

Direct-to-Consumer Advertising of Prescription Medicines in New Zealand

A discussion paper

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Foreword

The United States and New Zealand are the only industrialised countries that allow direct-to-consumer advertising (DTCA) of prescription medicines. Spending on DTCA in the US has grown rapidly, from around \$US25 million in 1988 to an estimated \$US1.8 billion in 1999. Expenditure in New Zealand on prescription and over-the-counter DTCA is estimated to be \$48 million during 2000, up 41.7 percent on 1999.¹ DTCA on prescription drugs was up 23.6 percent in 2000 to around \$17.9 million.

New Zealanders and US citizens are exposed to prescription drug advertising via television, radio, magazines and the Internet, as well as to a range of 'patient education' promotional activities. The aim of all prescription drug advertising is to increase sales. The postulated 'side effects' of this advertising has forced the policy debate and raised questions about DTCA's impact on:

- ?? individual and public health
- ?? the appropriateness or inappropriateness of pharmaceutical use
- ?? the patient/doctor relationship
- ?? overall health care costs.

This paper reviews the policy debate on DTCA as it relates to New Zealand. The policy debate provided is not exhaustive but brings together the main issues and findings. The paper outlines the current policy for DTCA of prescription medicines and provides a range of options, which form a basis for comment by interested individuals and agencies on the future of DTCA of prescription medicines in New Zealand. Later work may examine the efficacy of DTCA of over-the-counter non-prescription medicines and alternative natural products. This will be decided once the review of prescription drug advertising has been completed.

The specific terms of reference are to ensure that New Zealand has a DTCA policy that is:

- ?? *in the best interests of New Zealand consumers*
- ?? *safe*
- ?? *as practicable and as cost-effective as possible.*

We would appreciate hearing any comments you have on the content of this discussion paper. A number of questions are posed throughout the document to help focus your responses. Comments on these and other relevant issues should be directed to:

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Please send your submissions by **14 February 2001**.

Note: Your submission may be requested under the Official Information Act 1982. If this happens, the Ministry of Health will release your submission to the requester. However, if you are an individual (as opposed to an organisation), the Ministry will omit your personal details from the submission if you include the following statement at the front of your submission and sign it:

'I do not give my permission for my personal details to be released to persons requesting my submission under the Official Information Act 1982.'

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1 Introduction

The purpose of this paper is to provide a basis for discussion, and to allow the opportunity for feedback on the issue of the appropriateness of direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand. This feedback will contribute to advice given by the Ministry of Health to the Minister of Health on whether there should be changes to the current regime of DTCA of prescription medicines in New Zealand, and if so, what these changes might be.

The paper is confined to an examination of DTCA of prescription medicines. The rationale for this is that prescription medicines are the most important in terms of their impacts on consumers and on the medical profession, and (possibly) the most important too in terms of interest to the drug manufacturing industry. Depending on the outcome of this process, the appropriateness of DTCA of over-the-counter products, both manufactured and natural, may be investigated.

In undertaking this review the paper:

- ?? reports on views held by stakeholder groups (Appendix 1)
- ?? reviews the current policies in New Zealand and elsewhere in the world
- ?? develops and analyses policy options
- ?? forms the basis for advice to the Minister of Health on policy options and their associated risks.

The definitions used are those given in the Medicines Act 1981 (see Appendix 2). Definitions of 'advertisement' and 'medical advertisement' taken from the Act are:

'Advertisement' means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of medicines or medical devices or the use of any method of treatment; and includes any trade circular, any label, and any advertisement in a trade journal; and 'advertising' and 'advertised' have corresponding meanings.

*'Medical advertisement' means an advertisement relating, or likely to cause any person to believe that it relates, to any medicine or medical device or any ingredient or component thereof, or to any method of treatment.*²

Q1. Do you consider there is a need for the Government to review the regulatory environment governing DTCA for over-the-counter medicines or preparations (manufactured or natural)? If so, why?

² Section 56, Medicines Act 1981.

2 DTCA of Prescription Medicines: The New Zealand and International Situations

DTCA for prescription drugs refers to promotional material transmitted via television, radio, magazines and the Internet, as well as to a range of 'patient education promotional activities' (such as disease-oriented advertisements, toll-free telephone numbers, information materials distributed by company-funded organisations, media reports generated by company-sponsored press conferences, and public meetings) generated for the purpose of marketing prescription drugs. In this chapter we look at the situation in New Zealand, and compare it with how a number of other countries deal with DTCA.

New Zealand

In the last two to three years the increasing use of DTCA on television and radio and in print in New Zealand has focused attention on the debate over its influence and led to calls for it to be banned.

Why did DTCA of prescription medicines develop in New Zealand?

The most likely reason for DTCA developing in New Zealand is the identification in New Zealand's Medicines Act 1981 of a permissive environment for DTCA, coinciding with growth internationally in DTCA. New Zealand has never explicitly prohibited advertising of prescription drugs to the public. The issue had not arisen until the last three to four years. DTCA has been much less extensive in New Zealand than in the US.

The extent of DTCA of prescription medicines in New Zealand

Table 1: Estimated DTCA prescription and OTC expenditure by media category \$000, during 2000

Press	Magazines	Television	Radio	Cinema	Total
3498	11,186	29,226	3,475	238	47,623

Source: Association of New Zealand Advertisers

DTCA of prescription medicines in New Zealand is a relatively new and growing phenomenon. Expenditure in New Zealand on prescription and OTC DTCA is estimated³ to be in the order of \$48 million during 2000, up 41.7 percent on 1999.

Table 2: Estimated DTCA expenditure on prescription medicines by media category, \$000, 1999 and 2000

Year	Press	Magazines	Television	Radio	Cinema	Total
1999	1,023	5,817	6,832	754	71	14,497
2000	986	5,384	10,905	649	0	17,924
% of total in 2000	5.5%	30.0%	60.8%	3.6%	0%	100.0%
% change 1999–2000	-3.6%	-7.4%	59.6%	-13.9%	-100%	23.6%

Source: Association of New Zealand Advertisers

Table 2 gives estimated spending details of DTCA on prescription medicines by media category during 1999 and 2000. The table shows that the greatest growth was in television DTCA, an increase of 59.6 percent in the year. Television advertising with 60.8 percent accounted for the bulk of DTCA spending. Overall DTCA of prescription products grew by 23.6 percent between 1999 and 2000 to around \$18 million. (This compares with growth in US DTCA of prescription drugs between 1998 and 1999 of 38.5 percent to around \$US1.8 billion.) In the period October 1999 to September 2000 46 prescription products were advertised on television. Of these 12 were fully subsidised and eight were partially subsidised on the Pharmaceutical Schedule (PHARMAC 2000: 3).

Regulation

New Zealand's DTCA regulatory framework relies on industry self-regulation, with a fallback to judicial action in the case of non-compliance. All advertisements must comply with the Medicines Act 1981 and Medicines Regulations 1984, monitored by Medsafe (a business unit of the Ministry of Health charged with ensuring compliance with the Medicines Act 1981 and the Medicines Regulations 1984).

Other legislation covering prescription medicine advertising includes:

- ?? the Commerce Act 1986, which establishes the legal competitive environment within which prescription advertisers operate
- ?? the Fair Trading Act 1986, which legislates against unfair advertising
- ?? the Misuse of Drugs Act 1975, Consumer Guarantees Act 1994, Privacy Act 1993, and Health Information Privacy Code 1994. These also impact on how the pharmaceutical industry markets and sells prescription drugs.

³ Association of New Zealand Advertisers, prepared by AC Neilson/Hunter Research.

Medsafe works closely with the pharmaceutical industry and the Advertising Standards Authority (ASA) to facilitate the development of self-regulatory mechanisms. This led the Association of New Zealand Advertisers (ANZA) to establish the Therapeutic Advertising Advisory Service (TAAS), which, from 1 May 1999, provided the pharmaceutical industry with advice and a voluntary 'pre-clearance' service (advice on whether proposed advertisements comply with legal and code requirements) for their advertisements on a user-pays basis.

The ASA introduced the Code of Therapeutic Advertising in September 1996 to assist the industry in adopting a consistent and responsible approach to therapeutic advertising. After two years the Code was reviewed and, after consultation, the current Code was introduced on 1 February 1999. It applies to all forms of therapeutic advertising and covers prescription and non-prescription medicines, medical services, complementary medicines, and food when a therapeutic purpose is claimed (ASA 2000).

An assessment of regulatory compliance for DTCA of prescription and non-prescription medicines published between 1 November 1999 and 7 February 2000 was completed by Medsafe in March 2000. The survey showed there was a 69 percent compliance rate for advertising of prescription medicines compared with 33 percent compliance in a similar survey in 1998. The improved result is attributed to the introduction and activities of TAAS. This result is encouraging, but, according to Medsafe, it needs improvement.

The industry associations representing both sectors have since committed to working with their members to improve compliance rates, and their effectiveness will continue to be closely monitored by Medsafe. Companies that publish non-compliant advertisements will be required to withdraw this material and will be referred to the relevant industry association for disciplinary action. Repeat offenders will be prosecuted.

