

**Direct-to-Consumer  
Advertising of Prescription  
Medicines in New Zealand**  
Consultation document

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MANATŪ HAUORA

# Foreword

New Zealand and the United States are the only industrialised countries that allow direct-to-consumer advertising of prescription medicines (DTCA).<sup>1</sup> New Zealand and United States citizens view DTCA via the mainstream media, as well as through a range of ‘patient education’ promotional activities. Like all other forms of advertising, the aim of DTCA is to increase sales, although some would argue that the purpose of this kind of advertising is to educate consumers about diseases, allowing patients to participate in decisions concerning their health care.<sup>2</sup>

The policy debate on DTCA has raised questions about the impact of DTCA on individual and public health outcomes in terms of:

- provision of pharmaceutical information to consumers
- overall health care costs
- the appropriate use of pharmaceuticals
- the patient–doctor relationship.

DTCA policy in New Zealand is a contentious issue, and the adequacy of the current legislative and self-regulatory controls governing DTCA in New Zealand is a matter of public debate. DTCA in New Zealand is currently regulated under the Medicines Act 1981 and Medicines Regulations 1984 (outlined on pages 4-5). The Therapeutic Products Bill is set to repeal this legislation with the establishment of the Australia New Zealand Therapeutic Products Authority (*‘the Therapeutic Products Authority’*) (see pages 12-14).

Regardless of the decision on the future regulation of DTCA in New Zealand, it is proposed that the Australia New Zealand Therapeutic Products Advertising Code (outlined on pages 13-14) come into force under the Therapeutic Products Authority. Currently, the Therapeutic Products Advertising Code allows DTCA to continue in New Zealand, albeit with more stringent regulation than under the Medicines Act currently. For the purpose of clarity, the regulation of DTCA under the Therapeutic Products Advertising Code should be considered as the status quo, to provide the benchmark against which the other options for DTCA regulation may be measured.

The purpose of this document is to review 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 document outlines the current policy for DTCA, along with the Therapeutic Products Advertising Code, and provides three options for the regulation of DTCA, which form a basis for comment by interested individuals and agencies on the future of DTCA in New Zealand.

<sup>1</sup> For the purposes of this document, ‘DTCA’ will refer to direct-to-consumer advertising of prescription medicines.

<sup>2</sup> Pharmaceutical Research and Manufacturers Association, ‘Direct-to-consumer advertising strengthens our health care system’. URL: <http://www.phrma.org/publications/quickfacts//2002-10-04.581.pdf>.

Following consultation on this document, the Ministry of Health will be providing advice to the Government on policy options for the regulation of DTCA in New Zealand in the future.



# How to Have Your Say

## Make a submission

The Ministry of Health encourages you to make a submission, outlining your views on DTCA and how it should be regulated in New Zealand. A number of questions are posed throughout the document to help focus your responses.

Please forward only one copy of your submission to:

DTCA consultation  
Sector Policy Directorate  
Ministry of Health  
PO Box 5013  
WELLINGTON

Email: [DTCA\\_consultation@moh.govt.nz](mailto:DTCA_consultation@moh.govt.nz)  
Fax: (04) 496 2340

**All submissions are due by 5 pm, Friday 28 April 2006.**

If you require additional copies of this document, you can print them out from the publications section of the Ministry of Health website: [www.moh.govt.nz](http://www.moh.govt.nz)

The Ministry of Health will consider the arguments and views outlined in submissions when developing advice to the Government on policy options for the regulation of DTCA in New Zealand in the future.

The Ministry of Health is interested in any comment you may have on any aspect of the DTCA consultation document but is particularly interested in your views on the regulation of DTCA in New Zealand. It would help the analysis of submissions if your comments were referenced to either the specific questions raised throughout this document or to the relevant section of this document. To assist you in making a submission, the questions raised throughout the document are summarised below:

1. Are you concerned about DTCA in New Zealand?  
OR  
Are you supportive of DTCA in New Zealand?
2. Does your concern about or support for DTCA relate to:
  - the quality use of prescription medicines
  - the provision of consumer information to maximise public health and safety
  - practicable and cost-effective regulation
  - appropriate and proper standards for prescription medicine advertising
  - other issues? If so, what?
3. Which of the arguments outlined in Section 5, 'The Cases For and Against DTCA', do you find most persuasive: those for or against DTCA? Why?

4. Do you have any further information or arguments that you consider should be added to this review of the evidence that supports or opposes DTCA? If so, please forward this information to the Ministry of Health.
5. Which of the options outlined in Section 6, 'DTCA Regulatory Options', do you support? Why?
6. What further options, if any, relating to the regulation of DTCA in New Zealand do you support? Why?
7. Do you have any other views on how to achieve the purported benefits of DTCA (eg, consumer access to pharmaceutical information, enhanced doctor-patient relationship, increased diagnosis of previously untreated conditions), without experiencing the purported costs of DTCA? If so, please forward these views to the Ministry of Health.

If you are making a submission on behalf of an organisation, please describe the organisation and its interest in relation to the regulation of DTCA, identify your position within the organisation, and indicate the extent of any consultation or discussion you have undertaken with your organisation. If you are making a submission individually, please indicate the reason for your interest in the regulation of DTCA (eg, as a consumer, researcher or health practitioner).

Please note that your submission and all correspondence you have with the Ministry may be the subject of requests under the Official Information Act 1982. If there is any part of your submission or correspondence that you consider could properly be withheld under the Act, please include comment to this effect along with reasons why you want the information withheld. 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

## Purpose

The purpose of this document is to provide a basis for discussion and to encourage feedback on DTCA policy in New Zealand.

This document:

- provides an explanation of DTCA and other forms of prescription medicine advertising
- reviews the current advertising policies in New Zealand and Australia (international positions on DTCA are attached in Appendix 1)
- outlines the proposed advertising arrangements under the Therapeutic Products Authority
- outlines the main arguments for and against DTCA
- develops and analyses three policy options for the regulation of DTCA in the future.

## Policy objectives

The public policy objectives for the regulation of DTCA are to:

- ensure the quality use of prescription medicines is maximised
- contribute to the provision of consumer information that is balanced and easily understood by New Zealanders, to maximise public health and safety
- ensure regulation is as practicable and as cost-effective as possible
- ensure appropriate and proper standards for prescription medicine advertising.

This document is confined to an examination of DTCA of prescription medicines. The advertising of prescription medicines directly to the public has been the main focus of concern and debate about the impact of advertising of health products on health outcomes.

Q1. Are you concerned about DTCA in New Zealand?

OR

Are you supportive of DTCA in New Zealand?

Q2. Does your concern about or support for DTCA relate to:

- the quality use of prescription medicines
- the provision of consumer information to maximise public health and safety
- practicable and cost-effective regulation
- appropriate and proper standards for prescription medicine advertising
- other issues? If so, what?

## 2 Prescription Medicine Advertising

This section outlines what DTCA and disease-state advertising are. Descriptions of other forms of medicine advertising are attached in Appendix 2.

### Direct-to-consumer advertising

DTCA is the advertising of prescription-only medicines or treatments to consumers.<sup>3</sup> DTCA specifically advertises individual branded medicines for a specific condition, which is what differentiates DTCA from disease-state advertising (described below). DTCA refers to:

- promotional material transmitted via television, radio, magazines and the Internet
- a range of 'patient education promotional activities' (such as disease-oriented advertisements, toll-free numbers, information materials distributed by company-funded organisations, media reports generated by company-sponsored press conferences, and public meetings).

DTCA differs from all other advertising in two respects. First, consumers must visit a prescriber, usually a general practitioner (GP), to obtain a prescription before obtaining the product. This requirement provides a 'gate-keeper' function as prescribers are required to assess whether and what prescription medicine is appropriate for a patient, and it also impacts on the cost to the consumer (Calfee 2002). Secondly, DTCA is controlled via regulation, as is advertising of other products that have the potential to harm human health (eg, alcohol, tobacco).

### Disease-state advertising

Disease-state advertising comprises information that aims to raise awareness regarding specific diseases and treatments available, without identifying a specific therapeutic product. Information presented in this form of advertising focuses on encouraging consumers to seek health care practitioner advice about the diagnosis, treatment or prevention of a disease or condition. Disease-state advertisements often tell consumers that there is a therapeutic product available to treat the condition and include material that directs consumers to a source for further information. The information sources recommended by disease-state advertisements often contain information about individual branded products or specific programmes.

<sup>3</sup> The Medicines Act 1981 defines 'advertisement' broadly to mean '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'.

There are three main kinds of disease-state advertising (Association of New Zealand Advertisers 2004):

- **Unbranded advertising** promotes the use or supply of product by inviting the consumer to seek further information about symptoms or conditions and/or their treatment or management while not referring overtly to any particular branded product. For example: 'Did you know that there is a new product available for controlling {medical condition}? If you are suffering from {symptoms/conditions} ask your medical practitioner about appropriate treatment options.'
- **Generic advertising** promotes the benefits of a particular category of therapeutic products, substance, ingredient or medical device component and is not related to any particular branded product. For example: 'Have you considered the benefits of {substance}? Recent research has shown that {substance} in combination with exercise reduces oxidative stress in older adults. Call {phone number} for more information on products that contain this substance.'
- **Disease awareness campaigns** comprise information that aims to raise awareness regarding specific diseases, including public health campaigns. For example: 'Do you suffer from {symptoms/conditions}? If so, you could be experiencing {medical condition} or be at risk of developing {medical condition}. See your medical practitioner for more information about the diagnosis, treatment or prevention of {medical condition}.'

