley Clarke (RMI) are on the IAC.

Global situation

The USA permits DTCA subject to Food and Drug Administration (FDA) regulation.
In Canada, the UK and Europe, DTCA is not permitted but there is considerable debate about lifting these restrictions on advertising.

Changes in EU regulations have recently permitted information based on Disease Awareness Campaigns (DAC), which are usually mounted by pharmaceutical companies in conjunction with patient associations. The use of DAC has been included in UK legislation. Strict regulations of DAC does not permit specific brand name mention. The UK is the leading market in Europe for the use of DACs.

The European Commission has recently been considering a liberalisation of drug advertising rules and in July 2001 proposed a relaxation of the rules of the Advertising Directive that bans DTC advertising. The proposal considered making available accurate patient oriented information and included a five year pilot programme followed by a review, allowing pharmaceutical companies to promote medicines to three long term chronic

conditions with a high patient information requirement – Aids, Diabetes and Asthma.

The Commission was not proposing to legalise DTCA but to allow patients to request information from the industry about their condition and treatment options. The proposal was rejected in the European parliament. In June 2003 Ministers also rejected the proposal. The debate is continuing.

Was the report by Professor Les Toop et al on DTCA, an report academic or political exercise?

It should be noted that:

- The $12,000 Colmar Brunton survey of public opinion used in the Toop report was paid for by Pharmac.

- Pharmac supplied extensive information to the Toop researchers and altogether more than 600 pages of information and communications were exchanged between them. Pharmac re-drafted some sections of the report for consideration by Toop.

- In a review of a complaint about the Toop survey of GPs, Professor Donald Evans (Director Bioethics Centre, University of Otago, said the survey was not "research". He said: "**I concluded that this proposed report did not convey the impression that the survey was a research project but rather clearly demonstrated that it was an explicit gathering of evidence to support a protest to Government about DTCA".**

- A "protest to Government" like the Toop report should be judged on its merits, and not seen as 'bible' on the subject because of the academic qualifications of its authors. (See critique of the Toop report by Barrie Saunders, Saunders Unsworth, on the www.asa.co.nz website.

Appendix

Critique of case against DTCA

Some key arguments against DTCA as outlined by New Zealand commentators and our responses are as follows:

Claim 1: DTCA does not provide objective information on risks, benefits and options to assist people to participate in healthcare decisions.

Response: DTCA provides accurate information that helps people. The advertisements do not purport to provide all the information that is required, which is why they typically suggest patients discuss the matter with their GP. Adverse effects are noted. Modern consumers know the advertisements do not include all the necessary information. If all advertising was required to meet the test being applied to DTCA the Government would:

- Ban all political party advertising on the grounds that much of it is unbalanced and fails to present all the relevant facts, which could lead to the election of a government most people don't like;

- Ban the advertising of state run Lotto on the grounds that encourages people to gamble without explaining the poor odds, and when many may not be able to afford it;

- Ban all retail advertising on the grounds that it encourages some people to buy goods they may not need and cannot afford.

- Ban the advertising of all private schools on the grounds that they don't explain there will be a state school alternative, which may be of similar quality.

Claim 2: Consumers need greater access to reliable independent information on prescription medicines.

Response: There is much information available from the Ministry of Health's Medsafe website, and there may be a case for more. However this has nothing to do with DTCA – there is no reason why New Zealand should not have both DTCA and a government provided information service.

Claim 3: DTCA has a negative effect on health funding, which may create an inequity in health funding – due to increased GP visits and increased prescriptions.

Response: The meaning of this statement is not clear but it has been made in a New Zealand context. It should be noted that, first, Pharmac's expenditure on medicines has been held well below 1.5% for the past decade, unlike other OECD countries where access to effective medicines is greater. Second, most medicines advertised are not subsidised, and as such do not impact at all on Pharmac's budget. Third, to the extent that DTCA leads people to purchase the advertised pain killer for which they have to pay, there is less pressure on the Pharmac subsidised alternative.