As a result of the Medsafe assessment of compliance, the ASA developed and consulted on a proposal to pre-vet therapeutic advertisements in late August 2000. The principal elements of this proposal are:

- ?? TAAS would become TAPS (Therapeutic Advertising Pre-vetting Service).
- ?? All advertising pre-vetted by TAPS would be issued with a TAPS number. The media could then quickly identify compliance.
- ?? Large advertisements, new advertisements and advertisements with new concepts would be required to be pre-vetted by the industry's special advisor, who would issue a TAPS number.
- ?? Repeat advertisements with minor variations, but the central claim and TAPS requirements unaltered, could be subject to a delegated authority by the media/or the advisor.
- ?? TAPS could review, and if necessary revoke, any delegated authority.
- ?? All costs of TAPS would be borne by the industry.

The pre-vetting proposal was agreed to by the industry and introduced on 1 November 2000.

The previous review of DTCA in New Zealand

As a result of the growth in DTCA activity, specifically a high-profile advertising campaign for the anti-obesity drug Xenical, in 1998 the Minister of Health called for an inquiry into DTCA. The New Zealand Medical Association and individual health professionals had claimed that these advertisements put pressure on doctors to prescribe inappropriately. An IMS⁴ Health poll of 400 general practitioners with a 30 percent response rate found that 75 percent of respondents either wanted DTCA to stop altogether or to be decreased, 61 percent felt it created disharmony in the doctor/patient relationship, and 62 percent believed it was of no benefit to patients.

As a result of that inquiry, the then Government decided to keep a watching brief on DTCA of prescription medicines in New Zealand and to give the industry an opportunity to demonstrate a commitment to self-regulation (under the Medicines Act 1981), before deciding whether to continue with the permissive regime for DTCA under the planned Healthcare and Therapeutic Products Bill (which is to replace the Medicines Act).

United States

The US has never had any legislation specifically prohibiting advertising of prescription drugs to the public. The US Food and Drug Administration (FDA) directly regulates pharmaceutical advertising through the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act, which require advertisements to meet four conditions: they must not be false or misleading; they must present a fair balance of information about the risks and benefits of using the drug; they must contain facts that are material to the advertised product's uses; and in general, the advertisement's 'brief summary' of the drug must include every risk from the product's approved labelling (Henney 2000). The FDA has the authority to require an offending company to undertake corrective actions and (ultimately) to remove a product's marketing licence.

After the first DTCA advertising campaign of prescription drugs appeared in the early 1980s researchers began to question whether pharmaceutical advertisements could meet the promotional interests of the pharmaceutical industry and the health needs of the public. In response to the concerns of the public and manufacturers, the FDA asked the industry to suspend their prescription medicine advertising while it researched DTCA to assess its impact on consumers and, if necessary, to put appropriate reforms in place.

The American Medical Association and most of the consumer organisations and members of the public attending FDA public consultations during the moratorium were opposed to product-specific prescription drug advertising. DTCA was also controversial within the pharmaceutical industry. At a conference organised by the industry in 1984, nearly 80 percent of the pharmaceutical industry executives were opposed to DTCA, citing fear of increased product liability, increased marketing costs and lower profitability. However, in September 1985 the FDA ended the moratorium on DTCA satisfied that most of its

⁴ Formally known as Intercontinental Medical Statistics.

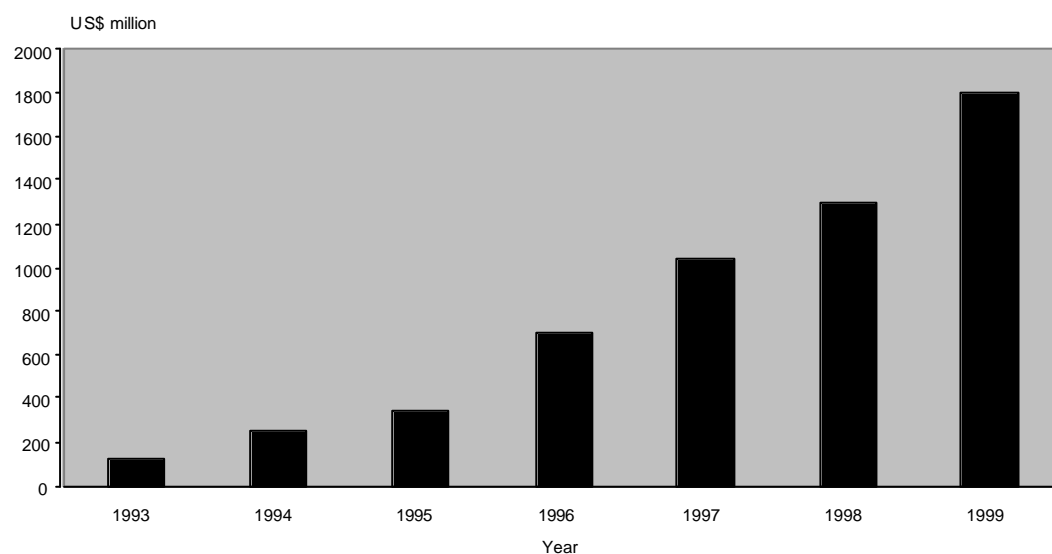
concerns had been met, and announced that DTCA would be regulated in a similar manner to advertisements targeting health professionals.

The FDA held a second set of public consultations on DTCA in 1995. Little new research evidence on the impacts of DTCA was brought forward. One significant change, however, was in the increased proportion of major companies supportive of DTCA and already engaging in this form of promotion. Another was the push for changes to the regulation of television and other broadcast advertising.⁵

In 1997 the FDA relaxed its rules governing broadcast advertising allowing omission of the 'brief summary'. Instead, it required manufacturers to state a product's major risks and provide additional sources of information: a toll-free phone number; an Internet web-site address; and simultaneous DTC print ads that included the brief summary or brochures in doctors' offices, libraries and stores.

This regulatory change led to a large increase in the amount of television advertising of prescription drugs, with over 30 drugs advertised in the following year and the majority of new DTCA spending focusing on television. Spending on DTCA in the US has grown rapidly, from around US \$25 million in 1988 to an estimated \$1.8 billion in 1999 (see Figure 1). Projections for 2000, are for expenditure growth to \$2.5 billion (Freeman 2000).

Figure 1: DTCA expenditure in the US, 1993–99



Source: Mintzes 2000: 5

The latest FDA announcement on broadcast advertising issued in August 1999 emphasised the need for balance in DTCA with equal time to be given to both benefits and side effects of prescription drugs advertised by brand name. Specific requirements include:

⁵ The industry had been pressing the FDA to relax its rules on broadcast advertising because regulatory requirements to provide the full 'brief summary' made full product advertising on television costly and unwieldy.

- ?? faxing of product labels to consumers is no longer an option
- ?? companies must broadly disseminate print advertisements during broadcast campaigns, so viewers can get detailed risk information in a way that does not threaten privacy
- ?? print brochures may only be used as a source of additional information for broadcast advertising to restricted audiences as it is difficult to disseminate them broadly
- ?? health care providers other than doctors and pharmacists can now be listed as sources of additional information
- ?? the requirements for telephone advertising have been clarified (Mintzes 2000).

In response to comments that the FDA's final guidance was inappropriate because of possible negative effects associated with DTCA the FDA advised:

FDA is unaware of any data supporting the assertion that the public health or animal health is being harmed, or is likely to be harmed, by the Agency's actions in facilitating consumer-directed broadcast advertising. FDA has repeatedly requested empirical data that would document the hypothesised effects – negative and positive – of DTC promotion on several factors related to public health. Despite years of print DTC advertising, no rigorous evidence has been presented to demonstrate that DTC advertising has had any of the hypothesised ill effects. In the absence of such data, FDA believed that the advantages of having a broadcast environment that would encourage communication of both the benefits and the risks of advertised products outweighed the postulated, but never demonstrated, disadvantages. In issuing the draft guidance, FDA again asked that research be conducted to document the effects of DTC promotion on the public health and animal health and specified that it would conduct an evaluation of such effects within 2 years of finalising the guidance (FDA 1999).

Canada

Canada is currently reviewing DTCA of prescription medicines as a result of the movement of advertising material across the US/Canada border. Although DTCA is not currently allowed under Canada's Food and Drug Act, the federal government is considering legislative changes to introduce it as part of a broader process of legislative renewal. Canadians are also exposed to cross-border prescription medicines advertising through US television, radio, magazines and the Internet, as well as through a range of promotional patient educational programmes from within Canada.

Regulation of pharmaceutical advertising is covered by the Food and Drugs Act, which requires that:

No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its composition, merit or safety.

The Act sets out a list of diseases for which treatments may not be advertised to the public, and states that prescription-only drugs may not be advertised to the public except for name, price and quantity.

Rx&D, Canada's brand-name industry association, regulates most forms of promotion aimed at health professionals through its Code of Marketing Practices. This covers information dissemination, free samples, continuing medical education, advertising displays, drug retailers, post-marketing surveillance, gifts and related promotional items, and market research.

Published advertisements of prescription drugs, in all forms, are subject to voluntary pre-screening by the Pharmaceutical Advertising Advisory Board, a semi-autonomous organisation with a majority of pharmaceutical and advertising industry board members, plus representatives of health professional associations, medical publishers and consumers.

Although the pharmaceutical industry cannot directly advertise prescription-only products to the public – with the exception of advertisements mentioning only product name, price and quantity – it can provide 'educational' information tied to specific products.