### **3 DTCA: The New Zealand and Australian Situations and the Role of Regulation**

#### **Introduction**

This section outlines the current systems that operate in New Zealand and Australia with regard to the regulation of DTCA. It should be noted that the Therapeutic Products Bill (outlined on pages 12-14) is set to repeal the existing legislation relating to advertising (outlined below) in both countries.

The explanation of the current arrangements for the regulation of advertising in New Zealand (provided below) and the arrangements for advertising proposed under the Therapeutic Products Authority (outlined on pages 12-14) provide the background and context for considering DTCA regulation in New Zealand.

#### **New Zealand**

The introduction and rapid growth of DTCA in New Zealand was not anticipated; the quick uptake of DTCA in the United States, where it first appeared in the 1980s, may explain its subsequent appearance in New Zealand. Legislation relating to medical advertising was drafted before DTCA became commonplace in New Zealand, and the introduction of the New Zealand Bill of Rights Act in 1990 that explicitly protected freedom of speech (including commercial speech) also fostered a regulatory environment in which DTCA could develop (Hoek and Gendall 2004). New Zealand has never explicitly prohibited DTCA.

#### **Medicines Act 1981 and Medicines Regulations 1984**

All medical advertising (including DTCA) in New Zealand is currently regulated under the Medicines Act 1981 and Medicines Regulations 1984.<sup>4</sup> This legislation prohibits false or misleading claims or branding, and endorsements by health practitioners.

The Medicines Act imposes a range of controls on activities relating to the supply of medicines in New Zealand in order to protect the public. The Medicines Act sets out the sort of information that must and must not be included in an advertisement for a medicine. Information that must be disclosed in any advertisements includes:

- the name of the advertiser
- the ingredients and authorised uses of the product
- most importantly, information detailing all the contraindications to use and appropriate precautions for using the medicine.

<sup>4</sup> Medicines Regulation 1984 and Medicines Act 1981 are available on the New Zealand Legislation website at <http://www.legislation.govt.nz>

Currently, the penalty provisions in the Medicines Act offer only limited disincentives against unbalanced or inappropriate DTCA. A successful prosecution will result in a fine of up to \$500 plus up to \$50 per day that a non-conforming advertisement continues to be disseminated. There are no suitable alternative statutory mechanisms under which to regulate DTCA. Although the Fair Trading Act 1986 includes prohibitions against false or misleading representations, it is not designed to regulate advertising of potentially dangerous substances, such as medicines, which require specific controls.

The current legislation relating to medical advertising in New Zealand is inconsistent with the World Health Organization's (WHO) *Ethical Criteria for Medicinal Drug Promotion 1988* (see Appendix 1), which states that DTCA 'should not generally be permitted for prescription medicines or to promote medicines for certain serious conditions that can be treated only by qualified health practitioners'. However, the WHO ethical criteria are not legally binding; they are standards that can be used to develop regulation. It is important to note that in New Zealand, a full prohibition on DTCA may constitute a limitation on the right to freedom of expression as outlined in section 14 of the New Zealand Bill of Rights Act. This issue is detailed on page 25.

### **Regulation of advertising**

DTCA is co-regulated in New Zealand. The system relies on legislation and, primarily, on industry codes of practice. Currently, there is far greater reliance on industry self-regulation, with a major role played by the media and advertising industries in ensuring that the advertising of therapeutic products is socially responsible. The industry in this context includes pharmaceutical companies and associations, advertisers and publishers. They have developed a self-regulatory system for ensuring that advertisements making therapeutic claims meet standards of social responsibility, as well as complying with legislative requirements. No formal framework for monitoring and evaluation on the effectiveness of the current advertising model is in place.

The Advertising Standards Authority (ASA) and the Researched Medicines Industry (RMI) administer the self-regulatory component of the co-regulatory model for DTCA. The ASA has developed a Code for Therapeutic Advertising that covers all advertisements making therapeutic claims and applies across all media. While New Zealand Medicines and Medical Devices Safety Authority (Medsafe) is consulted on any proposed changes to the Code, the Code is not linked to the Medicines Act 1981. However, the requirements of the Code are broadly consistent with the requirements of the Act. The principles and requirements of this Code are modelled on the proposed Australia New Zealand Therapeutic Products Advertising Code, which is intended to replace the ASA Code when the Therapeutic Products Bill is introduced.<sup>5</sup> The ASA is responsible for:

- setting and maintaining appropriate and proper standards for advertising
- establishing and promoting an effective self-regulatory system for advertising standards.

<sup>5</sup> Advertising Standards Authority, URL: <http://www.asa.co.nz/codes/codes.htm>.

The ASA requires advertisers and publishers who recognise its authority to also abide by the RMI Code of Practice when they are advertising pharmaceuticals. The RMI Code of Practice contains additional requirements for advertising to those set out in the ASA Code for Therapeutic Advertising. Membership of the RMI is voluntary and not all pharmaceutical companies are members. However, all pharmaceutical companies can be required to correct or withdraw an advertisement that does not meet the RMI or ASA codes of practice, regardless of membership of the RMI.

### **Pre-publication approval**

The Association of New Zealand Advertisers has developed and manages a system of pre-vetting of advertisements to ensure that they comply with the requirements of relevant legislation and the codes of practice administered by the RMI and ASA. This system is known as the Therapeutic Advertising Pre-vetting System (TAPS). Under this system, approval of advertisements is undertaken voluntarily by industry, with mainstream media agreeing not to accept an advertisement for publication unless there is evidence that the advertisement has been pre-approved by TAPS.

The ASA scheme also allows a TAPS approval number to be issued by a Delegated Authority within either a media company or a manufacturing company. To obtain a Delegated Authority the person in the company must be assessed and approved by several members within the ASA scheme. The Delegated Authority can then assess and approve advertisements for publication.

### **Complaints made to the ASA**

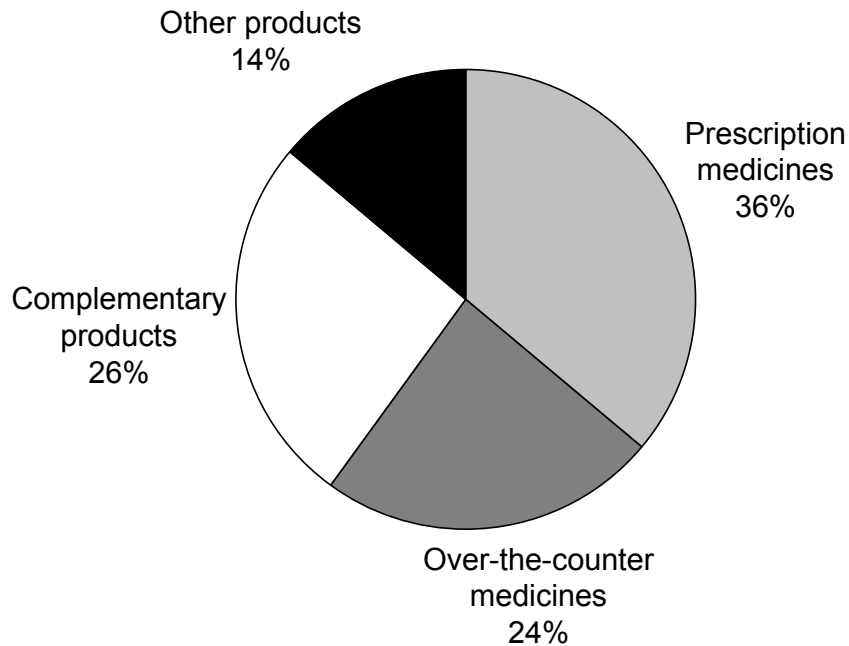
The ASA maintains a complaints and appeals system and has the ability to require an advertisement to be withdrawn if a complaint is upheld. The complaints and appeals boards include independent members of the medical profession and consumer representatives. The members are selected by the ASA. The scheme is entirely funded by industry and is essentially voluntary in nature, as the self-regulatory system is not formally linked to the regulator's powers (the Medicines Act and Regulations).

TAPS approved 1596 advertisements for therapeutic products during 2004 (see Figure 1 below). There were 34 complaints under the ASA Code for Therapeutic Advertising in 2004; three concerned prescription medicines advertised to consumers. One was a complaint against Pfizer concerning a Celebrex advertisement and was upheld. The other two complaints were against separate Ministry of Health advertisements concerning the meningococcal vaccine. One was upheld and the other was not accepted (Advertising Standards Authority 2004).