Whilst critics contend that DTCA encourages patients to visit their GP, research actually shows that most patients raise DTCA matters while on an already scheduled visit. There is no research that shows the visits inspired by DTCA are a misuse of resources or a waste of money by the patient. Even in cases where the patient is not provided with a prescription for the medicine discussed, the visit should still be considered as contributing value to the patient/physician relationship.

Claim 4: DTCA leads to switching to medicines that are more expensive and not necessarily superior.

Response: No examples of this with detailed costings have been provided. As noted the total Pharmac budget has grown by less than 1.5% pa over the last 10 years. Where medicines are subsidised and advertised, as in the case of asthma inhalers, the total cost has remained static over the past four years. Wayne McNee (September 23, 2003) said that the total cost of asthma inhalers was: $51,897,776 in the June 2000 year and $50,479,655 in the June 2003 year - a small reduction over four years despite more prescriptions being issued and extensive advertising.

There is no evidence that Pharmac permits GPs to switch to more expensive medicines when that is not appropriate. One concern is that Pharmac justifies their use of reference pricing by indicating that medicines are "the same or similar." That statement is in fact self-contradictory. If a medicine is deemed "similar", then it is in fact not the "same."

The broad application of Pharmac's philosophy also does not recognise that when a patient responds better to one medicine over another, then that medicine is in fact superior to the other. When a patient is able to be more compliant with a medicine because it simplifies dosing schedules, and thus better in control of their disease, then it is superior.

The concern is that Pharmac typically uses its own words in very selected contexts to suit its own purpose. Unfortunately, that is not how clinical medicine is practised. Nor is clinical medicine practiced only on the cost of medicines, which seems to be the mainstay of Pharmac's attitude and philosophy.

When asked "why would Pharmac would ever subsidise a drug that was more expensive than alternatives if it did not consider the new drug to be more effective", Pharmac CEO Wayne McNee said in a letter dated September 23, 2004, that, "Pharmac would consider subsidising a new drug in the above situation if the new drug was part of a "cross deal involving more than one pharmaceutical, where the overall effect was to make savings and/or improve health outcomes".

The salient message here is, once again, that Pharmac's only real focus is around cost. Their "deal cutting" use of loss leaders in negotiating drug subsidy prices is also anti-competitive by disadvantaging another company that has a medicine in the same therapeutic class as the referenced price medicine, but not fortunate enough to have another medicine with which to trade off on price. As this has been a continued practice by Pharmac for many years, it is no wonder that New Zealand is viewed as a hostile environment in which to conduct business.

Claim 5: DTCA leads to a measurable increase in dispensing

Response: It is bizarre to see this as a problem unless one assumes it is better to have patients or untreated or that GPs are so weak and unprofessional that they will issue prescriptions to anyone who asks. There is no evidence that either is the case. On the positive side, any DTCA stimulated increase in prescriptions means more New Zealanders are receiving appropriate treatment. Again, while dispensing may be up, the Pharmac budget has grown over the last decade by less than 1.5% pa.

Claim 6: DTCA has a negative effect on the patient-clinician relationship because patients place undue pressure on GPs to prescribe DTCA medicines.

Response: Clearly some GPs are uncomfortable with patients visiting in the expectation they will get an advertised medicine.

However:

- Some GPs make good use of the visit to turn the discussion to either better ways of handling the problem or deal with another issue not raised by the patient – see research papers by Massey University academics Dr Lynne Eagle and Associate Professor Janet Hoek;
- Informed patients are a reality of modern life and DTCA is just part of the move away from the passive acceptance of what doctors say;
- GP changing to get a DTCA medicine is very rare;
- While a GP might feel under pressure from some patients to prescribe a DTCA medicine, there is no evidence to suggest this is a very common experience;

- There is no evidence GPs are generally unwilling to handle such situations;
- If GPs are uncomfortable dealing with informed patients, their professional associations should provide them with some extra briefing and/or training on how to address the likely increase in the population of more well-informed patients that will present at their practises..