The Canadian federal health agency, Health Canada, initiated a regulatory review in 1996 and sponsored a consultative workshop to discuss DTCA in June 1996. The provincial governments, which are responsible for administration of health services, were opposed to the introduction of DTCA on the grounds that it might be a potential cost driver and that the effects of DTCA had not been sufficiently researched. Health Canada initiated a further round of consultations on DTCA in late 1998 as part of a broader discussion of renewal of Canada's health protection legislation, and a separate multi-stakeholder consultation on DTCA in April 1999. A White Paper outlining proposed legislative changes is being prepared, and this will include proposals related to DTCA.

Australia

Australia prohibits the advertising of prescription drugs to the public. Like the majority of other countries, Australia relies on industry self-regulation of promotion. The Australian Pharmaceutical Manufacturers' Association (APMA) Code of Conduct Committee is responsible for enforcing promotional regulations. The APMA's code specifies that:

Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only medicine is unacceptable. However, disease-oriented advertising is allowed as long as a product name is not mentioned.

A recent review (Galbally 2000: 53) examining a possible liberalisation of Australia's ban on DTCA ban prescription drugs concluded:

The Review could not support a relaxation of the current prohibition that would result in a situation such as those occurring in the US and New Zealand, which cannot be assessed as providing a net public benefit, despite some individuals also being helped.

The review made the following points:

- ?? In the US around 41 percent of the \$US 1.8 billion spent on prescription drug advertising in 1999 was spent on advertising just 10 products. A corresponding similar effect on the costs of publicly funded drugs could occur in Australia if it shared a similar advertising regime.
- ?? The bulk of US advertising is concentrated on a few new, higher-priced drugs and on drugs used to treat some of the more common serious conditions.
- ?? If there was a relaxation of the regime in Australia:
 - it would be unlikely that there would be advertising of older but still effective alternatives as it would be difficult to build these advertising costs into selling prices
 - the public might place too much credence in the advertisements just because government had allowed them to be made.
- ?? DTCA of prescription drugs is not supported by organisations representing doctors, pharmacists or veterinarians.

The review considers that the current prohibition of DTCA of prescription drugs should be maintained, except where it could contribute to a net public benefit:

Thus it is proposed that price advertising be permitted, that the CMI⁶ should be made more freely available, and that press releases, which comply with the APMA Code of Practice and are accompanied by a CMI be permitted. It is also proposed that advertising that is incorporated in a Government education campaign should be permitted. The nature of such advertising would be decided by the government agency running the campaign. The advertisement may also be time limited to fit in with the campaign (Galbally 2000: 59).

European Union

Currently, advertising of prescription drugs to the public is prohibited in all countries of the European Union (EU): 'Member States shall prohibit the advertising to the general public of medicinal products which are available on medical prescription only.'⁷ Like Canada, the EU has begun policy discussions on DTCA. This process is expected to result in lifting of the DTCA ban, partly because of industry pressure but also because of the realisation that it is impossible to eliminate DTCA over the Internet. It is reported that policy makers are, as a result, expected to support a liberal DTCA environment, since that can be strongly regulated

⁶ Consumer Medicine Information.

⁷ Council Directive 92/28/EEC, 31 March 1992.

within national boundaries to ensure consumers have access to balanced and honest advertisements to offset the unregulated Internet material. This prospect is of concern to many non-government organisations, which have begun campaigning to try to retain the status quo and are promoting research into the positive and negative impacts of DTCA to inform the policy decision.

Switzerland

Switzerland (not an EU member) allows DTCA for over-the-counter medicines but not for prescription drugs.⁸ Recently the Swiss government reviewed a proposal to liberalise its DTCA regime to include prescription drugs. The government decided against the proposal as support, even from the drug industry, was not strong. The review allows DTCA for over-the-counter products to continue.

Reasons for the low level of support from the industry include the following:

- ?? the lack of health insurance reimbursement for most drugs for which there is DTCA
- ?? the smallness of the Swiss market, which makes the return on prescription drug advertising marginal (given the reimbursement situation)
- ?? an expectation that cross-border advertising (for example, from Germany) will meet the industry's needs once the EU adopts DTCA.

International guidelines

In 1988 the World Health Organization (WHO) developed a set of criteria to guide the regulation of pharmaceutical promotion, the *Ethical Criteria for Medicinal Drug Promotion* (WHO 1988). This is the only international standard for drug promotion apart from industry marketing codes. The WHO ethical criteria recommended against DTCA, stating that:

Advertisements for the general public ... should not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can be treated only by qualified health practitioners, for which certain countries have established lists.

Several additional points are relevant; for example, that advertisements 'should not take undue advantage of people's concern for their health', and that 'scientific and educational activities should not be deliberately used for promotional purposes'. These criteria are not legally binding; they are standards that can be used to develop regulation.

Q2 Do you have any further information that you consider should be added to this review of the international situation relating to DTCA of

⁸ Markus Fritz, November 2000. Swiss Drug Information Center SDIC/SMI, personal communication.

prescription medicines? If so, please forward this information to the Ministry of Health.

3 The Case For and Against DTCA of Prescription Medicines

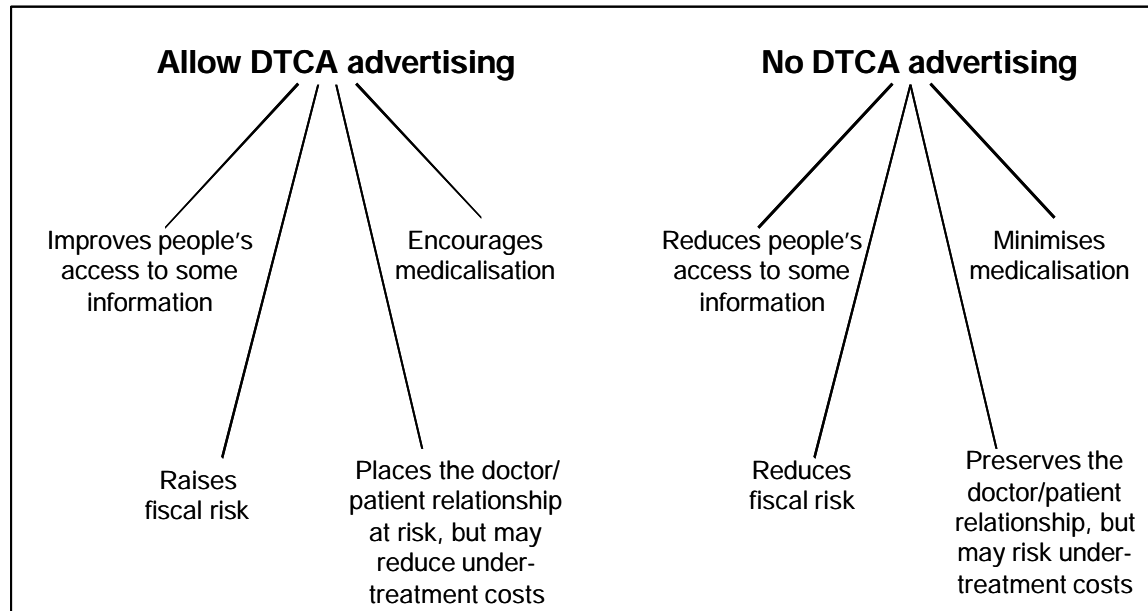
Introduction

Most of the DTCA debate takes the form of claim and counter claim rather than being evidence based. Consequently, the cases for and against DTCA of prescription drugs is inconclusive.

The concern with DTCA advertising is that prescription medicines differ from other consumer goods in their potential harmful effects as well as the potential benefits, the seriousness of many health conditions requiring prescription medicines, and the additional vulnerability of those with health conditions. DTCA also differs from other forms of advertising in that a person cannot simply go out and buy the product: they must first go to a doctor for a prescription.

The proponents of DTCA in New Zealand, while admitting they have a commercial interest in their DTCA activities do, nevertheless, act within a socially responsible framework set by their code of practice.

Figure 2: Main costs and benefits of DTCA



This section outlines the main arguments for and against DTCA indicated in Figure 2.

1 DTCA improves/does not improve people's access to some information

DTCA does not improve people's access to some information

- ?? An unbalanced picture of the potential risks of medicines is presented. This is particularly the case with television where it is almost impossible to get a balanced report given time limitations.
- ?? Key treatment information is ignored in the preparation of advertisements.
- ?? Little or no information about alternative treatments is provided.
- ?? The vulnerable (who may lack education or suffer from chronic or severe illness) are targeted with emotional rather than with rational information. As a result anxiety may be generated in the targeted consumer groups.
- ?? Consumers are confused or misinformed with too little knowledge rather than informed in a balanced way.
- ?? Consumers are provided with a superficial level of information that leads them to conclude they need a particular medicine.

DTCA improves people's access to some information

- ?? Consumers have the right to receive information about the availability of products.
- ?? The consumer is empowered with information to seek treatment and be better informed about decisions.
- ?? There is an improved likelihood of patients seeking early diagnosis and treatment.
- ?? Innovation for new and cheaper medicines may be brought forward.
- ?? There has been significant improvement in the quality of DTCA in New Zealand and the US recently in response to stricter regulation and code of conduct requirements.