## Extent of DTCA in New Zealand

**Figure 1:** Advertisements by product, 2004



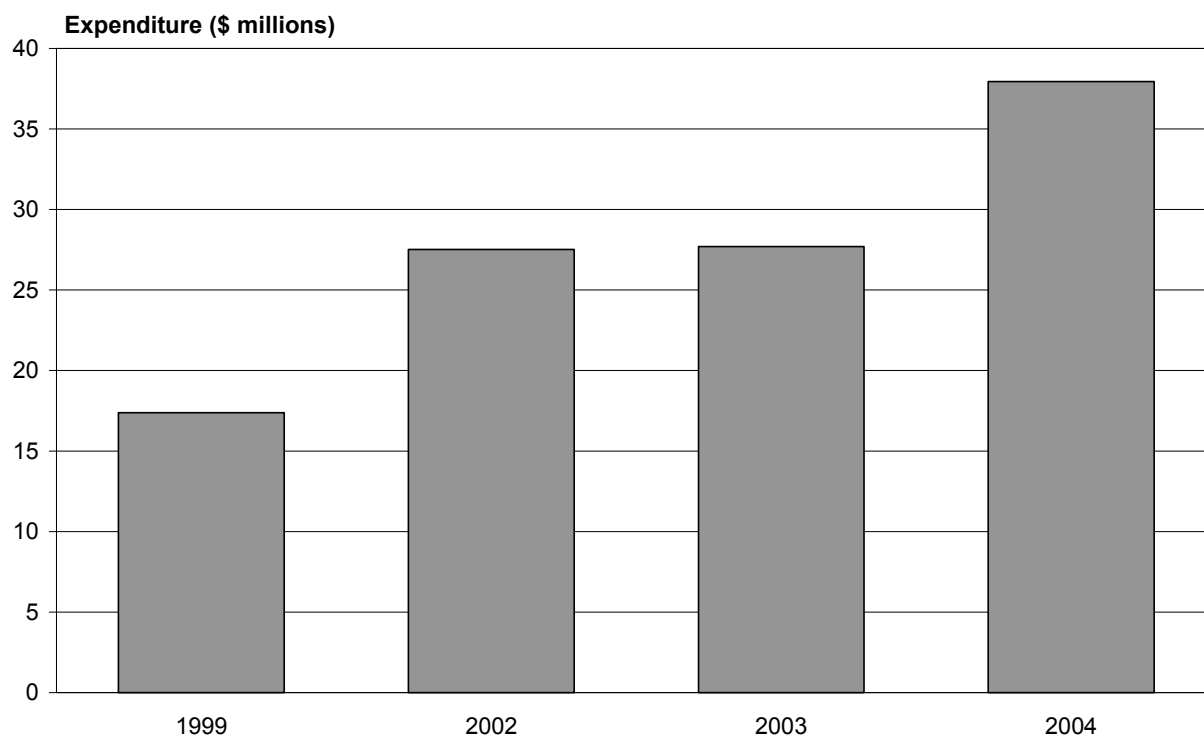
Source: Association of New Zealand Advertisers

For the purposes of this document, only the 'prescription medicines' section of Figure 1 should be considered.

In 2004, pharmaceutical companies spent approximately \$38 million on DTCA.<sup>6</sup> The figures presented in Figure 2 are for the category 'Analgesics, Remedies, Medicines' only, which represents most products involved in DTCA. Note that this category does not include advertising for products such as Xenical, as it is recorded in the category 'Diet/Slimming, Health Clinics'.

<sup>6</sup> Email correspondence with the Association of New Zealand Advertisers, 1 August 2005.

**Figure 2:** Expenditure on DTCA (Analgesics, Remedies, Medicines), 1999 and 2002–2004



Source: Association of New Zealand Advertisers

## Previous reviews of DTCA policy in New Zealand

### 1998 inquiry

As a result of the growth in DTCA activity, specifically a high-profile advertising campaign for the anti-obesity drug Xenical, in 1998 the then 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 Intercontinental Medical Statistics Health poll of 400 GPs,<sup>7</sup> with a 30 percent response rate, found that:

- 75 percent of respondents either wanted DTCA to stop altogether or to be decreased
- 20 percent of respondents wanted the levels of DTCA to remain the same or to be increased
- 61 percent felt DTCA created disharmony in the doctor–patient relationship
- 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 in New Zealand and to give the industry an opportunity to demonstrate a commitment to self-regulation (under the Medicines Act 1981).

<sup>7</sup> As cited in: Mansfield P. Report on DTC pharmaceutical promotion for PHARMAC. URL: <http://healthyskepticism.org/other/dtca/Report%20on%20DTCA%20for%20PHARMAC.doc>.

## **2001 public consultation**

Public consultation on DTCA was last undertaken in 2001 through a discussion document issued by the Ministry of Health. The discussion document reviewed the international positions on DTCA and provided a range of policy options for the future of DTCA in New Zealand. Forty-three submissions were received, with an almost even split between those in favour of DTCA (18) and those opposed to it (20). All of the pharmaceutical companies (5) and advertising companies (7) who responded to the discussion document were in favour of DTCA. However, the majority of submissions (77%) received from members of the public, health professionals, educational/research and other organisations and Pharmac were opposed to DTCA.<sup>8</sup> The outcome of this consultation was to continue to permit DTCA in New Zealand.

## **Current consultation**

Due to the considerable public and industry interest in DTCA policy and the impending Therapeutic Products Bill, the Minister of Health has asked the Ministry of Health to undertake further public consultation on the regulation of DTCA in New Zealand. The Ministry of Health will consider the arguments and views outlined in submissions when providing advice to the Government on policy options for the regulation of DTCA in New Zealand. The timing of this consultation will allow for public debate on the issue of DTCA and, if required, for any recommended changes to be reflected in the Therapeutic Products Bill prior to its introduction.

<sup>8</sup> A summary of submissions can be found online on the Ministry of Health website, URL: [www.moh.govt.nz](http://www.moh.govt.nz).

## Australia

In Australia DTCA is prohibited, but disease-state advertising about a particular condition and general treatments is permitted. As noted above, the Therapeutic Products Bill is set to repeal existing advertising legislation in Australia. The Therapeutic Products Advertising Code will not change Australia's policy towards DTCA; however, it will tighten restrictions around disease-state advertising.

### Current regulation

Medical advertising in Australia is currently regulated under the Therapeutic Goods Act 1989, which prohibits DTCA, but allows disease-state advertising and advertising directed to health professionals. Therapeutic Advertising is a co-regulatory system in Australia, with advertisements regulated by the Government and the advertising industry. Advertisements for therapeutic goods in Australia are subject to the requirements of the Therapeutic Goods Act 1989, the Trade Practices Act 1974 and other relevant laws. Additionally, advertisements for therapeutic goods directed to consumers must comply with the Therapeutic Goods Advertising Code, which is generally consistent with the World Health Organization's *Ethical Criteria for Medicinal Drug Promotion 1988*. The Medicines Australia (previously the Australian Manufacturers Association) Code of Conduct complements the legislative requirements laid out in the Therapeutic Goods Act, and requires the promotion of all prescription products to comply with the requirements of the Code. The object of the Code is to ensure that the marketing and advertising of therapeutic products to consumers is conducted in a manner that promotes the quality use of therapeutic products, is socially responsible and does not mislead or deceive the consumer.

### Australia–United States Free Trade Agreement

The Australia–United States Free Trade Agreement (AUSFTA) came into force on 1 January 2005. The Agreement did not change the Australian prohibition on DTCA. AUSFTA requires websites advertising pharmaceutical products to comply with the law of the respective country (eg, Australian websites need to comply with Australian law). This means Australian websites cannot contain DTCA; however, the Agreement does allow Australian websites to include links to US sites that contain DTCA provided there is clear notification of the move from an Australian to a US website.

### Previous review of DTCA policy in Australia

In 2001 the Therapeutic Goods Administration (TGA) reviewed Australian legislation on drugs, poisons and controlled substances, which included reviewing the controls on DTCA ('the review'). The review examined a possible liberalisation of Australia's ban on DTCA, conducting a cost-benefit analysis of the current Australian restrictions and comparing this with a cost-benefit analysis of alternatives such as no regulation and co-regulation. The review 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 (Galbally 2001).

The review made the following points in response to the possibility of a relaxation of the advertising regime in Australia.

- Should DTCA be permitted, the bulk of the advertising would be for a few new and generally high-priced products and for those used to treat some of the more common serious conditions (as is the case in the US).
- It would be unlikely that Australian manufacturers would advertise older (possibly cheaper) 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, with the consequence of a greater expectation that the health professional will prescribe on request.
- DTCA of prescription products for Australia is not supported by organisations representing doctors, pharmacists or veterinarians.

On balance, the review considered that the current prohibition on DTCA of prescription drugs in Australia should be maintained, except where it could contribute to a net public benefit through information rather than promotion. This is a precautionary approach. It is important to note that the Galbally Review was considering DTCA regulation from the Australian status quo position of a ban on DTCA. Jurisdictions where DTCA is not currently permitted commonly require evidence that allowing DTCA would confer a clear benefit or at least have a neutral impact before change is endorsed.

## **Regulation of advertising under the Australia New Zealand Therapeutic Products Authority (Therapeutic Products Bill)**

This section provides an overview of the advertising arrangements that will come into effect under the Therapeutic Products Authority that New Zealand is establishing with Australia. For the purposes of this document, the arrangements for the regulation of advertising outlined below should be viewed as the status quo.

### **Background**

On 10 December 2003, the Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products was signed. The Therapeutic Products Authority will replace Australia's Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

The role of the new Therapeutic Products Authority will be to safeguard public health through regulation of the quality, safety and efficacy or performance of therapeutic products in both Australia and New Zealand. This includes prescription and over-the-counter medicines, complementary medicines, medical devices, tissue-based therapies and blood. The new Therapeutic Products Authority will be equally accountable to both the New Zealand and Australian Governments. It will be recognised in law in both countries and will assume responsibility for the regulatory functions undertaken by the TGA and Medsafe.

### **Advertising controls**

The Therapeutic Products Bill is to repeal the Medicines Act 1981, at which point advertising controls will be continued and strengthened under the Therapeutic Products Authority. A proposed trans-Tasman model for regulating the advertising of therapeutic products has been considered by the Therapeutic Products Interim Ministerial Council.<sup>9</sup> The proposed model aims to balance the benefits of consumer access to accurate and balanced information and the right to freedom of speech, on the one hand, with the need to ensure public health and safety, on the other.

In keeping with the overall approach to the Joint Regulatory Scheme, the model for advertising is risk-based. The model provides for a joint approach to regulation that draws on and strengthens the co-regulatory model in Australia (medical advertisements are regulated by the Government and the advertising industry), and preserves the existing functions of the Advertising Standards Authority in New Zealand.

<sup>9</sup> The Therapeutic Products Interim Ministerial Council comprises the New Zealand Minister of Health and the Australian Parliamentary Secretary of Health and Ageing. The Interim Ministerial Council oversees the development of the Joint Regulatory Scheme. A Ministerial Council will be established once the Therapeutic Products Bills are passed and the Treaty is ratified.

