Can direct-to-consumer advertising of prescription drugs be effectively regulated?

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ABSTRACT

The government of New Zealand is currently considering a new Therapeutic Products Regulatory Scheme that includes how direct-to-consumer advertising (DTCA) of prescription drugs should be regulated. This article reviews three different types of possible regulation of DTCA: government regulation, industry self-regulation and a mixture of the two. Recent studies demonstrate that DTC ads in the US continue to be misleading and contain minimal if any educational value, despite governmental regulatory efforts by the Food and Drug Administration. Other regulatory models are equally unsuccessful at controlling DTCA. Available evidence suggests that DTC ads are commonly misinterpreted as trusted public health messages and are more likely to affect vulnerable subgroups of New Zealanders. Taken together with the international evidence that regulation has consistently failed to prevent the inappropriate promotion of prescription medicines, these findings suggest that DTCA is more likely to cause harm than benefit and should be banned.

New Zealand and the US are the only two developed countries where direct-to-consumer advertising (DTCA) of prescription drugs is legal. In New Zealand, DTCA developed because the Medicines Act 1981 did not specifically prohibit the practice;[1] in the US, it was enabled by a 1982 ruling by the Food and Drug Administration (FDA) that DTCA did not inherently violate FDA administrative law and regulations. In 1985 the FDA announced that it had sufficient power to adequately regulate DTCA while protecting public health.[2]

The New Zealand government has undertaken a number of reviews of DTCA. Following a 1998 inquiry, the government decided to keep a watching brief on DTCA and observe the effects of industry self-regulation before deciding on further action. The second review occurred in 2000 and, despite a majority of submissions supporting a ban or significant tightening of regulations, DTCA was once again allowed to continue. A third review took place in 2006, again with public consultations. More than half of the submissions taking a policy position advocated for a ban,[3] but legislation allowed DTCA to continue. According to the Minister of Health at the time, Annette King, the new proposed regulatory scheme would have better controls to ensure that consumers were provided with balanced and truthful information. King acknowledged that the Labour government would have preferred an outright ban but there was not sufficient support in parliament to achieve this.[4] (The legislation, part of an effort to harmonise the regulation of medicines between Australia and New Zealand, was ultimately scrapped.)

The draft Therapeutic Products Bill, currently out for consultation,[5] includes yet another effort to solicit public opinion about banning or regulating DTCA. The consultation document proposes to continue to allow DTCA subject to regulation by an independent authority, the nature of which is yet to be decided.

This review focuses on the extent to which DTCA can be adequately regulated and examines three options for doing so: direct government regulation, a mixture of government and industry self-regulation, and industry self-regulation alone. The first model applies in the US and Canada, the second reflects how both DTCA and promotion to doctors is controlled in New Zealand. There are no examples of pure industry self-regulation of DTCA and so we also briefly consider the extent to which industry self-regulation of pharmaceutical promotion to physicians has been successful in Sweden and the UK.

Quality of DTCA in the US

Television advertising

Studies looking at the three main forms of DTCA—broadcast advertising, print advertising and sponsored websites—have each found that the quality of information that they contain is seriously flawed. By far, the largest amount of money is spent on television advertising, about US $4 billion out of a total of $6.5 billion.[6] A review of DTCA ads airing on television between 2008–2010 concluded that 46/84 (55%) of the most frequently made claims were potentially misleading.[7] An earlier analysis of television ads found that while 82% made some factual claims and 86% made rational arguments for product use, only a quarter described the causes of the condition, risk factors or prevalence. Without an understanding of why health problems develop, patients are unable to develop strategies to modify lifestyle and other risk factors. In addition, more than half of the ads portrayed the product as a medical breakthrough[8] whereas in fact only about 11% of new drugs offer a substantial therapeutic improvement over existing products.[9]

Two more recent papers show continuing significant deficiencies in pharmaceutical ads; one included all English-language broadcast DTC ads for prescription drugs that aired in the US from January 2015 to July 2016.[10] No ads described drug risks quantitatively, whereas drug efficacy was presented quantitatively in 25 (26%) ads. Thirteen (13%) ads, all for diabetes medications, suggested off-label uses for weight loss and blood pressure reduction, despite off-label advertising being prohibited by the Food and Drug Administration (FDA). Few ads were fully compliant with FDA guidelines. In the most recent paper, Applequist and Ball[11] examined 61 ads that were broadcast during prime time in the US on four major cable television networks from July to October 2016. The ads largely showed how products can enable users to undertake more recreational activities and only 7% of ads presented alternatives to product use. Overall, despite existing regulations, televised American DTCA continues to promote prescription drugs inappropriately; it is apparent that the purported educative and public health role of such ads has taken a back seat to companies' commercial agendas.