Comment

The main thrust of the critics of DTCA of prescription drugs as a medium for information transfer is that the fundamental nature and goals of advertising make it an inappropriate mechanism for the dissemination of high-quality information to consumers, patients and the general public. Advertising, it is argued, aims to sell a product. It will always present the product in as positive a light as possible. It will not advise potential consumers they do not need to take the advertised product, or that a competitor's products are superior or that changes in lifestyle may be more successful.

As noted earlier, the record of the industry in New Zealand has caused concern. Medsafe's February 2000 examination of non-compliance suggests that the status quo DTCA position is unlikely to guarantee a medicines advertising environment that, on

balance, will provide either net health benefits or, at least, an absence of net health costs in terms of information transfer.

The supporters of DTCA believe that if regulated in the right way DTCA can be a good means of disseminating high-quality information to consumers. They argue on the basis that consumers have the right to information and that the quality of this information is improving. They also take the view that consumers are sufficiently sophisticated to use DTCA to their advantage. This is illustrated by the following:

... as hard as it may be for many of us in my industry to admit, consumers are skeptical about advertising. Research shows that over half feel it insults their intelligence. Now, granted, we have studies that show DTC to be far more credible than the average consumer advertising. Over seven in ten call it valuable and worthwhile. Nevertheless, only one in four considers DTC to be objective and less than half consider it reliable. They have come to expect advertising to try and sell something. So, frankly, their resistance is up.

At the same time, they have learned that DTC ads can educate and inform them and they welcome this information even as they remain suspicious about the objectivity of its provider (FDA 1995).

2 DTCA raises/does not raise fiscal pressures

DTCA raises fiscal pressures

- ?? Demand for new higher-priced pharmaceuticals is raised. For example, the bulk of US advertising is concentrated on a few, new, higher-priced drugs and on drugs used to treat some of the more common serious conditions. US sales of these types of drugs are increasing disproportionately (for example, there was a 15 percent increase in the sale of DTCA drugs in the US compared with half that rate of growth in the top five European countries during the same period) (Galbally 2000).
- ?? Pressure is exerted by the public, and others, on PHARMAC to subsidise the new, higher-priced pharmaceuticals. For example, PHARMAC reports that drug companies use advertising to create a demand and once a market has been created for the product they apply to PHARMAC to have the product subsidised (PHARMAC 2000: 5).
- ?? The cost of subsidies for medicines and patient visits to doctors is escalated, particularly where consumers visit a number of physicians in an attempt to find a doctor prepared to prescribe the advertised medicine. There is a consequent pressure on the pharmaceutical budget and on the General Medical Subsidy. PHARMAC notes, for example, major advertising promotions for Flixotide, Zocor and Lamisil led to demand growth for these products and additional expenditure of \$7.4 million from the pharmaceutical budget (PHARMAC 2000: 3).
McCarthy (2000) again reporting on the US situation notes:

.....we see that in 1998, the average price per prescription for new drugs (those introduced in 1992 or later) was \$71.49, more than twice the average \$30.47 price for previously existing drugs.

- ?? Where the medicine is not subsidised, high prices become an issue for individuals. For example, a month's supply of Xenical, will cost an individual \$165⁹ or more.
- ?? Public confidence in the state-funded health care system is undermined when individuals either find it difficult to access advertised medicines or are required to fund these medicines themselves.

DTCA does not raise fiscal pressures

- ?? Most of the drugs advertised are not subsidised by PHARMAC. As noted earlier, between October 1999 and September 2000, 26 of 46 drugs advertised were not on the Pharmaceutical Schedule.
- ?? The health interventions that result from DTCA can assist in offsetting the need for more expensive secondary services care that might otherwise be required later.

Comment

There is little argument that the interests of advertisers are commercially based and raise demand for the products advertised. For example:

The RMI acknowledges the commercial motive for advertising, but contends that the spin-off public health benefits, including the benefits that a more informed and motivated patient brings to the doctor patient relationship are considerable and undeniable (RMI 2000: 6).

In another example, an employee of Glaxo in Canada reported:

What companies would do, and I was actually part of the process, is create a demand for a product before it was actually released. We went around to various communities and organised public health seminars on migraines and that topic was really popular ... seminars that we actually charged five dollars for, another marketing tactic that makes the patient think that this thing isn't being funded by a pharmaceutical company. We held these seminars right across Canada (Mintzes 1998).

A US national survey found:

Direct-to-consumer advertising encouraged a projected 21.2 million consumers to talk with their doctor about a medical condition or illness they had never talked with their doctor about before seeing an advertisement.

⁹ The retail price is in the approximate range of \$165-\$210.

As many as 12.1 million consumers received a prescribed drug as a direct result of seeing a DTC advertisement (Holmer 1999).

The critics of DTCA note that the majority of DTCA is for medicines for which there are lower-cost alternatives, which in most circumstances are equally efficacious (that is, in offsetting possible later secondary care). They also argue that other regimes – diet and exercise in the case of obesity, for example – may be a better, cheaper, long-term solution than Xenical.

Critics of DTCA also argue that the health budget is limited, and funds spent on DTCA drugs that are subsidised, or may potentially be subsidised, may be better spent elsewhere in the health sector.

3 DTCA damages/preserves or enhances the doctor/patient relationship

DTCA damages the doctor/patient relationship

Pressure is placed on doctors to prescribe a particular advertised medicine. For example, a recent US survey indicates:

... more than one third of patients have asked their physicians for information on drugs they have seen in a DTC ad and nearly one fourth have asked for the drug itself. Perhaps more significantly, three quarters of the patients requesting drug prescriptions received them from their physicians (Huang 2000: 2240).

- ?? There is a failure, particularly in broadcast DTCA, to provide patients with all information relevant to the prescribing decision, such as other options to treat a particular condition. This requires significant additional explanation and time by doctors to explain why a particular drug or treatment may not suit a patient's situation.
- ?? There may be an erosion of public trust in doctors. For example, IMS Health has found that half of physicians surveyed do not believe that DTCA contributes positively to the doctor/patient relationship (Canadian Association of Medical Publishers 1999). It is also reported that some US doctors are concerned that patients lose faith in doctors when DTCA conflicts with professional advice (Steinman 2000).

DTCA preserves or enhances the doctor/patient relationship

- ?? Patients may assist health professionals by suggesting treatments for their particular condition and, as a result, constructive pressure could arise for prescribers.
- ?? There are greater opportunities for a partnership between doctors and patients.

- ?? More initial or preliminary diagnosis by patients may improve their understanding of the treatments available and encourage them to visit their doctor.

Comment

The critics of DTCA raise the issue of the conflicts that advertising brings to the doctor/patient relationship, particularly when physicians decide that the advertised drugs requested are not suitable for their patients and are not prescribed. In response, DTCA proponents suggest that the prescribing behaviour of some doctors could be improved – and sometimes is – through DTCA. However, their stronger argument is that the doctor/patient relationship is an evolving one that has already gained momentum towards a mutual partnership. This is a consequence of consumers taking more responsibility for their health as they become more educated about health and more financially responsible for it. This, they argue, may lead to better health outcomes through more appropriate use of safe and effective prescription drugs.

The evidence is inconclusive. This is illustrated by a further US survey (Charnow 1998), which found that of the 454 family doctors that responded:

- ?? 89 percent did not see DTCA as enhancing the doctor/patient relationship
- ?? 71 percent believed that DTCA pressures doctors to use medications they may not ordinarily use
- ?? 75 percent agreed that DTCA results in increased prices for drugs
- ?? 72 percent indicated that it discourages the use of generics.

On the other hand, the survey found that:

- ?? 60 percent of doctors agreed that DTCA encourages patients to take a more active role in their health care
- ?? 56 percent agreed that DTCA encourages patients to seek medical advice for conditions that may otherwise go untreated.

Mintzes (2000) is of the view that:

Effects of DTCA on the doctor/patient relationship remain largely unknown. The hypothesis that exposure to advertising leads to a more informed patient, better able to be a partner in decisions about care, remains untested.

4 DTCA encourages/does not encourage the medicalisation of the population

Medicalisation refers to the increasing tendency for people to seek pharmacological treatment for a growing number of conditions: this is also known as the ‘pill for any ill’ behaviour.

DTCA encourages medicalisation

- ?? Medicines become more accepted as lifestyle solutions, to the detriment of the use of better alternatives (for example, diet and exercise) and with an associated increase in the risks of adverse reactions to these medicines.
- ?? Medicines may be used widely before a population risk profile is developed.
- ?? Advantage may be taken of those most vulnerable in society (through lack of education or chronic or severe illness).

DTCA does not encourage medicalisation

- ?? Many with limited education and severe illness will receive simple, accessible information about potential therapy.
- ?? Anxiety about disease risk may be eased by wider and earlier knowledge of treatment possibilities.
- ?? Prescription drugs by definition have been approved for medical use.
- ?? Prescription medicines still need to be prescribed by a physician or an approved health professional

Comment

The proponents of the 'DTCA causes medicalisation' view argue that some DTCA medicines are substitutes for lower-cost generic drugs that are equally efficacious. More importantly, they argue that DTCA promotes the view that 'there is a pill for all ills' and that treatment of 'lifestyle' conditions has serious consequences for limited health resources. This view is reported by McCarthy (1998):

These are drugs that have little to do with medical necessity. They have quite a lot to do with the 'enhancement' of people who aren't sick ...

The upsurge of cosmetic pharmacology and the boom in 'recreational' drugs like Viagra pose problems in medical ethics; specifically, what is the most appropriate allocation of scarce resources?