Claim 7: DTCA compromises patient safety because advertisements generally focus on new medicines which maybe more risky.

Response: Medicines approved in New Zealand go through a rigorous review of the medicine's safety and efficacy. Where there are serious safety concerns about a medicine, it is not approved. Sometimes newer medicines are actually better in efficacy and/or safety than the older alternatives. In other situations, despite the contention that new medicines are merely "me-too" versions of older medicines, patients will be seen to respond to one medicine within a therapeutic class and not to another within the same class. It would be wrong to deny consumers knowledge of newer medicines – their GPs can always provide an alternative perspective if that is warranted.

Claim 8: DTCA promotes the medicalisation of normal health and ageing processes.

Response: Defining normal health and ageing processes is not a simple matter. Dying in childbirth was once accepted as normal as was dying under the age of 50. Erectile dysfunction can create relationship issues, and may also be a marker for underlying diabetes or cardiovascular disorders. In the case of obesity, any DTCA that results in a patient visiting their GP actually provides the physician with the opportunity to establish an effective, comprehensive treatment regime that may include alternatives to medicines, such as exercise and a dietary changes, which would improve their overall health outcomes.

Claim 9: There is increased opposition to DTCA amongst consumer and professional groups overseas.

Response: In countries where DTCA is not allowed, the opposition of some groups exists only because of discussion or proposals that rules be relaxed, and the policy trend is towards liberalisation. In the USA where DTCA is allowed, there are consumer groups that are supportive and those that are not. New Zealand has unique policies in many areas, and the fact similar issues are debated overseas is not a reason for New Zealand to change. As a proponent for a smaller, more efficient, and knowledge-based society, wouldn't it make more sense for New Zealand to show the rest of the world how DTCA can and should be effectively implemented, rather than spitting the dummy?

Interestingly, research on DTCA conducted by the US Food and Drug Administration (FDA) has shown that there are few if any risks associated with DTCA, and in fact, that DTCA benefits healthcare by increasing the flow of patients into doctors' offices for treatment of diseases that might otherwise have gone undiagnosed and/or under treated.

Claim 10: There is increasing opposition to DTCA amongst professional and consumer groups in New Zealand.

Response: Consumers: There is no organisation that can speak on behalf of all consumers, so measurement of public opinion can only be done by surveying public opinion. Independent surveys undertaken by Massey University show that the New Zealanders find DTCA helpful and they would like more information on risks or side effects. The research does not support a ban of DTCA.

The Consumers Institute (March 2003 Consumer) is on record as saying that industry controls on DTCA are not tough enough and that "the ads need to be factual, informative and comprehensive enough to spell out the important limitations of the medicine. If the industry resists, then a ban must be a real option". The Institute has yet to have a dialogue with the industry on this subject to understand what measures have been put in place to address their issues, (i.e, the rewriting of the RMI Code of Practice).

"New Zealand Consumers are fortunate – they have laws supporting their right
to make informed choices. This is why the fuss over the marketing of prescription drugs to the public is unnecessary… The fact that patients are now learning of treatments through advertisements should make no difference.
The information contained in such advertisements is theirs of right." Robyn K Stent
NZ Health & Disability Commissioner, 19 December 1998

It is true that some professional medical associations favour a ban. Whether this reflects the views of their members is not known, nor whether any serious research by them was done on the impact of DTCA on the health of New Zealanders.

The views of the consumer should always be given more weight than the provider, particularly in the case of the freedom to communicate; a much higher hurdle must be cleared before restrictions are imposed. If the Government legislated in response to every public opinion survey, New Zealand would cease to have a functioning economy and society.

Claim 11: Some patients will get expensive medicines prescribed which they cannot afford, when better non medicinal alternatives exist.

Response: This assumes that both the GP and patients are stupid and the GP is also unethical. There is no reason to make such an assumption.