Print advertising

Ads in magazines generally demonstrate the same problems as broadcast ads. In 67 unique drug ads that appeared in 1998 and 1999, two-thirds used emotional appeals and almost 90% described the benefits of the medication with vague, qualitative terms while only 13% used hard data. None of the ads mentioned cost.[12] Ads for bleeding disorders in a patient-directed magazine devoted twice the amount of text to benefits as compared to risks/adverse effects, and the information about the latter was more difficult to read. Based on appraisals by experts, only slightly more than one-third of the ads presented the claims fairly and accurately.[13]

Website advertising

DTCA websites were found to describe benefits on the homepage 82% of the time, whereas risk information was two clicks away in 75% of cases. While most websites had a direct link to benefit information in the main navigational button set on the homepage, only 8% of websites provided the same tool for risk information.[14] Industry-funded mental health websites were significantly more biased towards genetic and other biological causes of illness and towards medication than were sites that were financially independent of the industry.[15]

Failure of government regulation of DTCA in the US

The available evidence, summarised above, shows that effective regulation of DTCA has been virtually impossible to achieve in the US. Furthermore,

the number of FDA violation letters is decreasing despite a growth in the volume of DTCA[6] without any evidence that the quality of DTCA has improved. The reason for this decline is unclear but may relate to the under-resourcing of the FDA's Office of Prescription Drug Promotion which now receives nearly 100,000 promotional material submissions annually.[6] As of 2008 when the volume of promotion received by the FDA was three quarters of the present total, there were only 50 full-time staff and a budget of US $9 million.[16]

Government regulation of DTCA in Canada

The Food and Drug Regulations[17] prohibit advertising of prescription drugs to consumers that mentions both the name of the product and its indication, but starting in 1996 Health Canada has allowed 'help-seeking' advertising, where a condition is named and consumers are advised to see their doctor about a treatment. Since November 2000, 'reminder advertisements' for prescription-only medicines targeting the general public have been legal. A reminder ad is a form of DTCA that states the name of the product, but does not mention its indication or make health claims; this form of advertising now appears on television, billboards, in print advertising, and Canadian internet sites. A case study looked at 10 examples of DTCA involving eight different drugs that appeared to contravene the policy on DTCA and where complaints had been made to Health Canada.[18] Complaints often took years to be addressed and overall, Health Canada adopted a narrow approach to enforcement and ignored broader concerns such as off-label promotion, targeting of vulnerable groups and poor safety profiles of products. Only one enforcement tool was used, namely negotiation with the responsible company; fines, sanctions, requirements for remedial action or prosecutions have not been used.

Mix of government and industry self-regulation of DTCA and promotion to doctors in New Zealand

Regulation of DTCA

There are two laws that specifically deal with medical advertising: the Medicines Act 1981 and the Medicines Regulation 1984. In addition, DTCA also needs to comply with the general provisions in the Fair Trading Act 1986, administered by the Commerce Commission.[19] Besides legislative regulation there are also two self-regulatory systems. The self-governing Advertising Standards Authority (ASA), an amalgam of media and communication agencies and advertisers, has developed the ASA Therapeutics Products Advertising Code, while Medicines New Zealand, a lobby for research-based pharmaceutical companies, covers DTCA in its Code of Practice.[19,20]

Anyone can file a complaint about an advertisement with Medsafe, the New Zealand regulatory authority, but neither Medsafe nor the Commerce Commission proactively monitor DTCA; whatever monitoring is done only takes place after the ads have appeared. Moreover, the limited resources available to both organisations makes it very unlikely that there is any significant level of examination of ads.[19] As of 2001, the Ministry of Health could not recall ever having prosecuted a company for violating provisions about DTCA and in fact, at that point, it was referring complaints to the ASA as this was considered "more cost effective than prosecution".[21]

All DTCA in New Zealand needs to go through the the Therapeutic Advertising Pre-vetting System (TAPS) before it can appear in any media. TAPS was established by the Association of New Zealand Advertisers (ANZA) in 1999 to assist advertisers, advertising agencies and the media to comply with the ASA Advertising Code of Practice for therapeutic products and services.[22] There is no information about how the TAPS examiners are selected[19] and there is no regular prospective monitoring of the system.[23] ASA has set up the Advertising Standards Complaints Board (ASCB) to handle complaints about DTCA but ASCB has no authority to impose penalties on advertisers.[23] Although four of the members of ASCB come from the public, they are appointed by the ASA,[24] which is itself an industry body. In the past, the executive director of the ASA said that the organisation preferred voluntary compliance and an educational approach: "We concentrate on changing future behaviour rather than punishing past conduct".[21]

Non-members of Medicines New Zealand who file a complaint with its Code of Practice Standing Committee are required to pay a fee of NZ $7,500. Although members of the public can apply for a fee waiver there is nothing in the Code that guarantees that such a waiver will be granted and the prospect of having to pay that amount may discourage people from complaining.[20] The maximum penalty for violating the Code is NZ $80,000,[20] which may be considered to be the price of doing business.