The contrary view is that DTCA prescription medicines have been approved by the authorities responsible, and individuals are entitled to the information that DTCA provides. Furthermore, individuals in many cases bear the costs of these medicines themselves.

Conclusions

From the research carried out, largely in the US, it is apparent that patient and physician behaviours do alter in response to DTCA of prescription medicines. Patients are going to doctors to discuss and request advertised medicines and are receiving prescriptions from which they are likely to benefit. At the same time, DTCA is raising prescription drug costs.

Perhaps most important, lifestyle and some other DTC-advertised drugs have the potential to 'crowd out' expenditure that would otherwise be spent on treating illness rather than helping people who may not be ill.

However, the evidence, such as it is, is inconclusive. Clearly, more evidential studies are needed to establish definitively the cost effectiveness of DTCA and its precise impact on improving health outcomes and the public health in New Zealand and elsewhere.

In the meantime, the critics of DTCA argue that in the absence of evidence that shows DTCA to have a positive or at least a neutral impact, the precautionary principle should apply. The DTCA industry, in contrast, argues for the status quo or little change to it.

Q3 Which of the arguments outlined above do you find most persuasive: those for or against DTCA of prescription medicines? Why?

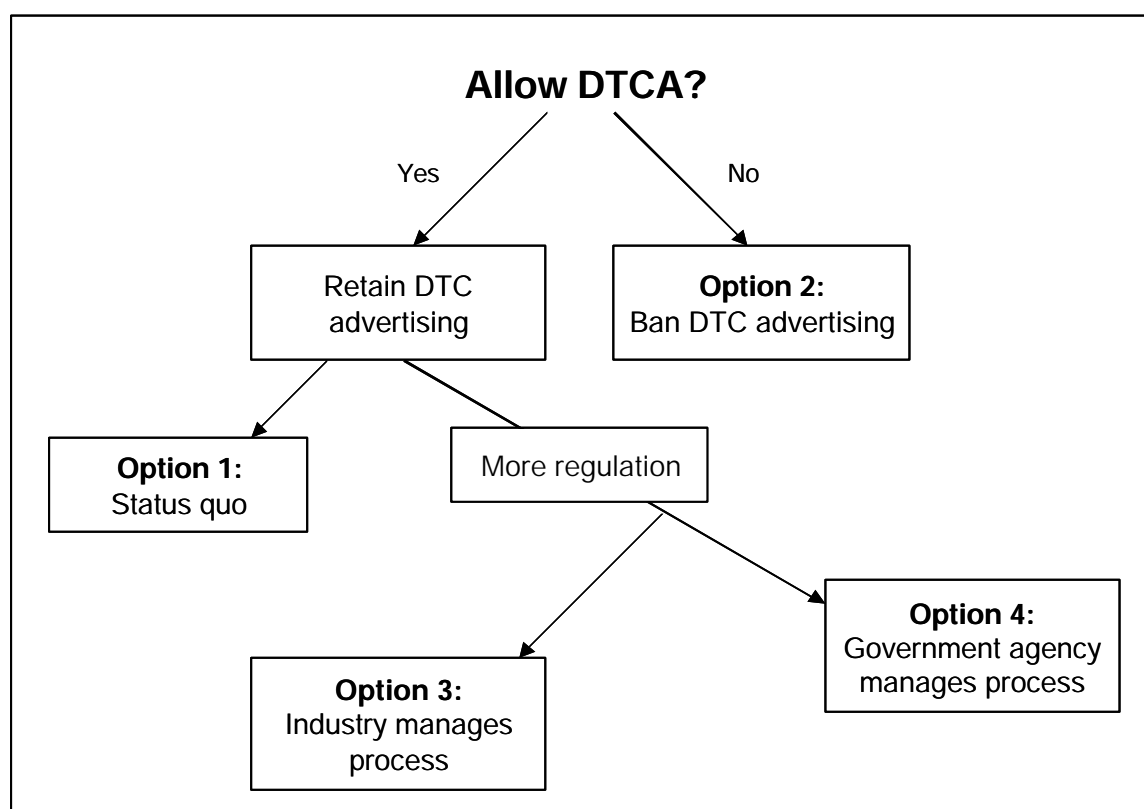
Q4 Please provide further arguments, or evidence, that you are aware of that either support or are critical of DTCA advertising of prescription medicines.

4 DTCA of Prescription Medicines: Policy Options

Introduction

The primary decision that will determine the future of DTCA in New Zealand hinges on the question: Is it in the best interests of New Zealanders for there to be advertising of prescription drugs direct to the consumer, or is banning this type of advertising preferable? (Figure 3). Once a decision to this question is made a number of possible policy options present themselves.

Figure 3: Main decisions in arriving at DTCA policy



This section reviews the high-order costs and benefits of the four principal DTCA policy options.¹⁰ (Clearly, there are other possible policy responses such as a partial ban or a

¹⁰ With the exception of the additional costs relating to Option 2, the costs and benefits of a review of the Medicines Act 1981 have not been included in the analysis as the review is not attributable to the DTCA debate and has been planned for some time.

moratorium. But these are not discussed further here.¹¹) It also provides criteria for assessing the options. The four options are:

1. retain DTCA under the current rules and regulations under the management of the industry (the status quo position)
2. ban DTCA
3. retain DTCA under more stringent rules and regulations than are presently in place, but continue with industry management of the process
4. retain DTCA under more stringent rules and regulations than are presently in place, but replace industry management of the process with management by a government agency.

Option 1: Retain DTCA under the current rules and regulations and under the management of the industry (the status quo position)

The status quo, or no change, option – self-regulation of prescription medicine advertising within the current legislative framework of the Medicines Act 1981 (and in the future the Healthcare and Therapeutic Products Bill) – provides the benchmark against which the other options may be measured.

Comment

This approach may provide some assurance of reasonable ongoing co-operation from those involved in the DTCA industry and some level of balance, particularly given the recent tightening of procedures put in place via TAPS.

The proponents of the status quo argue that this option and variations of the self-regulation model, are significantly more flexible and faster-acting than government regulation, and consequently industry is better equipped to manage DTCA industry activities where the dynamics are constantly changing.

The counter argument is that the self-regulatory model is inappropriate in this situation: DTCA regulatory bodies must be seen to be transparently independent, and therefore individuals or agencies receiving payment for services from the drug industry are ineligible.

Option 2: Ban all DTCA advertising

Under this option consumers would be prohibited from receiving information about prescription medication through advertising. The source of consumers' information about

¹¹ These options will be assessed if they arise in the course of the consultation on this paper.

such products would be limited to their health care professionals and the instructions that accompany their medication or Medsafe's information leaflets. Implementation of this option would require a major reframing of the legislative environment necessary to effect a ban. Much of this work would be necessary to ensure consistency with the New Zealand Bill of Rights Act 1990.

Section 14 of the New Zealand Bill of Rights Act 1990

Section 14 of the New Zealand Bill of Rights Act 1990 provides for the right to freedom of expression. Applied literally, that would give the industry the absolute right to advertise prescription medicines. However, section 5 provides that the rights and freedoms contained in the New Zealand Bill of Rights Act may be subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society. Thus legislation seeking to fully or partially ban DTCA would need to demonstrate a clear justification.

Costs

If a ban on DTCA advertising was put in place the following implications are likely:

- ?? the rights of consumers to access some information could be seen to be reduced
- ?? the risk of a possible under-treatment of at-risk groups
- ?? significant costs associated with the implementation of legislative change
- ?? there could be a reduction in economic activity and employment in the broadcast advertising industry of up to \$18 million a year, which, according to the industry, is unlikely to be offset by revenues from other areas. This could also have downstream impacts (for example, on the New Zealand television programme production industry).

Benefits

Conversely, a ban on DTCA advertising could:

- ?? provide a higher level of protection for the vulnerable, easily exploited target groups
- ?? preserve the doctor/patient relationship
- ?? reduce the risks of medicalisation
- ?? reduce the fiscal risk arising from pressure on the pharmaceuticals budget
- ?? provide a possible reduction in adverse reactions.

Comment

This option would incur significant costs associated with the implementation of legislative change and a reduction in economic activity, in particular.

There is a question too, as to whether this option is even practical given the existence of the Internet and satellite television and other international media services. While government control of national Internet domains is possible, it is unlikely that the New Zealand

Government could put in place blanket provisions on foreign country Internet domains. Even if there were to be international conventions that might allow such controls to exist (by way of reciprocal agreements between countries with similar views), at best this would only allow a very partial control of international foreign Internet domains. But, as earlier noted, there appears to be a ground swell abroad (illustrated by the EU) to move towards rather than away from DTCA for prescription medicines despite the recent movement to the contrary by Australia and Switzerland.

There is also an argument that it would be paternalistic to ban DTCA of prescription medicines as this would assume that people are unable to decide whether to trust the information they see in such advertisements. It also promotes the view that 'doctors know best'. The counter view is that in some cases doctors, despite their superior prescribing knowledge, also make mistakes in prescribing.

This option carries with it both the greatest risk, and the greatest opportunity to minimise the effects, positive and negative, of DTCA of prescription medicines.

Option 3: Retain DTCA under more stringent rules and regulations than are presently in place but continue with industry management of the process

This option involves a continuation of the status quo, with some tightening of the regulatory regime. The regulatory regime required would, as with Option 2, necessitate a review of the Medicines Act. It would also require a review of the procedures currently used by the industry in its self-regulatory role.