## **Consultation**

There was extensive industry consultation in both Australia and New Zealand as part of the development of a proposed advertising regulatory model by the Interim Advertising Council. Three formal rounds of stakeholder consultation were held between July 2003 and October 2004 in Australia and New Zealand to inform the work of the Interim Advertising Council. TGA, Medsafe and Therapeutic Products Authority websites were kept up-to-date with Interim Advertising Council activities and proposals, and written submissions were welcomed throughout the process. Additionally, there were many informal briefings provided to different stakeholder groups by the TGA and Medsafe on a 'by invitation' basis. The Interim Advertising Council considered all issues that were put forward through the consultation process.

## **Australia New Zealand Therapeutic Products Advertising Code**

The Australia New Zealand Therapeutic Products Advertising Code is to be applied as the standard for all advertisements of therapeutic products (directed at consumers and health care practitioners), which will be legally underpinned in legislation. The Key Advertising Principles and the Advertising Requirements are to be set out in the Rules. Any changes to these principles or requirements will require approval by the Ministerial Council. The draft Code that has been developed accommodates the status quo in each country with respect to DTCA. That is, the draft Code recognises that in New Zealand DTCA is permitted, and in Australia it is not. These different approaches could continue once the Therapeutic Products Authority is established.

An Advertising Council is proposed to be established as an expert advisory committee that will provide advice to the Therapeutic Products Authority on the operation of the Advertising Code for both Australia and New Zealand. The Council will have New Zealand and Australian representatives. The Council will monitor the effectiveness of the processes associated with the controls on therapeutics advertising in Australia and New Zealand and provide feedback to the Therapeutic Products Authority.

All advertising of therapeutic products (including advertising on the Internet) in Australia and New Zealand would be required legally to comply with the Therapeutic Products Advertising Code. Criteria will be established to distinguish between those medicines that require pre-approval of advertisements and those that do not. The authority to require pre-approval of advertisements published in mainstream media will be established in the Rules and in the Advertising Code. Currently pre-approval is undertaken voluntarily in New Zealand by industry with advertising media agreeing not to publish advertisements that are not pre-approved. In New Zealand TAPS will continue to pre-approve advertisements. However, delegation will come from the Therapeutic Products Authority.

Compliance with the Code will be enforced through a range of administrative sanctions, civil penalties and criminal penalties or other regulatory action (eg, suspension or cancellation of licences). The levels of penalties and sanctions for breaches to the Code are yet to be decided; however, they will be commensurate with the risk posed and likely to be higher than the current penalties in New Zealand and Australia. Consistent outcomes for similar offences will be maintained between New Zealand and Australia.

More information on the Therapeutic Products Advertising Code can be found online at: [www.jtaproject.com](http://www.jtaproject.com).

**Table 1:** Instruments of control over DTCA under the Therapeutic Products Authority

Instrument	Purpose
Treaty	<ul style="list-style-type: none"> <li>• Establishes the Ministerial Council.</li> <li>• Provides the ability for the Ministerial Council to make rules about advertising controls.</li> <li>• Provides for the establishment of the Therapeutic Products Authority.</li> <li>• Establishes the Therapeutic Products Authority Board.</li> </ul>
Therapeutic Products Bill	<ul style="list-style-type: none"> <li>• Gives effect to the Treaty.</li> <li>• Sets out offences, penalties and sanctions across the range of issues in the therapeutic products area, including DTCA.</li> </ul>
Rules	Rules will build on the principles in legislation and provide broadly for the circumstances in which products are not to be promoted, requirements for the promotion of products, and representations that are not to be made about products. Rules will refer to the Therapeutic Products Advertising Code.
Australia New Zealand Therapeutic Products Advertising Code	Sets out the advertising principles and requirements (drawing from the implementing legislation and the Ministerial Council Rules) and is to be approved and amended by order of the Managing Director of the Therapeutic Products Authority on the advice of the Advertising Council. The Therapeutic Products Advertising Code is detailed and the current draft reflects different policy settings in New Zealand and Australia with respect to DTCA.



## 4 The Cases For and Against DTCA

This section outlines the main arguments used to support and oppose DTCA:

- provision of health care information to consumers
- increased and unnecessary fiscal pressures on the pharmaceutical budget
- medicalisation of normal bodily processes
- impact on patient–doctor relationships.

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 are inconclusive.

### Reported concerns and benefits of DTCA

The Australian Galbally Review (Galbally 2001) provides a useful summary of commonly raised concerns and benefits of DTCA.

Concerns identified in regard to DTCA were that it:

- leads to inappropriate use of medicines where doctors succumb to patient pressure to prescribe a particular medicine
- undermines the doctor–patient relationship where patients aggressively demand that a particular product be prescribed or leave the surgery dissatisfied because the product was not prescribed
- results in confused or misinformed consumers because they have too little knowledge about a medical condition or treatment, and the information available to inform them is unbalanced
- generates consumer anxiety through exaggerated promotion of the risk of disease, which may adversely impact on vulnerable populations, such as the uneducated or those with chronic or severe illness
- leads to wide use of medicines in the community before a population risk profile has been developed
- leads to acceptance of medicines as ‘life solutions’, to the detriment of better alternatives, such as diet and exercise (ie, increased medicalisation of society, with an associated increase in risk of medical misadventure)
- results in escalating costs to subsidise medicines and patient visits to doctors, particularly where consumers are ‘doctor shopping’ in an attempt to find a doctor prepared to prescribe a particular medicine.

An alternative perspective on these concerns is that, as a consequence of DTCA:

- some prescribers will react constructively to consumer pressure by ensuring that they have all of the relevant information about a DTC-advertised medicine and related condition to inform their prescribing decisions
- the doctor–patient relationship will be improved as a result of increased contact and discussion regarding patient health care
- earlier knowledge of treatment possibilities will, in some cases, ease anxiety about disease risk – those with limited education and severe illness may receive simple accessible information about potential therapy
- medicines will be used to treat conditions earlier and result in better patient outcomes
- in some cases, where professional advice would not otherwise be sought, preliminary awareness and diagnosis by patients will improve therapy by enhancing patient understanding and increasing the likelihood that they will present to professionals
- innovation for new medicines will, in some cases, be brought forward.

The above summary demonstrates the range of views held about DTCA. Clearly such propositions and counter-propositions have varying degrees of merit. The literature available does not clearly demonstrate unequivocal evidence of harm or benefit in relation to DTCA.

## Provision of information

### Arguments for and against

The main argument against DTCA is that the fundamental nature and goals of advertising make it an inappropriate mechanism for the dissemination of high-quality information to the general public about high-risk products. All advertising aims to sell a product, and will always present the product in a positive light as much as possible. Advertisements will not advise potential consumers that they do not need to take the advertised product, that a competitor's products are superior, or that changes in lifestyle may be more appropriate.

Several trends have emerged in advertisements for prescription medicines including:

- lack of balance between benefit and risk
  - overstatement of the benefits offered by the product
  - minimisation of the risk associated with the product
- poor presentation of risk data
  - printing risk data in very small fonts
  - oversimplification of risk data
  - use of technical language
- absence of cost information.

Critics argue that DTCA does not fully inform patients, which may lead them to form mistaken perceptions of an advertised medicine's effects or potential appropriateness. There is little information provided about potentially unpleasant or serious side effects of advertised drugs.

The arguments used to support DTCA centre on the benefits of the provision of information to consumers that may not otherwise be accessed and its potential to avert underuse of effective treatments. Increasing numbers of consumers want to play an active role in the management of their health. Proponents of DTCA argue that it provides information that prompts consumers to discuss medication issues with their doctor and to raise questions about otherwise underdiagnosed or undertreated conditions.

### Comment

There are multiple agencies, including government agencies (eg, Medsafe and the Pharmaceutical Management Agency of New Zealand), non-government organisations (eg, the New Zealand Guidelines Group), private companies (eg, pharmaceutical companies), consumer groups and health practitioners, that provide consumers with medicine and health information. Other avenues by which consumers receive information include the media, Internet, family and friends. The relationships among these organisations, institutions and individuals and the way information is provided to health practitioners and consumers will influence the information consumers receive.

There is little doubt that the format and method of dissemination used for DTCA make it very difficult for an advertiser to provide all of the risk and benefit data necessary for consumers to make informed decisions about which medicines might be appropriate for them. It is unclear whether there was ever an expectation that DTCA would or could fulfil the purpose of fully informing the public. It should be noted that the final decision about the appropriateness of a prescription medicine lies with the prescriber, not the patient, and prescribers are professionally accountable for their prescribing decisions.

Research indicates that most consumers view their GP as their primary source of reliable medicines information. Pharmacists are identified as a second preferred source of information, partly because the advice is free, and also because the information provided is considered to be reliable. In a recent study, information from medical and health professionals was preferred over that from advertisements, friends and family as it was associated with reliability and accuracy. Concerns expressed about other sources of information such as advertisements, friends and family were based on uncertainty about the accuracy of the information and the motives of those providing it (Health Services Research Centre 2004).

Despite being sceptical about the commercial nature of the advertising of medicines, some consumers may find DTCA useful. Hoek et al (2004) report that 23% of a sample of New Zealand consumers 'had asked their doctor about a medicine after seeing it advertised and 15% had discussed a health issue they had not previously discussed following exposure to DTCA'.

Mauback and Hoek's (2005) study of New Zealand GPs found favourable views of DTCA's ability to increase awareness of some health conditions. However, some GPs expressed serious concerns about the adequacy of the risk and contraindication information provided and the lack of cost information.

