

Editorial

The impact of advertising prescription medicines directly to consumers in New Zealand: lessons for Australia

Les Toop, Professor and Head of Department, and Dee Mangin, Senior Lecturer, Department of Public Health and General Practice, Christchurch School of Medicine and Health Sciences, University of Otago, Christchurch, New Zealand

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Advertising prescription medicines directly to consumers is allowed only in the USA and in New Zealand. Its effectiveness is attested to by the growth in advertising expenditure. More than US\$4 billion was spent on direct-to-consumer advertising in the USA in 2004 and tens of millions are spent annually in New Zealand. As in the USA, direct-to-consumer advertising is 'allowed' in New Zealand by default rather than by design. Regulators failed to, or chose not to, enact legislation to stop it and the medical and public watchdog groups did not complain loudly enough until it was too late.

Freedom of speech, commercial freedom, providing valuable information on new medicines to consumers, and countering medical paternalism are the main arguments put forward by the proponents of direct-to-consumer advertising. These are summarised in a paper by the New Zealand Marketing Association which also contains an interesting appraisal of the current Australian situation. 1 Unfortunately, partial and

In this issue...

From this month, patients with hepatitis C will no longer require a liver biopsy before accessing subsidised treatment. Robert Batey suggests how patients can be managed following removal of this restriction on prescribing the recommended regimen of antiviral drugs.

While hepatitis C affects thousands of Australians, obesity is much more prevalent. Ian Caterson reminds us that drug treatment is just part of the management.

Raising awareness of treatments for obesity has been the objective of advertising campaigns in Australia. Across the Tasman there are fewer restrictions on advertising. Les Toop and Dee Mangin alert us to the impact that directly advertising prescription drugs to the public has had on New Zealand. They are concerned that a trans-Tasman regulatory agency will not curb direct-to-consumer advertising.

unbalanced misinformation, which is the hallmark of New Zealand's direct-to-consumer advertising, is promotion clearly designed to drive choice rather than inform it.

Four years ago New Zealand general practitioners were abruptly awoken to the effectiveness of direct-to-consumer advertising. Overnight they had to cope with an unexpected and unwelcome increase in workload. Patients using the leading brand of beclomethasone appeared at surgeries in droves asking to switch to an orange inhaler (fluticasone), as a television advertisement had told them that their brown inhaler was to be withdrawn in a few weeks, to protect the ozone layer. In the view of many prescribers, the television advertisements contained several inaccuracies and raised patient anxiety unnecessarily as neither patients nor many general practitioners realised that generic beclomethasone would continue to be available. A senior company official would later admit that the timing of this campaign was chosen for marketing rather than environmental reasons. In particular, a generic equivalent to the company's inhalers was in the wings.

Many general practitioners were incensed at being pressured to switch well-controlled patients to what they considered to be a drug with little or no added therapeutic benefit.² Perhaps more worrying, the longer-term health effects of a near doubling of average daily doses of inhaled steroids (many prescribers seemed unaware of the potency of fluticasone) are yet to be quantified.

There was also a significant increase in cost to the New Zealand taxpayer from the switch in prescribing driven by direct-to-consumer advertising. At the time, fluticasone carried a premium on the equivalent dose of beclomethasone. In addition, the increase in effective dose by many prescribers not making the 2:1 switch in dose increased this price differential and the overall subsided cost. The true cost will never be made public as there was a confidential, out-of-court settlement days before a Fair Trading Act case (initiated by the Pharmaceutical Management Agency of New Zealand to recover the costs to the health budget) was due to start in the High Court.

The increase in workload from the television campaign was exacerbated by the start of a counter direct-to-consumer advertising campaign by a rival company. This company promoted its own red combination inhaler which the advertisements assured would 'kick asthma' and 'work better than your brown or orange inhaler'. Some general practitioners reported patients with well-controlled asthma presenting in quick succession, first demanding to switch to the orange inhaler and then asking for the red one!

A very brief television campaign for oral terbinafine for onychomycosis resulted in a rapid doubling of national prescription sales. Some general practitioners reported several patients appearing in the same surgery demanding treatment for minimal nail discolouration. Many general practitioners gave up the unequal struggle of repeatedly spending 15-20 minutes explaining why prescribing a modestly effective, but very expensive (to the taxpayer) and potentially hepatotoxic, drug for a minor cosmetic problem broke most of the principles of rational prescribing. It is easier after all just to write the prescription and keep the patient happy. Indeed compliance with requests seems to be the common response. Surveys of consumer experiences both in New Zealand and in the USA consistently show that when a patient asks for a specific drug by name they receive it more often than not.^{3,4,5}This occurs even when the prescribers report they would not have prescribed the drug had it not been requested.3,4

In 2002, the heads of three of the four Departments of General Practice wrote to general practitioners setting out their intention to lobby for a ban on direct-to-consumer advertising and asking for colleagues to share their experiences. Within days more than half of all the general practitioners in New Zealand responded. The advertising and pharmaceutical industries were incensed and actively tried to discredit this advocacy.2 Four out of five general practitioners writing back felt negatively about direct-toconsumer advertising. This feeling is reflected in the statements supporting a ban issued by all of the main New Zealand health professional bodies and a number of consumer groups.³The then Health Minister repeatedly stated a desire to heed this advice and to ban brand direct-to-consumer advertising. 6The New Zealand cabinet supported exploring this through the trans-Tasman harmonisation process. Whether that promise can be fulfilled may now rest with yet another round of public consultations.