These more stringent conditions could include some of the following:

- ?? The exclusion of certain medicines from advertising, for example, allowing only unsubsidised prescription medicines to be advertised.
- ?? The exemption of advertising for public health campaigns, for example, immunisation.
- ?? Implementation of stronger penalties for non-compliant advertisements.
- ?? Giving the Ministry of Health the power to prohibit a company from advertising if it breaches the regulations.
- ?? Implementation of specific penalties for both the advertising media who publish non-compliant advertisements and the pharmaceutical company involved.
- ?? A stipulation that companies must demonstrate there is a real benefit to the public before an advertising campaign is planned.

Costs

If Option 3 was put in place the following implications are likely:

- ?? ongoing risk of exploitation of the vulnerable, but perhaps to a lesser degree than for Option 1
- ?? ongoing pressure on the publicly funded drug budget.

Benefits

The benefits of Option 3 could include:

- ?? more assurance that the vulnerable would not be exploited than Option 1
- ?? less pressure on the doctor/patient relationship than Option 1
- ?? lower risk of medicalisation than Option 1
- ?? lower fiscal risk arising from pressure on the pharmaceuticals budget than Option 1
- ?? possible lower adverse reactions than Option 1
- ?? continuation of the high level of compliance due to industry self-regulation
- ?? continued self-funding of the regime by the industry
- ?? retention of the flexibility of the self-regulatory model.

Comment

Given that there is concern with the status quo option from those that are opposed to the current DTCA of prescription medicines regime, and that there is some willingness to compromise by the industry (within the current self-regulatory model) and others in favour of DTCA, this option could provide the least cost change option from the Government's standpoint. Option 3 retains the benefits of the status quo option: a continuation of the high level of compliance by the industry said to be attributable to industry self-regulation, and a continuation of self-funding of the process by the industry.

As noted above, however, it has been argued that self-regulation does not work in the DTCA environment. For example, the recent Australian legislative review of drugs, poisons and controlled substances concluded that 'self-regulation (of DTCA) is not a viable alternative for regulating prescription advertising' (Galbally 2000: 52).

Option 4: Retain DTCA under more stringent rules and regulations than are presently in place but replace industry management of the process with management by a government agency

This option involves, a tightening of the regulatory regime (similar to but not necessarily the same as for Option 3) and a government agency taking control of overseeing the compliance of the industry to the rules governing DTCA. It would also require a review of the Medicines Act.

Costs

If Option 4 was put in place the following implications are likely:

- ?? There would be a fiscal impact on the Government in the order of \$1 million to \$2 million per year. This is the estimated additional annual cost to Medsafe (as the most likely agency to inherit oversight of the new regime) of taking up additional responsibilities.
- ?? The pharmaceutical budget would remain under pressure.
- ?? The balance of compliance might be altered from the present level of compliance under industry control to a lesser level of compliance under government control.
- ?? The government regulatory model is less flexible than industry self-regulation.

Benefits

The benefits of Option 4 compared with Option 1 could be:

- ?? more assurance that the vulnerable would not be exploited
- ?? less pressure on the doctor/patient relationship
- ?? lower risk of medicalisation
- ?? lower fiscal risk arising from pressure on the pharmaceuticals budget
- ?? possible lower rate of adverse reactions.

Comment

Implementation of this option would raise government expenditure and could be unpalatable to some members of the industry. However, it would result in the Government gaining full control of the process and thereby minimising the negative elements of the current situation. Adoption of this option would also counter the view that self-regulation in assuring the quality of advertising and other forms of promotion is ineffective, and respond to those arguing for maximum transparency and accountability in decision-making on DTCA.

Assessment of options: principles and criteria

A fundamental question when assessing the options outlined above is what assessment criteria should be used? These could include health-sector-oriented criteria and pragmatic considerations.

Health-based criteria

These could include factors such as:

- ?? evidence of health improvements
- ?? evidence of harm
- ?? improved health provision
- ?? higher or lower health care costs.

As a baseline, and from the national viewpoint, any change in health policy would be expected to lead at best to improved health outcomes and at worst to no deterioration in public health.

The Australian review of DTCA (Galbally 2000) conducted its assessment of DTCA options in the context of the following discussion framework:

- ?? Are there documented health benefits from DTCA?
- ?? Is there sufficient evidence about potential harmful effects to exclude the likelihood of harm from a policy change to introduce DTCA?

Pragmatic considerations

Another important criterion is whether a change in health policy is practical or consistent with international trends, technological advance, and the globalisation of information arising from the Internet and other border-crossing media.

Concluding comment

The Ministry of Health will be applying the criteria outlined above in its assessment of the four options discussed in this chapter. This will be undertaken once formal consultation on this paper has been concluded in mid-February 2001.

Q5 Which of the options outlined above do you find most persuasive? Why?

Q6 What further options, if any, relating to DTCA of prescription medicines do you support? Why?

- Q7** Do you agree with the assessment criteria outlined above? If not, why not?
- Q8** Do you consider that other assessment criteria should be considered? If so, what are they?

Appendix 1: Pre-consultation Stakeholder Views

This appendix outlines the views held by some of the main stakeholders in the DTCA of prescription medicines debate. The views of those responding to the invitation to provide feedback to this document will be added, and will inform the advice provided to the Minister of Health.

PHARMAC

In its briefing advice to the incoming Minister of Health, PHARMAC noted:

The current system of voluntary review is wholly unsatisfactory. PHARMAC believes it is inappropriate for the industry body, the Association of New Zealand Advertisers to act as judge and jury when it is a direct beneficiary of DTC advertising. Many of the advertisements currently being run on television do not comply with the voluntary code. Any misunderstanding or misinterpretation of claims about powerful drugs is potentially dangerous.

Pharmaceutical suppliers are understandably committed to the promotion of their own products, so their advertising ignores:

- ?? other pharmaceuticals that may be fully subsidised*
- ?? other pharmaceuticals that may treat the condition just as well*
- ?? whether pharmaceuticals are the most appropriate course of treatment (PHARMAC 1999b: 26).*

In a recent submission to the Ministry of Health PHARMAC (2000) notes that it has financial and clinical concerns relating to DTCA, arguing that it:

- 1. Places a fiscal strain on the New Zealand pharmaceutical budget as it:
 - (a) drives up demand for subsidised pharmaceuticals, which has a significant fiscal impact on New Zealand's pharmaceutical expenditure*
 - (b) distorts demand by moving patients to high cost medicines*
 - (c) increases demand for PHARMAC to subsidise pharmaceuticals that are advertised.**
- 2. Increases the medicalisation of the population.*
- 3. Presents an unbalanced picture of the potential risks all medicines carry.*

4. *Ignores key treatment information.*
5. *Damages the doctor/patient relationship.*
6. *Targets the vulnerable with emotional rather than rational information.*
7. *Is not appropriately managed through self-regulation.*

The Researched Medicines Industry (RMI)

In a recent paper RMI (2000) noted:

The Researched Medicines Industry (RMI) contends that advertising prescription medicines is – by its nature – a socially responsible activity that harnesses private incentives to cover the cost of disseminating information to patients and doctors.

The format of the advertising used to promote prescription medicines is also, by and large, socially responsible. While there have been a few isolated cases of prescription medicine advertising falling foul of the Advertising Standards Complaints Board, the RMI contends that industry conformity with new and more rigorous voluntary advertising codes will improve with experience over time.

...

The RMI takes a step beyond the public safety issue to make the case that prescription medicine advertising actually presents some real public health benefits. It supports this thesis with New Zealand case studies outlining the benefits that have arisen from four recent and ongoing direct-to-consumer prescription medicine campaigns promoting the asthma medicine Flixotide, the flu vaccine Fluarix, the erectile-dysfunction medicine Viagra, and the anti-obesity medicine, Xenical. Evidence presented on these campaigns indicates that they are reaching people not receiving information from other traditional sources, prompting people to seek treatment who might not otherwise do so, providing a basis on which a doctor could discuss sensitive issues with the patient, and, in the case of Fluarix, improving the uptake of a vaccine deemed to be in the public health interest.

Drawing on international research and literature, the RMI has concluded that the value of direct-to-consumer prescription medicine is considerable in that it:

- ?? *Harnesses private incentives to cover the cost of disseminating knowledge and to close the gap between what research has found and what doctors and patients know.*
- ?? *Meets increasing consumer demand for medical information, in a well-controlled and responsible way.*
- ?? *Informs consumers about new treatments.*

- ?? *Encourages people to seek medical attention for conditions or symptoms that might otherwise go untreated, including asymptomatic diseases.*
- ?? *Promotes patient compliance, and persistence, with recommended treatment.*
- ?? *Promotes better communication between patients and their doctors.*
- ?? *Improves the efficiency of public health care spending.*

...

In conclusion, health officials, doctors, patient groups and pharmaceutical companies can work together to harness the commercial incentives behind DTC prescription medicine advertising to ensure the best possible outcomes for patients, to shift the burden from secondary health care to primary health care, and, as a consequence, from the public purse.

Increased use of pharmaceuticals to control or prevent disease that would otherwise require hospitalisation and/or other expensive medical intervention leads to better health outcomes for the money spent on health, increased efficiency in the use of total health resources, increased patient satisfaction with health care, and improved overall outcomes for the general population, the workforce and the economy.