## **Fiscal pressures**

### **Arguments for and against**

Advertising is a key marketing strategy employed by the pharmaceutical industry to increase brand recognition and sales revenue. Critics argue that DTCA increases pressure on PHARMAC, from the public and others, to subsidise the new, higher-priced pharmaceuticals. Some opponents argue that in the majority of cases the product advertised offers little advantage over existing products. Concern has also been raised that DTCA increases demand for unsubsidised 'lifestyle medications' (eg, treatments for unwanted weight gain, erectile dysfunction and hair loss). However, this argument is based on the premise that lifestyle medications offer no health benefits to consumers and makes the value judgement that lifestyle medications are unnecessary in medical practice.

There is also a claim that the cost of subsidies for medicines and patient visits to GPs is escalated as a result of DTCA, particularly if consumers visit a number of physicians in an attempt to find one willing to prescribe the advertised medicine. This cost is borne by both the consumer and the government (taxpayers).

Where the medicine is not subsidised, high prices become an issue for individuals. It has been suggested that public confidence in the state-funded health care system can be undermined when individuals find it difficult to access advertised medicines that do not attract a government subsidy.

Advocates of DTCA argue that many of the medicines advertised are not subsidised and GPs do not generally issue prescriptions that are not necessary. As a result, any increase in prescriptions due to DTCA is seen as positive as it means more New Zealanders are receiving appropriate treatment.

### **Comment**

PHARMAC's previous analysis of the impact of DTCA on the pharmaceutical budget for Flixotide and Lamisil has shown a relationship between advertising expenditure and government expenditure. For example, after the product Flixotide began to be advertised directly to consumers in 1998, there was 62 percent growth in Flixotide dispensings from 1998/1999 to 1999/2000. Another example is Lamisil (a treatment for fungal infections) – \$539,000 was spent in advertising Lamisil and dispensings increased by 39%, which resulted in increased pharmaceutical expenditure of \$0.770 million or 41% on Lamisil.

It should be noted that the Flixotide advertising campaign may have achieved a large movement from existing asthma inhaler products and to the newer product, Flixotide, in part because it led many asthmatics to believe that their current preventer inhaler was being withdrawn and that they had no choice but to swap to Flixotide. In reality, an alternative brand of their existing treatment was available. Use of Flixotide has increased significantly, not only in New Zealand but also in countries that do not permit DTCA.

It is also important to note that Lamisil has fewer side effects and a shorter course of treatment than other treatments for chronic fungal infections. Once funding for Lamisil became available, GPs may have felt more compelled to prescribe Lamisil, given the opportunity to treat a previously undertreated condition more safely and effectively.

Reports such as the General Accounting Office's *FDA Oversight of Direct-to-Consumer Advertising Has Limitations* (United States General Accounting Office 2002) identify a number of factors that may increase the use of pharmaceuticals and, if they are occurring at the same time as DTCA, will confound the assessment of the effects of DTCA on sales. These factors include:

- an ageing population that is increasingly dependent on multiple medications
- increased diagnosis of chronic conditions such as arthritis
- the emergence of safer, more effective treatments
- the uptake by prescribers of published international and local guidelines advocating use of particular medicines
- direct-to-practitioner advertising.

Hoek et al (2004) reviewed patient surveys of DTCA in the United States and New Zealand in 2003. They found that the data indicated:

that the great majority of patients neither asked for, nor received, a prescription as a result of DTCA: [the data] also show that doctors often responded to explicit requests with alternative treatments or lifestyle advice.

The literature suggests that there are a number of confounding variables surrounding the data that indicate there is increased prescribing in response to DTCA.

## Medicalisation

### Arguments for and against

Medicalisation refers to the increasing tendency for people to seek pharmacological treatment for a growing number of conditions: this is also known as 'pill for any ill' behaviour. So-called 'lifestyle medicines', such as treatments for unwanted weight gain, erectile dysfunction and hair loss, have been the subject of a significant proportion of DTCA in New Zealand. As mentioned earlier, the argument against DTCA on the grounds that it further medicalises normal body processes is based on the premise that lifestyle medications offer no health benefits to consumers. Lifestyle medicines are usually not government subsidised and fall between medical and social definitions of health.

The effects of DTCA on individual health habits, in particular DTCA for certain lifestyle medications, should also be taken into account, as it could be argued that some consumers may care less about maintaining healthy lifestyles because they know drug treatments are available should they become sick. On the other hand, DTCA may alert people to adopt healthy habits by reminding them that there are potential diseases they might suffer that may require medical treatment.

Toop et al (2003) argue that DTCA commonly redefines normal processes or social problems as medical problems:

Pharmaceutical solutions are offered for normal physiological or ageing processes and encourage the belief that there is a quick fix drug for every condition. This results directly in the medicalisation of normal health and ageing and discourages sustainable behaviour change to address health problems, such as physical exercise and dietary change to reduce weight.

The contrary view is that the accepted definition of health has always been about more than just the absence of disease and has now expanded to include the management of processes associated with ageing. In addition, some of the conditions identified as 'lifestyle conditions' can be associated with significant morbidity or mortality.

Erectile dysfunction is an example of a condition that is classed as a lifestyle condition, which is potentially caused by a number of diseases such as diabetes. It can be argued that this label undervalues the personal and relationship problems caused by erectile dysfunction. It also discounts the potential positive effects that may be forthcoming from screening a patient who presents complaining of erectile dysfunction.

### Comment

Maubach and Hoek's (2005) qualitative analysis of interviews with 20 New Zealand GPs found divergent views on the effect of DTCA on the medicalisation of normal bodily processes. Some respondents reported concerns about medicalisation on the basis that it diverts attention from more appropriate treatments such as changes in diet and exercise. Others, however, thought that DTCA could promote discussions between patients and GPs about lifestyle conditions, such as obesity and the prevention of chronic disease.

Hoek et al (2004) found that consumer evidence suggests DTCA may prompt earlier diagnosis of conditions that require management. New Zealand consumers reported that they typically asked about an advertised medicine during an already scheduled consultation made to discuss another matter.

Iizuka and Zhe Jin (2005) studied the effects of DTCA on two health habits: smoking and exercise. The study found that DTCA of tobacco cessation products did not decrease the tendency of smoking in the adult population, and more disturbingly, appeared to increase the proportion of smokers within educated and insured adults. In terms of exercise, the study focused on DTCA that targeted four chronic conditions: diabetes, hypertension, heart diseases and overweight. The study found that DTCA related to the four conditions decreased the likelihood of moderate exercise (but had zero impact on vigorous exercise). One explanation offered for this phenomenon is that, by learning the existence of a drug treatment, people substitute medical treatment for moderate exercise.

While it is appropriate for both doctors and consumers to be concerned about the impact of DTCA on medicalisation of normal bodily processes, other drivers for medicalisation – such as the media news, editorials, medical advertisements, research journals and other publications – should also be acknowledged. The effects of DTCA on individual health habits should also be taken into consideration; however there is little evidence available to suggest that all DTCA results in negative health outcomes (only one study has found evidence of a negative effect of DTCA on individual health outcomes in the cases of smoking cessation and exercise).



## Impact on patient–doctor relationships

### Arguments for and against

Critics of DTCA argue that advertising can create conflict in the doctor–patient relationship, particularly when physicians decide that the advertised drugs requested should not be prescribed. Toop et al (2003) argue that there is evidence that prescribers often feel pressured to write prescriptions for DTCA medicines that they would not otherwise have used for particular patients.

Advocates of DTCA argue that advertising helps patients learn about new medicines and encourages patients to talk to their doctors about possible treatments for a particular condition. It may also create greater opportunities for a partnership between patients and doctors to work together to find appropriate treatments for medical conditions.

### Comment

Prescription medicines can only be accessed through a consultation with a prescriber recognised by the Medicines Act 1981 – a medical practitioner, dentist, midwife or nurse. During a prescriber–patient consultation, the Code of Health and Disability Services Consumers' Rights expects that the prescriber will:

- assess the medical condition of the patient
- determine whether a prescription is necessary
- determine the appropriateness of a medicine for that particular patient
- discuss any relevant issues in relation to the medical diagnosis and the prescribed medicine with the patient.

There is often a failure, particularly in broadcast DTCA, to provide consumers with all the information necessary to determine the best treatment outcome. Queries initiated by DTCA can therefore require significant additional explanation by doctors to explain why a particular drug or treatment may not suit a patient's situation, and this can take considerable time.

The Auckland University Centre for Health Research conducted research on prescribing information resources used by GPs. GPs reported that DTCA did not have a significant impact on their decision-making when prescribing medications. DTCA was acknowledged, however, as a factor that influenced patients' expectations of prescribing (Auckland University Centre for Health Research 2005).

Maubach and Hoek's (2005) qualitative analysis of interviews with 20 New Zealand GPs found a low incidence of DTCA-related queries. In addition, respondents did not report feeling under undue pressure to prescribe requested medications.

Maubach and Hoek (2005) also found that while some GPs resented having to deal with DTCA-generated questions, few considered that this form of advertising undermined the relationship they had with their patients. Many of the 20 GPs interviewed appreciated the influence DTCA had on patients, in terms of encouraging them to take a more active role in managing their health care. However, GPs also reported spending time dispelling misunderstandings created by DTCA, which caused frustration for some GPs due to the impacts on already tight schedules. The study found strong disquiet amongst GPs with regard to particular aspects of DTCA. The researchers concluded that:

While some doctors' responses suggest DTCA has the potential to provide information that fosters better dialogue between doctors and their patients, it is clear that this potential is far from being realised.