Even if brand advertising can be banned via the trans-Tasman agreement, both countries (and many others) will still be faced with the growing problem of regulating 'disease awareness' advertising which is seen by many as direct-to-consumer advertising by the back door.⁷

The Australia-US FreeTrade Agreement could be a step towards less regulation in Australia. The Australian Consumers' Association website lists some of the tricks used to circumvent the current Australian regulations, with several examples of

back door direct-to-consumer advertising.⁸ All of this would be fine if direct-to-consumer advertising actually informed consumers, but the evidence suggests it does not. The recent and ongoing debacle with COX-2 inhibitors and the increased harm resulting from the extensive and misleading direct-to-consumer advertising in the USA have reawakened calls for stricter regulation of drug promotion around the world.

New Zealand has adopted a system of 'self-regulation' for all drug promotion. This includes a much publicised, industry-run, pre-vetting service, the Therapeutic Advertising Pre-vetting System (TAPS). On the strength of TAPS, central regulators (Medsafe) have relinquished any active monitoring role. As expected, given their diametrically opposed perspectives, the pre-vetting process is simultaneously lauded by the industry and decried as ineffective by those with a public health focus. It is very brief and importantly does not involve any technical pre-vetting of the accuracy or balance of the scientific basis for the claims. Larger companies can, on payment of a fee, apply to pre-vet their own advertisements.

Complaints about advertising to consumers can be made to an industry-funded advertising standards authority complaints board.* The identity of complainants is publicised and the process can be daunting for individual consumers and organisations alike.9 Penalties for breaching the code are limited to withdrawing advertisements, usually after the offending material has had its impact and finished its run. Direction to publish corrective statements is rare. The New Zealand pharmaceutical industry organisation also has its own code of conduct on promotion which considers complaints about all promotion of medicines. This can impose minor financial penalties which are occasionally invoked, usually following a complaint from a competitor. The recently proposed advertising regime under the joint trans-Tasman agency developed by the Interim Advertising Council¹⁰ will in our view be ineffective without a mechanism for independent technical and scientific pre-vetting (very expensive), tight monitoring and stiff penalties for violations. Without these three crucial components we have little confidence that anything will change, with partial, unbalanced and misleading promotion predominating. It seems unlikely that anything will really change while the policy of user pays and self-regulation of medicines promotion remains. Neither self- (New Zealand) nor central (USA) regulation has been able to control direct-to-consumer advertising. Australia would do well not to let the genie out of the bottle. In the two countries where no one thought to provide a cork it is proving very difficult to get it back in. It is important that prescribers who are at the sharp end of direct-to-consumer advertising make their views known now, before the lobbyists influence

the politicians to further liberalise an increasingly hands-off

See www.asa.co.nz for a description of the Advertising Standards Authority, including TAPS

approach which allows industry to set its own standards.

In summary, what both New Zealand and Australia need is greater and more accessible independent consumer health information, not impossible to regulate, industry-sponsored direct-to-consumer advertising.

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Letters

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Eplerenone

Editor, - I read with interest the new drug review of eplerenone (Aust Prescr 2005;28:130-1). This review contains a number of statements that require clarification.

First, it is stated that gynaecomastia and breast pain still occur with eplerenone (as has been a major adverse effect of spironolactone). This is a somewhat disingenuous interpretation of the data as in fact no study has shown an excess of these events with eplerenone compared to placebo. As with any adverse effect, there is a spontaneous background event rate that is not further added to by eplerenone therapy.

Next, it is implied that because spironolactone reduces relative risk of death by 30% in patients with severe heart failure it is a more effective drug than eplerenone, that 'only' reduced risk of death by 15% in post-myocardial infarction (MI) heart failure patients. Again, making comparisons regarding the impact of therapies across trials is poor science and tells us nothing about the relative merits of individual drugs because of the differing disease states and background treatments in the differing trials.

Finally, and most importantly, it is stated that spironolactone is well known and inexpensive and 'thus unlikely to be superseded until more data about eplerenone are available'. This statement clearly implies that the two drugs can be used interchangeably for the same clinical indication. Just as eplerenone should not be given to patients with severe heart failure (because it has not as yet been tested in such a patient population) the same is true of spironolactone