The Advertising Standards Authority Inc (ASA)

The ASA's position on advertising in general, and on advertising prescription drugs in particular, rests on its interpretation of the New Zealand Bill of Rights Act 1990. ASA (2000) notes:

Section 14 of the New Zealand Bill of Rights Act states:

'Freedom of Expression – everyone has the right to freedom of expression, including the freedom to seek, receive, and impart information and opinions of any kind in any form.'

Therefore not only do advertisers have the right to impart information in advertisements but consumers have the right to receive it.

This right is, of course, not absolute but pursuant to Section 5 of the Bill of Rights which may be fettered if the fetter 'can be demonstrably justified in a free and democratic society'. The Medicines Legislation, Therapeutic Code and the proposed TAPS are examples of such fetters. However, it should be noted that the threshold is extremely high and there are a number of New Zealand and Canadian cases which are relevant. However, a general theme is that the consumer's rights are sacrosanct and have precedence over the rights of the state. Indeed that is the whole thrust of the Bill of Rights.

A ban of prescription medicine has been mooted by PHARMAC. The reasons given are primarily fiscally based on the argument that advertising increases demand for prescription medicines which puts pressure on the public purse. This is an extreme fetter which would not meet the requirements of Section 5.

Former Health and Disability Commissioner, Robyn Stent

The former Health and Disability Commissioner, Robyn Stent, is quoted as saying:

New Zealanders are fortunate – they have laws supporting their right to make informed choices. This is why the fuss over the marketing of prescription drugs 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 (New Zealand Herald, 19 December 1998).

The Consumers' Institute

In an article in PHARMAC's 1999 Annual Report (PHARMAC 1999a), David Russell, Chief Executive of the Consumers' Institute of New Zealand, stated:

Since 1996, 10 drugs have been promoted directly to New Zealand consumers. They cover health problems ranging from psychology damaging lifestyles ailments such as hair loss and sexual dysfunction to drugs for the treatment of asthma, high blood pressure, prostate cancer and obesity.

When these ads began to appear the Consumers' Institute publicly criticized them. We considered the advertisements were putting an uncritical gloss on the efficacy and application of the drugs they were promoting. For example, useful, intelligible consumer information about side effects, limitations on use, and price was either missing or obscured. Some ads cynically followed the letter of the law in the way they presented the legally required consumer information but this was neither accessible nor appropriate for the non-professional audience to which it was directed ...

The Institute thought the DTC advertising of prescription medicines should be banned. The industry responded with the claim that most of the advertisements were offering further information through 0800 telephone help lines or freepost services. Much of this was sound factual material but we felt it hardly compensated for the lack of responsibility the industry was showing in its primary advertising.

... the industry has responded to consumer concern with a voluntary scheme promoted by the association of New Zealand Advertisers. This

centres on the Advertising Authority's Code of Therapeutic Products and an industry appointed adviser who will provide advice and vet advertisements before they are released.

The Institute acknowledges that voluntary, industry-controlled restraints have worked well in other sectors – the liquor industry for example. A six-month trial of the industry self-control proposal is now underway. This is a freedom that, apart from the US, is not given in any other developed country of the world. The pharmaceutical industry must take its responsibilities to the consumers of New Zealand seriously. The Consumers' Institute will be monitoring its performance. Nothing short of an impeccable record of balanced, informative, DTC advertising of prescription drugs at the end of the trial will restrain the Institute from pressing for the introduction of specific controls.

The New Zealand Medical Association (NZMA)

The NZMA does not oppose DTC *per se* but it is opposed to advertising that interferes with the doctor/patient relationship and advertising that is emotive or manipulative.

...GPs have considerable anxiety about the advertisements now "bombarding" the public and wouldn't oppose tightening up the regulations.

Lets be honest, the reason they advertise is to sell their drugs...but some of the ads are very manipulative, very emotive (McKay 2000).

General Practitioners Council of the NZMA

The chair of the GPs Council of the NZMA, Dr Philip Rushmer, is quoted as saying he had 'serious concerns about DTC advertising of drugs here and that the Australian Government had recently been recommended it was inappropriate for prescription medicines' (*Otago Daily Times*, 10 October 2000).

Q9 If your position is outlined above do you wish to alter or provide additional information? If so, please do so.

Q10 Do you wish to provide any further information? If so, please do so.

Appendix 2: Definitions from the Medicines Act 1981

(A) Definitions of ‘medicine’, ‘new medicine’, ‘prescription medicine’ and ‘restricted medicine’

Section 3

- (1) Subject to subsection (2) of this section, in this Act, unless the context otherwise requires, the term ‘medicine’ means any substance or article, other than a medical device, that is manufactured, imported, sold, or supplied wholly or principally –
- (a) For administering to one or more human beings for a therapeutic purpose; or
 - (b) For use as an ingredient in the preparation of any substance or article that is administered to one or more human beings for a therapeutic purpose where it is used –
 - (i) In a pharmacy or a hospital; or
 - (ii) In the course of any business that consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale or herbal remedies; or
- (2) In this Act unless the context otherwise requires, the term ‘medicine’ does not include –
- (a) Substances used in dental surgery for filling dental cavities; or
 - (b) Bandages and other surgical dressings, except medicated dressings where the medication has a curative function that is not limited to sterilising the dressings; or
 - (c) Any Radioactive material within the meaning of section (1) of the Radioactive Protection Act 1965; or
 - (d) Any animal food in which a medicine is incorporated;
 - (e) Any animal remedy; or
 - (f) Any other substance or article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of substance or article that is not a medicine for the purpose of this Act.
- (3) In this Act, unless the context otherwise requires, – ‘New Medicine’ means –
- (a) Any medicine that has not been generally available in New Zealand –

- (i) Before the commencement of this Act; or
 - (ii) At any time during the period of five years immediately preceding that date on which it is proposed to become available:
- (b) Any medicine that, immediately before the commencement of Part II of this Act was a therapeutic drug to which section 12 of the Food and Drug Act 1969 applied, and in respect of the sale or distribution of which the Minister had not given his consent under that section:
 - (c) Any medicine that becomes a medicine within the meaning of this Act for the first time after the commencement of this Act:
 - (d) Any medicine that is referred to the Minister under section 24(5) of this Act:

‘Pharmacy-only medicine’ means a medicine that is declared by regulations made under this Act or by a notice given under section 106 of this Act to be one that, except as may be permitted by the regulations may be sold by retail, or supplied in circumstances corresponding to retail sale, only in –

- (a) A pharmacy or a hospital or
- (b) Any shop described in section 51(2) of this Act and in accordance with a licence issued under Part III of this Act.

‘Prescription medicine’ means a medicine that is declared by regulations made under this Act or by a notice given under section 106 to be one that, except as may be permitted by regulations made under this Act may be –

- (a) Sold by retail only under a prescription given by a practitioner, registered midwife, veterinarian, or a designated prescriber; and
- (b) Supplied in circumstances corresponding to retail sale only –
 - (i) Under a prescription given by a practitioner, registered midwife veterinarian, or a designated prescriber; or
 - (ii) In accordance with a standing order; and
- (c) administered only in accordance with –
 - (i) A prescription given by a practitioner, registered midwife, veterinarian or a designated prescriber; or
 - (ii) A standing order

Section 4 – Meaning of Therapeutic Purpose

Meaning of ‘therapeutic purpose’ – In this Act, unless the context otherwise requires, the term ‘therapeutic purpose’ means –

- (a) Treating or preventing disease; or
- (b) Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or

- (c) Effecting contraception; or
- (d) Inducing anaesthesia; or
- (e) Altering the shape, structure, size, or weight of the human body; or
- (f) Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way; or
- (g) Cleaning, soaking, or lubricating contact lenses.

...

Section 32 – Exemptions for Natural Therapists and Others

32. Exemptions for natural therapists and others – Notwithstanding sections 17 and 20 to 24 of this Act or anything in any licence, but subject to the other provisions of this Act and to any regulations made under this Act, any natural therapist or other person may manufacture, pack, label, sell by retail, or supply in circumstances corresponding to retail sale, any medicine that neither is nor contains –

- (a) A prescription medicine; or
- (b) A restricted medicine; or
- (c) A pharmacy-only medicine.

For administration to a particular person after being requested by or on behalf of that person to use his own judgement as to the treatment.

(B) Definition of ‘medical advertisement’

Section 56 - Interpretation

‘Advertisement’ means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of medicines or medical devices or the use of any method of treatment; and includes any trade circular, any label, and any advertisement in a trade journal; and ‘advertising’ and ‘advertised’ have corresponding meanings:

‘Medical advertisement’ means an advertisement relating, or likely to cause any person to believe that it relates, to any medicine or medical device or any ingredient or component thereof, or to any method of treatment:

‘Method of treatment’ means any method of treatment for reward undertaken, or represented to be undertaken, for a therapeutic purpose:

‘Publish’ means –

- (a) Insert in any newspaper or any other periodical publication printed or published in New Zealand; or
- (b) Send to any person through the Post Office or otherwise; or
- (c) Deliver to any person or leave upon premises in the occupation of any person; or
- (d) Broadcast within the meaning of the Broadcasting Act 1976; or
- (e) Bring to the notice of the public in New Zealand in any other manner.