Hoek and Gendall's 2003 survey of New Zealand consumers (Hoek et al 2004) found that just over half of the respondents (51 percent) thought DTCA promoted more informed discussions with their doctors. The same survey found that:

11% of respondents considered that DTCA would harm patients' relationships with their doctor, and a slightly higher proportion (16%) felt it could actually improve the relationship. But the majority considered DTCA would have no effect on their relationship with their doctor.

The doctor–patient relationship is an evolving one that has already gained momentum towards a more mutual partnership, with patients more willing to question doctors' advice and seek alternative forms of treatment. The effects of DTCA on the doctor–patient relationship remain largely unquantified.

## **Section 14 of the New Zealand Bill of Rights Act 1990**

Section 14 of the New Zealand Bill of Rights Act 1990 (NZBORA) provides for the right to freedom of expression. This right extends to all forms of communication that attempt to express an idea or meaning, and extends to commercial speech, such as advertising.

Overseas case law suggests that not all forms of expression are equally deserving of the protection of freedom of expression and that commercial expression is considered to be at the edge of being part of that right to freedom of expression. The courts have held the view that commercial expression is of less importance than political or artistic expression and consequently limitations on the right in this context are easier to justify.

An argument may be advanced that the advertising of prescription medicines is protected by section 14 of the NZBORA. However, a restriction on DTCA could be justified under section 5 of that Act if the restriction serves an important and significant objective, and the restriction achieves that objective in a logical and proportional way.

## Conclusions

From the research to date, it is apparent that patient and physician behaviours do alter in response to DTCA. Prompted by DTCA, people are going to doctors; discussing and requesting advertised medicines; and receiving prescriptions. While not quantifiable, these behaviours can influence increasing prescription medicine costs.

To date, the debate over the positive versus negative impact of DTCA on health outcomes has been supported primarily by indirect evidence, however one recent study has found evidence of a negative effect of DTCA on individual health outcomes in the cases of smoking cessation and exercise (Iizuka and Zhe Jin 2005). The majority of research has focused on the effects of DTCA on consumer awareness, attitudes, perceptions and self-reported behaviour, and physician attitudes and self-reported behaviour. The Ministry is not aware of any published analysis establishing whether DTCA creates additional use of pharmaceuticals that is primarily appropriate or cost-effective or the opposite. As stated by Meredith Rosenthal, 'it is not the case that the health services community has missed the point, but that the methodological challenges of conducting such a study are substantial' (Rosenthal 2004).

Until evidential studies are able to establish the direct impact of DTCA on health outcomes and public health in New Zealand and elsewhere, the evidence pointing to either a predominantly positive impact or a predominantly negative impact is likely to remain inconclusive.

In the meantime, the critics of DTCA argue that in the absence of evidence that DTCA has a positive or at least neutral impact, the precautionary principle should apply and DTCA should be restricted or banned. Proponents of DTCA, in contrast, argue that in the absence of evidence that DTCA has a negative impact, the status quo or little change to it should apply.

- Q3. Which of the arguments outlined in Section 5, 'The Cases For and Against DTCA', do you find most persuasive: those for or against DTCA? Why?
- Q4. Do you have any further information or arguments that you consider should be added to this review of the evidence that supports or opposes DTCA? If so, please forward this information to the Ministry of Health.

## 5 DTCA Regulatory Options

### Introduction

This section outlines the costs and benefits of three options for the regulation of DTCA. Clearly, there are other possible responses such as a moratorium, but these are not discussed further here.

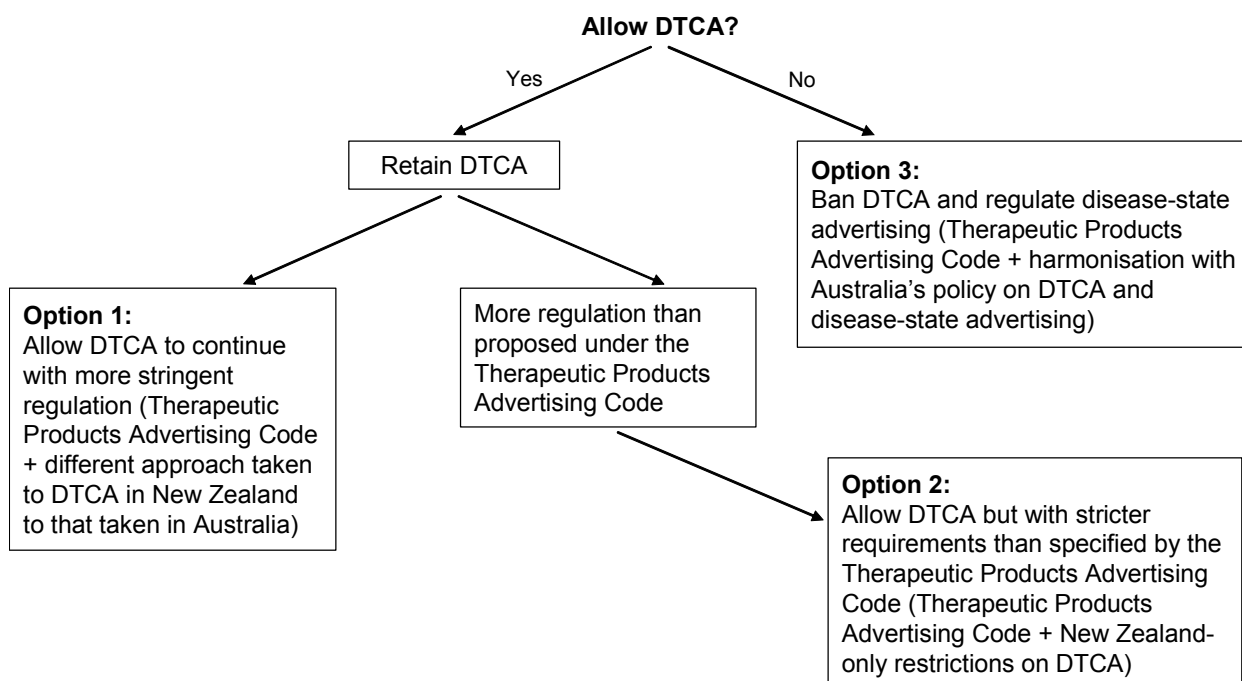
The current regulatory requirements for DTCA under the Medicines Act 1981 and Medicines Regulations 1984 are outlined on pages 4-5. However, regardless of the decision on the future regulation of DTCA in New Zealand, these arrangements are to be superseded by the Therapeutic Products Advertising Code applied under the Therapeutic Products Authority (outlined on pages 12-14). As currently proposed, the Therapeutic Products Advertising Code allows DTCA to continue in New Zealand, albeit with more stringent regulation than under the Medicines Act currently. For the purposes of this document, therefore, option 1 should be considered as the status quo, providing the benchmark against which the other two options may be measured.

The regulatory options for DTCA are:

- **Option 1** – Allow DTCA to continue with more stringent regulation (Therapeutic Products Advertising Code + different approach taken to DTCA in New Zealand to that taken in Australia).
- **Option 2** – Allow DTCA but with stricter requirements than specified by the Therapeutic Products Advertising Code (Therapeutic Products Advertising Code + New Zealand-only restrictions on DTCA).
- **Option 3** – Ban DTCA and regulate disease-state advertising (Therapeutic Products Advertising Code + harmonisation with Australia’s policy on DTCA and disease-state advertising).

It is important to note that under the Therapeutic Products Authority, New Zealand has the ability to consider adopting proposed future changes to the Therapeutic Products Advertising Code or DTCA policy, as does Australia.

**Figure 3:** Main decisions in arriving at DTCA policy conclusion



### **Problem statement**

As outlined above, the evidence is not definitive regarding the impact of DTCA on health outcomes.

The Toop report (Toop et al 2003) highlights that the medical and pharmacy professions remain very concerned about DTCA, and report finding themselves under significant pressure from partially informed consumers. While the evidence from the local research conducted by Maubach and Hoek (2005) indicates this may not be a major problem for the majority of practitioners, the Toop report indicates that DTCA is a current focus of dissatisfaction amongst many health care practitioners.

Some consumer groups in New Zealand have opposed DTCA. Other consumer groups, however, have challenged both sides of the debate by questioning critics' assertions about DTCA and challenging the pharmaceutical industry to do more to deliver on the purported benefits of DTCA.

### **Public policy objectives**

As stated in Section 2, the public policy objectives for the regulation of DTCA are to:

- ensure the quality use of prescription medicines is maximised
- contribute to the provision of consumer information that is balanced and easily understood by New Zealanders, to maximise public health and safety
- ensure regulation is as practicable and as cost-effective as possible
- ensure appropriate and proper standards for prescription medicine advertising.

## **DTCA and the internet**

The internet has seen a proliferation of sites advertising prescription and over-the-counter medicines, as well as more general health information. The quality of such sites varies considerably. There can be direct or hidden bias depending on the source and/or sponsor of the website, which is not always obvious to consumers.

The global nature of the Internet makes it hard to regulate. DTCA is permitted in the United States, which means pharmaceutical companies are effectively able to promote DTCA worldwide. It is questionable whether New Zealand's DTCA regulatory requirements could be implemented beyond New Zealand domain websites.

It could be argued that the ability of New Zealanders to access DTCA information from United States websites undermines New Zealand's regulation of DTCA and is a reason against tightening the current regulatory requirements. However, this argument could lead to the lowest common denominator approach, where New Zealand allows any DTCA if another country allows it, despite any New Zealand-based concerns about negative impacts of DTCA.