Failure of regulation of promotion to physicians

Like DTCA, promotion to physicians in New Zealand is covered by a mixture of government legislation and industry self-regulatory codes developed by the ASA and Medicines New Zealand. Ma and Parkin analysed pharmaceutical advertisement claims targeting health professionals that were supported by randomised controlled trials (RCTs) cited in the advertisements. One in five times, the published paper did not support the promotional claim. Of 78 cited RCTs, only 14% had a low risk of bias, while 49% had an unclear risk and 37% had a high risk. Their conclusion was that a high proportion of advertisements failed to meet the regulatory requirement that required claims to be "valid and…substantiated".[25]

Industry self-regulation of promotion to prescribers in Sweden and the UK

Two of the strongest European self-regulatory codes are reputed to come from industry associations in the UK and Sweden. An analysis of antidepressant advertisements in Swedish medical journals between 1994 and 2003 concluded that companies failed to provide reliable drug information and that this failure may be attributable to lax oversight, combined with the temporal lag between advertisement and censure, and low fines for violations.[26] The ability of the self-regulatory codes in both countries to adequately monitor and control promotion was further called into question by an examination of complaints and rulings for the period 2004–2012. Fines for code violations averaged in total €447,000 and €765,000 per year in Sweden and the UK, respectively, equivalent to about 0.014% and 0.0051% of the total annual sales revenues of all pharmaceuticals, respectively. According to the authors, the prevalence and severity of breaches demonstrates a discrepancy between the ethical standard implicit in industry codes and the actual conduct of industry.[27]

Can DTCA be effectively regulated?

In light of the evidence presented about the problems of government, mixed, and self-regulation of DTCA, and considering the vigorous and evolving promotional strategies used by the pharmaceutical industry, it is unrealistic to expect that a revised regulatory system in New Zealand could ensure that commercially-driven DTCA can serve the public interest by presenting realistic and unbiased drug information.

The consultation document[5] is equivocal about whether in sum DTCA has positive or negative effects, but as Gleeson and Menkes note "Drugs promoted via DTCA are often early in their product lifecycle and sometimes subsequently manifest serious harms leading to market withdrawal".[28] What happened with rofecoxib (Vioxx) is a prime example of what Gleeson and Menkes refer to. It was introduced onto the American market in 1999 and one year later, Merck spent $160 million on DTCA to drive its use.[29] By the time it was pulled from the market in late 2004, the estimate is that in the US it was responsible for 88,000–140,000 excess cases of serious coronary heart disease.[30]

Conclusion

Further evidence regarding the impacts of DTCA on the health of New Zealanders indicates that these ads are commonly misinterpreted as trusted public health messages[31] and are more likely to affect vulnerable subgroups who are 'at-risk', ie, with poorer self-reported health status, older, less educated, lower income and ethnic minorities[32] and those with unhealthy lifestyles.[33] Taken together with international evidence that regulation has consistently failed to prevent the inappropriate promotion of prescription drugs, these findings suggest that DTCA is more likely to cause harm than benefit and should be banned.

Competing interests:
In 2015–2018, Joel Lexchin was a paid consultant on three projects: one looking at indication-based prescribing (United States Agency for Healthcare Research and Quality), a second to develop principles for conservative diagnosis (Gordon and Betty Moore Foundation) and a third deciding what drugs should be provided free of charge by general practitioners (Government of Canada, Ontario Supporting Patient Oriented Research Support Unit and the St Michael's Hospital Foundation). He also received payment for being on a panel that discussed a pharmacare plan for Canada (Canadian Institute, a for-profit organisation), a panel at the American Diabetes Association, for a talk at the Toronto Reference Library and for writing a brief for a law firm. He is currently a member of research groups that are receiving money from the Canadian Institutes of Health Research and the Australian National Health and Medical Research Council. He is member of the Foundation Board of Health Action International and the Board of Canadian Doctors for Medicare.
David Menkes serves on two New Zealand Government committees relevant to pharmacotherapy, and has been active in the International Society of Drug Bulletins (ISDB).

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