Section 57 - Restrictions on advertisements –

- (1) No person shall publish or cause to be published, either on that person's own account or as the agent or employee of the person seeking to promote the sale, any medical advertisement that —
 - (a) Directly or by implication qualifies or is contrary to any statement or other particulars required by regulations made under this Act to be marked on or attached to medicines or medical devices of the description, kind, or class, to which the medicines or medical devices advertised or appearing to be advertised, belong or appear to belong, or on or to packages or containers enclosing medicines or medical devices of that description, kind, or class; or
 - (b) Is prohibited by any such regulations from being marked on or attached to, or on or to packages or containers enclosing, medicines or medical devices of that description, kind, or class; or
 - (c) Omits from the name or description of the medicines or medical devices advertised any word or words required by any such regulations to be included in the name or description marked on or attached to, or on or to packages or containers enclosing medicines or medical devices of that description, kind, or class; or
 - (d) Fails to make any statement required by any such regulations to be made in an advertisement relating to medicines or medical devices of that description, kind, or class; or
 - (e) Makes any statement prohibited by any such regulations from being made in an advertisement relating to medicines or medical devices of that description, kind, or class; or
 - (f) Is false, or is likely to mislead any other person, with regard to the nature, quality, strength, purity, composition, origin, age, uses, or effects of medicines or medical devices of that description, kind, or class or of any ingredient or component thereof; or
 - (g) Directly or by implication states or suggests that medicines or medical devices of that description, kind, or class, cannot harm any person, or any person belonging to a particular class of persons, or is not habit-forming.

- (2) For the purposes of subsection (1) of this section, any words that must be included in an advertisement in order to avoid a contravention of the subsection shall, where they appear in an advertisement published by television or otherwise in a transitory manner on a screen, be disregarded unless they are exposed in clearly legible lettering for a length of time sufficient to enable them to be read by the ordinary viewer.
- (3) For the purposes of subsection (1)(f) of this section, a medical advertisement shall be deemed to be likely to mislead any person with regard to the uses or effects of medicines or medical devices of a particular description, kind or class, or of any ingredient or compound thereof, if it is likely to mislead with regard to –
 - (a) Any purposes for which medicines or medical devices of that description, kind, or class, or any ingredient or component thereof, can be used with reasonable safety; or
 - (b) Any purposes for which such medicines or medical devices, or any such ingredient or component, cannot be so used; or
 - (c) Any effects that such medicines or medical devices, or any such ingredient or component, when used, or when used in any particular way referred to in the advertisement, produce or are intended to produce.
- (4) Without prejudice to any liability in respect of any offence against any regulations made under this Act, every person commits an offence against this Act who contravenes any of the provisions of subsection (1) of this section.

Section 58 - Further restrictions on advertisements –

- (1) Subject to section 60 of this Act, no person shall publish, or cause or permit to be published, any medical advertisement that –
 - (a) Directly or by implication claims, indicates, or suggests that medicines of the description, or medical devices of the kind, or the method of treatment, advertised will prevent, alleviate, or cure any disease, or prevent, reduce, or terminate any physiological condition specified, or belonging to a class of disease or physiological condition specified, in Part I of the First Schedule to this Act; or
 - (b) Directly or by implication claims, indicates, or suggests that medicines of the description, or medical devices of the kind, or the method of treatment, advertised will prevent or cure any diseases or prevent or terminate any physiological condition specified, or belonging to a class of disease or physiological condition specified, in Part II of the First Schedule to this Act; or
 - (c) Directly or by implication claims, indicates, or suggests that a medicine of the description, or a medical device of the kind, or the method of treatment, advertised –
 - (i) Is a panacea or infallible; or
 - (ii) Is or has been used or recommended by a practitioner, nurse, or pharmacist, or by any other person qualified to provide therapeutic

treatment in the course of a profession or occupation and registered under any enactment as a person so qualified or by a person who is engaged in study or research in relation to any of those professions or occupations or the work performed by persons employed therein;

- (iii) Has beneficially affected the health of a particular person or class of persons, whether named or unnamed, and whether real or fictitious, referred to in the advertisement; or
 - (d) Invites correspondence or the sending of hair, blood, urine, or other bodily specimens or photographs for the purposes of diagnosis or treatment concerning any disease or physiological condition.
- (2) Every person commits an offence against this Act who contravenes any of the provisions of subsection (1) of this section.
 - (3) It shall be a good defence in a prosecution for an offence against paragraph (a) or paragraph (b) of subsection (1) of this section if the defendant proves that the matter claimed, indicated, or suggested in the advertisement is true.

Section 59 - Advertisements to contain true name of advertiser –

- (1) Subject to subsection (2) of this section, no person shall publish, or cause or permit to be published, any medical advertisement that does not contain a statement of the true name of the person for whom or on whose behalf the advertisement is published, and the address of that person's place of residence or business.
- (2) In the case of a body corporate, it shall be sufficient compliance with subsection (1) of this section if instead of the address of the body corporate's place of business, the advertisement states the name of the place where the body corporate has its registered company, other headquarters.
- (3) Any statement that is contained in any medical advertisement and purports to set forth the name of the person for whom or on whose behalf the advertisement is published, shall, until the contrary is proved, be sufficient evidence of the name of the person for whom or on whose behalf the advertisement has been published.
- (4) Nothing in this section applies to –
 - (a) Any medical advertisement that complies with any regulations made under this Act relating to the disclosure or otherwise of the name and address of the place of residence or business of the manufacturer or seller of the medicines of the description or medical devices of the kind advertised, or the agent of either of them; or
 - (b) Any medical advertisement relating to any description of medicines or any kind of medical devices in respect of which an exemption granted under or by virtue of this Act from the material provisions of any such regulations is for the time being in force.

- (5) Every person commits an offence and is liable to a fine not exceeding \$1,000 who contravenes subsection (1) of this section.

Section 60 - Exemption for certain advertisements – Without limiting any power to make regulations under this Act, nothing in section 57(1)(g) or section 58 or section 59 of this Act shall apply to any medical advertisement that –

- (a) Is distributed only to persons referred to in section 58(1)(c)(ii) of this Act; or
- (b) Is contained in a publication that in the ordinary course circulates solely or principally, or is distributed solely or principally, to those persons; or
- (c) Not being an advertisement relating to a prescription medicine, or a restricted medicine, or a pharmacy-only medicine, is distributed solely to persons claiming to be available for consultation by other persons for therapeutic purposes and to persons privately consulting them.

Section 61 - Misleading branding –

- (1) No person shall sell any medicine or medical device –
- (a) That bears or has attached to it, or is enclosed in a package or container that bears or has attached to it, any false or misleading statement, word, brand, picture, label, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion, of the medicine or medical device enclosed in the package or container, or of any ingredient thereof; or
 - (b) That has been packed, processed, or treated in a manner that is false or misleading in relation to any of the matters mentioned in paragraph (a) of this subsection
- (2) Every person commits an offence against this act who contravenes subsection (1) of this section.

Section 62 - Regulations relating to advertisements –

- (1) Without limiting section 105 of this Act but subject to subsection (2) of this section, the Governor-General may from time to time, by Order in Council, make regulations for all or any of the following purposes:
- (a) Requiring and regulating the insertion in any medical advertisement, or any particular class of medical advertisement, of such information or warning, or kind of information or warning, concerning any unwanted, incidental, or untoward effects of medicines of the description, or of medical devices of the kind, or of the method of treatment, advertised, and such statement or kind of statement of the precautions to be taken by any user of medicines of that description, or of medical devices of that kind, or of that method of treatment as may be prescribed.

- (b) Prohibiting the advertising of any specified description of medicine, or kind of medical device, or method of treatment, or of any specified class of medicine, medical device, or method of treatment, in any medical advertisement, or a particular class of medical advertisement, and prohibiting, or requiring and regulating, the mention in any medical advertisement, or a particular class of medical advertisement, and prohibiting, or requiring and regulating, the mention in any medical advertisement of such matters relating to the composition, properties, nomenclature, origin, and use of medicines of the description or medical devices of the kind or method of treatment advertised, as may be prescribed:
 - (c) Enabling the Minister to require, after consultation with such organisations as appear to him to represent any class or classes of persons whose interests might be affected by the requirement, the insertion of particular words specified by the Minister in, or the omission of particular words or other matter so specified from, any particular medical advertisement, and to give directions with respect to the location, size and appearance of any such insertion and with respect to other matters incidental thereto, and providing a right of appeal in respect of any such requirement or direction:
 - (d) Generally regulating medical advertisements or any particular class of medical advertisements, or medical advertisements relating to medicines of a particular description, or to medical devices of a particular kind, or to medical devices of a particular kind, or to a particular method of treatment, or relating to particular classes of medicines, medical devices, or methods of treatment.
- (2) Any regulations made under subsection (1)(a) of this section –
- (a) Shall be made only on the recommendation of the Minister after consultation with such organisations or bodies as the Minister considers likely to be substantially affected by the regulations; and
 - (b) Shall be designed to achieve a fair and balanced indication of the potential effects of the medicine or medical device or method of treatment advertised; and
 - (c) Shall not require the disclosure of information that may reasonably be regarded as confidential, or that cannot reasonably be expected to be in the possession of the person on whose behalf the advertisement is published, or the inclusion of which in the advertisement is otherwise impracticable.

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