## **Option 1 – Allow DTCA to continue with more stringent regulation**

(Therapeutic Products Advertising Code + different approach taken to DTCA in New Zealand to that taken in Australia)

This option would allow both Australia and New Zealand to retain different policies regarding DTCA (ie, DTCA would continue in New Zealand but be prohibited in Australia). As outlined on pages 12-14, the trans-Tasman model would apply a single Therapeutic Products Advertising Code that specifies the requirements for all advertisements of therapeutic products (directed to consumers and health care practitioners). There was extensive industry consultation in both Australia and New Zealand as part of the development of the proposed advertising regulatory model.

Regardless of the decision on the future regulation of DTCA in New Zealand, it is proposed that the Therapeutic Products Advertising Code come into effect under the Therapeutic Products Authority. This option should thus be considered as the status quo, against which the other options may be measured.

### **Description**

This option involves the following:

- DTCA would continue in New Zealand.
- Medical advertising controls would continue to be co-regulatory (medical advertisements would be regulated by the Therapeutic Products Authority and the advertising industry), however less reliance would be placed on industry self-regulation (as is currently the case).
- There would be mandatory pre-approval of DTCA. TAPS would continue to pre-approve advertisements in New Zealand; however, delegation would come from the Therapeutic Products Authority.
- The Therapeutic Products Advertising Code would cover the advertising of all therapeutic products, including prescription medicines, over-the-counter medicines, complementary medicines and medical devices in Australia and New Zealand.
- Stronger penalties for non-compliant advertisements would be implemented.

### **Expected costs and benefits**

#### **Costs**

- Information provided to consumers may not adequately identify the risks, contraindications and costs of advertised prescription medicines.
- Possible fiscal risks may arise from pressure on the pharmaceutical budget due to overprescribing or prescribing of newer, more expensive medicines when generic medicines may be as or more effective.
- There may be potential for prescribing pressure and stress on the doctor-patient relationship.



## **Benefits**

- Some may consider that there would be more appropriate deterrent penalties for individuals and corporations, which could be expected to enhance consumer safety through encouraging the provision of more balanced information.
- Information would continue to be provided to consumers from a source that some may find useful.
- The industry would continue to self-fund the regime.

## **Option 2 – Allow DTCA but with stricter requirements than specified by the Therapeutic Products Advertising Code**

(Therapeutic Products Advertising Code + New Zealand-only restrictions on DTCA)

Under this option DTCA would continue to be permitted in New Zealand, but with stricter requirements than specified under the Therapeutic Products Advertising Code. Criteria for stricter regulatory requirements on DTCA would be developed in consultation with the sector.

### **Description**

This option involves the following.

- The Therapeutic Products Advertising Code (outlined on pages 13-14) would be applied.
- Additional New Zealand-specific DTCA requirements would be developed.
- Criteria for approval of DTCA before advertisements could be shown would be developed.

### **Examples of possible additional requirements under this option**

- More explicit generic warning statements in all DTCA could be required (eg, warning statements must be provided at the beginning of the advertisement, or be of a certain size).
- Advertising a product could be prohibited until it had been on the market for a set period (eg, two or five years).
- Require mandatory pre-approval of all DTCA by the Therapeutic Products Authority (in addition to industry self-regulation of advertisements).

### **Expected costs and benefits**

#### **Costs**

- Advertising revenue through DTCA may fall (although this may be redirected into other forms of advertising).
- The pharmaceutical and advertising industry may react negatively.
- Consumer access to information about prescription medicines from DTCA may decrease.

## **Benefits**

- The risk of a negative influence on the doctor–patient relationship is lower than with Option 1.
- The risk of medicalisation of normal bodily processes is lower than with Option 1.
- Approved DTCA would continue to provide a source of information to consumers that some may find useful.
- It may provide assurance of reasonable ongoing co-operation from pharmaceutical companies involved in the DTCA industry who view this option as a compromise between Option 1 and banning DTCA.

### **Option 3 – Ban DTCA and regulate disease-state advertising**

(Therapeutic Products Advertising Code + harmonisation with Australia's policy on DTCA and disease-state advertising)

Under this option DTCA would be prohibited and disease-state advertising would be regulated. This approach would align New Zealand's regulatory position with that of Australia and other Organisation for Economic Co-operation and Development countries with the exception of the United States.

Under this option consumers' information about specific prescription products would be limited to that provided by health care professionals and the instructions that accompany their medication or Medsafe's information leaflets. In addition, providing Consumer Medicine Information (instructions and contraindications of use of a particular medicine) for prescription medicines is proposed to be compulsory under the Therapeutic Products Authority (currently pharmaceutical companies are not legally required to produce this information). As almost all DTCA is for pharmaceuticals for which there are already equally effective treatments, consumers are not likely to be deprived of information about innovative medicines.

It is important to note that under this option there would be an ability to advertise where there is a clear public health benefit, such as for Ministry of Health vaccination campaigns (eg, meningococcal vaccine).

#### **Disease-state advertising**

There is international concern that where DTCA is banned or restricted, inappropriate disease-state advertising has been used to create a demand for prescription medicines. As outlined on pages 2-3, disease-state advertisements are designed to raise awareness about particular medical conditions without mentioning specific medicines. They are also used to inform the public that new medications are available and that consumers should contact their GP for further information.

#### **Costs of disease-state advertisements**

- Consumers may make unnecessary doctor visits due to the inadequacy of information supplied to them.
- Disease-state advertisements often fail to raise awareness of potential risks associated with the use of a particular category of medicines.

#### **Benefits of disease-state advertisements**

- They encourage consumers to seek medical advice for conditions that might otherwise have gone untreated, or where initiation of treatment would otherwise have been delayed.
- They promote awareness of specific conditions and available treatments.
- Consumers can participate in decisions concerning their health care without being 'sold' on a particular product prior to consulting with a doctor.

Many of the costs and benefits associated with DTCA could also apply to disease-state advertising, although to a lesser extent.

## **Description**

This option involves the following:

- The Therapeutic Products Advertising Code (outlined on pages 13-14) would be applied.
- New Zealand policy would be harmonised with Australia's current policy on DTCA and disease-state advertisements, and the Therapeutic Products Authority would take the same approach to regulation of advertising in both countries.
- The Therapeutic Products Bill would include a prohibition on DTCA.

## **Expected costs and benefits**

### **Costs**

- The ability of consumers to access information may be reduced.
- There may be a risk of undertreating undiagnosed health conditions.
- The decision to ban DTCA could be interpreted by the pharmaceutical industry as a discouraging signal for their further investment in New Zealand. There could be a flow-on impact on the development of the biotechnology sector, where New Zealand companies look to investment from the pharmaceutical industry.
- There could be a reduction in economic activity and employment in the broadcast industry. However, it is possible that DTCA revenue may be reverted to other forms of advertising, such as advertising over-the-counter medicines or advertising direct-to-prescribers.

### **Benefits**

- It may satisfy a significant proportion of the medical profession who are unhappy with DTCA.
- A higher level of protection may be provided for the vulnerable, easily exploited target groups.
- The risk of a negative influence on the doctor–patient relationship would be lower than with Option 1 or Option 2.
- The risks of medicalisation of normal bodily processes may be lowered.
- The fiscal risk arising from pressure on the pharmaceuticals budget could be lowered.

### **New Zealand Bill of Rights Act 1990 issue**

As outlined on page 25, putting stricter controls on DTCA would need to be justified under the New Zealand Bill of Rights Act 1990.

## Considering the options for DTCA

If you consider that the evidence fails to demonstrate the costs of banning DTCA outweigh the benefits of DTCA, you may support Option 1 – allow DTCA to continue with more stringent regulation (Therapeutic Products Advertising Code + different approach taken to DTCA in New Zealand to that taken in Australia) or Option 2 –allow DTCA with stricter requirements than specified by the Therapeutic Products Advertising Code (Therapeutic Products Advertising Code + New Zealand-only restrictions on DTCA).

Alternatively, a decision to ban or restrict DTCA can be drawn from the application of a precautionary approach, if the lack of evidence of benefit to the community is considered more important. If you consider that the costs of DTCA outweigh the benefits, or consider a precautionary approach<sup>10</sup> is merited, you may support either Option 2 – allow DTCA with stricter requirements than specified by the Therapeutic Products Advertising Code (Therapeutic Products Advertising Code + New Zealand-only restrictions on DTCA) or Option 3 – ban DTCA and regulate disease-state advertising (Therapeutic Products Advertising Code + harmonisation with Australia's policy on DTCA and disease-state advertising).

Now that you have considered the arguments for and against DTCA, this paper asks you to consider whether you support the level of controls proposed under the Therapeutic Products Advertising Code (Option 1), DTCA with stricter requirements than specified under the Code (Option 2) or a complete ban on DTCA and regulation of disease-state advertising (Option 3).

- Q5. Which of the options outlined in Section 6, 'DTCA Regulatory Options', do you support? Why?
- Q6. What further options, if any, relating to the regulation of DTCA in New Zealand do you support? Why?
- Q7. Do you have any other views on how to achieve the purported benefits of DTCA (eg, consumer access to pharmaceutical information, enhanced doctor-patient relationship, increased diagnosis of previously untreated conditions), without experiencing the purported costs of DTCA? If so, please forward these views to the Ministry of Health.

<sup>10</sup> For the purposes of this document, a 'precautionary approach' refers to banning or restricting DTCA in the absence of evidence that shows DTCA to have a positive or at least neutral impact.

# Appendix 1: DTCA – International Situations and the Role of Regulation

## United States

The United States is the only other country in the OECD that allows DTCA, although it has adopted a regulatory model and processes that are strikingly different to New Zealand. DTCA critics in the US acknowledge that DTCA is unlikely ever to be banned, as the First Amendment in the US Constitution would make this impossible (Meek 2001).<sup>11</sup>

## Regulation

The United States 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 the following conditions:

1. They must not be false or misleading in any respect.
2. They must present a fair balance of information about the risks and benefits of using the drug.
3. They must include a 'major statement' of the drug's major risks.
4. They must make 'adequate provision' for dissemination of further details provided in package labelling.
5. They must provide information in 'consumer friendly' language (Hoek and Gendall 2004).

The FDA oversees the advertising of prescription drug products through a comprehensive surveillance, enforcement and education programme, and by fostering better communication of labelling and promotional information to both health professionals and consumers. The FDA has the authority to require an offending company to undertake corrective actions and (ultimately) to remove a product's marketing licence.

<sup>11</sup> The US First Amendment – Freedom of religion, press, expression states: 'Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances'.

## **Previous review of DTCA in the United States**

After the first DTCA campaigns began to appear in the US 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 its prescription medicine advertising while the FDA researched DTCA to assess its impact on consumers and, if necessary, 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 pharmaceutical industry in 1984, nearly 80 percent of the 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 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 produced. 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.

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; a website address; and simultaneous DTC print advertisements that included the brief summary or brochures in doctors' offices, libraries and stores.

This regulatory change led to considerably more 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 continued to accelerate, reaching US \$1.3 billion in 1998, \$1.9 billion in 1999, \$2.5 billion in 2000 and \$2.7 billion in 2001 (Calfee 2002), and rising to an estimated \$3.2 billion in 2003 (Kaiser Family Foundation 2004).

An 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.



In response to comments that its 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 two years of finalising the guidance (FDA 1999).

In June 2005 the American Medical Association voted to further study the issue of DTCA because of concerns about the effects of these advertisements on the patient–doctor relationship and on health care costs. The American Medical Association will study the effect of DTCA on patient care and consider strategies that could minimise its potential negative impact.

In August 2005 the Pharmaceutical Research and Manufacturers of America (PhRMA) issued voluntary 'Guiding Principles' on DTCA for its member companies. These guidelines are to address concerns expressed by American Psychiatric Association, the American Medical Association, and public policy officials, among others, about DTCA. The PhRMA guidelines were also issued in response to a proposal by Senate Majority Leader Bill Frist for a voluntary moratorium on DTCA, in an effort to cap spiralling health care costs and promote patient safety.

Among the PhRMA Guiding Principles are provisions that would encourage drug makers to:

1. refrain from running misleading advertisements
2. educate doctors about a new drug for an 'appropriate' amount of time before starting DTCA on that drug (giving the drug maker the sole discretion to decide the meaning of 'appropriate')
3. avoid targeting audiences who are not age-appropriate.

The guidelines also establish a PhRMA 'Office of Accountability' responsible for receiving comments from the general public and health care professionals regarding DTCA.

Although the PhRMA Guiding Principles are not mandatory, the *Wall Street Journal* reports that 23 companies have already promised to comply (Wasserstrum 2005). The PhRMA Guiding Principles are available online at: [www.phrma.org](http://www.phrma.org).

## Canada

DTCA is prohibited in Canada. However, concerns have been expressed in medical publications about the interpretation of the policy governing this marketing strategy, as a result of the partial introduction of DTCA showcased in reminder advertisements and help-seeking advertisements. Canada also has the difficulty of dealing with the cross-border drift of advertisements from the United States, where DTCA is legal.

### Regulation

Regulation of pharmaceutical advertising in Canada is covered by the Food and Drugs Act, which explicitly prohibits DTCA. The Act prohibits the advertising of any drug to the general public as a treatment, preventive or cure for serious diseases and prohibits the advertising of prescription-only drugs.

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 in the form of reminder or help-seeking advertisements. *Reminder* advertisements provide the name of a product without stating its use, and *help-seeking* advertisements inform consumers of new but unspecified treatment options for diseases or conditions (Gardner et al 2003).

Published advertisements of prescription medicines, in all forms, are subject to a voluntary pre-clearance review by independent agencies endorsed by Health Canada. These agencies are Advertising Standards Canada and the Pharmaceutical Advertising Advisory Board, who provide advisory opinions on messages directed to consumers for prescription drugs to ensure that they meet the regulatory requirements. In addition, Advertising Standards Canada reviews advertising material for non-prescription drugs directed to consumers, while the Pharmaceutical Advertising Advisory Board reviews advertisements for all drugs directed to health professionals. Advertising Standards Canada and the Pharmaceutical Advertising Advisory Board review and pre-clear advertising material in order to determine compliance with the regulatory provisions of the Food & Drugs Act and Regulations and the various codes of advertising. These regulations are intended to protect the health of Canadians.

Health Canada is the national regulatory authority for drug advertisements. Health Canada provides policies to effectively regulate marketed health products and oversees regulated advertising activities. Although it is not mandatory, Health Canada and various manufacturer associations such as the Non-prescription Drug Manufacturers’ Association of Canada and Canada’s Research-Based Pharmaceutical Companies encourage all sponsors to comply with the voluntary pre-clearance review by Advertising Standards Canada and the Pharmaceutical Advertising Advisory Board.

## **Previous review of DTCA in Canada**

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. One of the goals of the Health Protection Legislative Renewal initiative was to address the situation around advertising of prescription drugs.

In June 2003 Health Canada launched national consultations on a detailed legislative proposal for a new framework for health protection legislation. The proposal outlined a number of possible tools that could be used to better control DTCA. As part of the consultative process, Health Canada held focused sessions on issues related to health product promotion, including DTCA. While there was no agreement on whether or not to allow DTCA, stakeholders did indicate that whichever tool is used to control DTCA it should ensure access to balanced information based on valid data for health practitioners and consumers.

The health and safety of Canadians is the primary consideration in the Government of Canada's approach to Health Protection Legislative Renewal. Health Canada is finalising its analysis of what Canadians have said on this issue with a view to moving forward with new legislation as soon as possible. Ensuring a system that provides balanced and objective information to consumers so that they may make informed decisions about their health is key to decisions around the regulation of DTCA.

## **European Union**

### **Regulation**

Currently, advertising of prescription drugs to the public is prohibited in all countries of the European Union (EU), despite pressure from drug companies and the European Commission. The relevant European legislation on advertising is contained in Title VIII of European Directive 2001/83/EC ('the Codified Directive'), which states: 'Member States shall prohibit the advertising to the general public of medicinal products which are available on medicinal prescription only'.<sup>12</sup> Title VIII contains rules on the contents of advertising and promotions, and requirements for national monitoring of advertising. Individual legislation in Member States of the European Union implement Title VIII of the Codified Directive.

<sup>12</sup> Council Directive 92/28/EEC, 31 March 1992.

## Previous review of DTCA in the European Union

In 2002 the European Parliament rejected the European Commission's proposals to permit advertising of prescription medicines for certain conditions (HIV/AIDS, asthma and diabetes) to the public for a five-year trial period. This proposal was part of the broad review of EU medicines legislation. The European Parliament committee with lead responsibility for the review of EU medicines legislation also rejected the Commission's proposals (Royal Pharmaceutical Society of Great Britain 2003). As an alternative to the European Commission's proposals on DTCA, the committee suggested that the European Commission should draft a comprehensive patient information strategy to ensure that good-quality, objective and reliable information is made available. The Commission has been asked to prepare '*a report on current practice with regard to information provision – particularly on the internet – and its risks and benefits to the public*' (Directive 2004/27/EC, article 88a) (Anon 2004).

## 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*. The WHO ethical criteria recommended that while advertisements to the general public 'should take account of people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health'. The WHO ethical criteria recommended against DTCA, stating that:

Advertisements to 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.

The WHO ethical criteria are not legally binding; but they are standards that can be used to develop regulation.

## **Appendix 2: Other Forms of Medicine Advertising**

### **Direct-to-prescriber advertising**

Direct-to-prescriber advertising is the promotion of prescription drugs directly to prescribers by pharmaceutical companies. While the ostensible purpose of these meetings between pharmaceutical company sales representatives and prescribers is educational, direct-to-prescriber advertising is a contentious issue as it has proven to be extremely effective in facilitating the sales of drugs and influencing prescribers' prescribing (Vaithianathan 2004).

The concerns over direct-to-prescriber advertising originate from the notion of consumer informed consent, as consumers are not aware of pharmaceutical advertising that is directed at their GP. The reasoning behind this link is that while patients can choose to ignore DTCA, they cannot choose to ignore a GP who is biased by direct-to-prescriber advertising (Vaithianathan in press). The alternative view is that because health care practitioners have expert and professional knowledge in their relevant field, they are able to discriminate between information of value and advertising hyperbole.

The Therapeutic Products Advertising Code is to be applied as the standard for all advertisements of therapeutic products, including those aimed at health care practitioners. More information on the requirements for direct-to-prescriber advertising under the Therapeutic Products Advertising Code can be found online at: [www.jtaproject.com](http://www.jtaproject.com).

### **Advertising of over-the-counter medicines**

Advertising of over-the-counter medicines is the promotion of medicines that do not require a prescription for use, such as some cold and flu remedies. Advertising for over-the-counter medicines must comply with the Medicines Act 1981 and the Medicines Regulations 1984 to ensure consumers are provided with a balanced presentation of the benefits and risks associated with all medicines. These Guidelines incorporate provisions for 'Generic Risk/Benefit' and 'Generic Limitation' statements as well as 'Major Risk' information. This is considered to fulfil those requirements under Regulation 8 covering Appropriate Precautions, Contra-indications and Adverse Effects for over-the-counter medicines consistent with their various classifications under Pharmacist Only, Pharmacy or General Sale medicines.

Regulations for advertising of over-the-counter medicines will be continued under the Therapeutic Products Advertising Code. More information on the requirements for advertising of over-the-counter medicines under the Therapeutic Products Advertising Code can be found online at: [www.jtaproject.com](http://www.jtaproject.com).

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