

**Direct-to-Consumer
Advertising of Prescription
Medicines in New Zealand:**
Summary of submissions

Citation: Ministry of Health. 2006. *Direct-to-Consumer Advertising of Prescription Medicines in New Zealand: Summary of Submissions*. Wellington: Ministry of Health.

Published in September 2006 by the
Ministry of Health
PO Box 5013, Wellington, New Zealand

ISBN 0-478-30057-3 (Book)
ISBN 0-478-30058-1 (Web)
HP 4304

This document is available on the Ministry of Health's website:
<http://www.moh.govt.nz>



MANATŪ HAUORA

Contents

1	Introduction	1
	Consultation process	2
	Purpose of consultation	2
	Participants in the consultation	2
2	Level of Support and Concern for DTCA, and Common Themes	4
	Information	5
	Fiscal impacts and equitable resource allocation	5
	Confidence in the regulatory system	5
	Quality use of medicines	6
	Proposal for providing independent consumer information	6
3	The Cases For and Against DTCA	7
	Provision of health care information to consumers	7
	The appropriate and quality use of medicines	10
	Practicable and cost-effective regulation	13
	Appropriate and proper standards for prescription medicine advertising	16
	Medicalisation	18
	Impact on patient–doctor relationships	21
	Fiscal pressures and costs to consumers	24
4	Further Information or Arguments that Support or Oppose DTCA	28
5	Section 14 of the New Zealand Bill of Rights Act 1990	29
6	Options for Regulating DTCA in New Zealand	31
	Option 1: Allow DTCA to continue with more stringent regulation	32
	Option 2: Allow DTCA but with stricter requirements than specified by the Therapeutic Products Advertising Code	34
	Option 3: Ban DTCA and regulate disease-state advertising	35
	Option 4: Ban DTCA and for-profit disease-state advertising	38
7	Further Options for the Regulation of DTCA	40
8	Other Views on Achieving the Purported Benefits of DTCA Without Experiencing the Purported Costs of DTCA	41
	Appendices	
	Appendix 1: Participants in the Consultation	42
	Appendix 2: Questions from the Consultation Document	46

1 Introduction

Direct-to-consumer advertising of prescription medicines (DTCA) is the advertising of branded prescription-only medicines or treatments to consumers. Currently, DTCA is permitted in New Zealand and is regulated under the Medicines Act 1981 and Medicines Regulations 1984. Another related form of advertising, disease-state advertising, aims to raise awareness of specific diseases and the treatments available, without identifying a specific therapeutic product.

Due to the considerable public interest in DTCA policy, the Ministry of Health undertook public consultation on the regulation of DTCA during March and April 2006, and a consultation document, *Direct-to-Consumer Advertising of Prescription Medicines in New Zealand: Consultation document*, was released in March 2006. The purpose of the consultation was to identify the level of support for DTCA in New Zealand, the level of concern about DTCA and the arguments for and against DTCA, and to receive feedback on the identified options for the regulation of DTCA.

The overall goal of the review of DTCA regulation in New Zealand was to ensure there is a regulatory framework in place that:

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

The consultation document reviewed the policy debate on DTCA as it relates to New Zealand, outlining the current policy for DTCA along with the Therapeutic Products Advertising Code, and provided three options for the regulation of DTCA in New Zealand in the future:

- 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).

This document summarises the feedback the Ministry received on the consultation document. The feedback from the public consultation has also provided important and useful information that fed into the process of advising the Government on the future regulation of DTCA in New Zealand.

Throughout this document, text in *italics* at the beginning of each section provides a summary of the consultation document proposals. A list of the questions from the consultation document is attached in Appendix 2. For the majority of submissions, feedback was concentrated on two of the questions posed in the document: arguments relating to concern about or support for DTCA (Question 2) and options for the regulation of DTCA (Question 5). As a result, this summary concentrates mostly on these two questions and the feedback they received.

Consultation process

Consultation centred on the *Direct-to-Consumer Advertising of Prescription Medicines in New Zealand: Consultation document* and written submissions. The consultation document was released on 3 March 2006 and sent to approximately 84 organisations and individuals with a known interest in the regulation of direct-to-consumer advertising. A media statement was released at the time the document was distributed and information was placed on the Ministry's website.

Submissions closed on 28 April 2006. A number of requests for extensions to this timeframe were received and accepted by the Ministry.

Purpose of consultation

Consultation provides different types of important information, including:

- an indication of the potential gaps in analysis and issues that need further thought or clarification
- the higher-level themes and principles that may underpin policy
- a sense of the strength of feeling about an issue (although it is important to note that while consultation is used to indicate the strength of opinion on an issue, it is not a voting process).

In order to gain this information, the consultation document sought submitters' comments and perspectives so that the Ministry could get a broad understanding of why different views are held, and to inform and refine the policy analysis. This information is one important input to the policy development process, along with evidence from the literature, international experience, cost–benefit implications, legal implications (eg, consistency with the New Zealand Bill of Rights Act 1990), and consistency with other public policy objectives and policy directions (such as the proposed establishment of the Australia New Zealand Therapeutic Products Authority). The task for the Ministry was to bring all this information together and propose a preferred option for regulating DTCA in New Zealand.

Participants in the consultation

The Ministry received 115 submissions from a wide variety of individuals, health professionals, organisations, pharmaceutical companies and educational/research organisations. Table 1 shows a breakdown of the types of respondents who made a submission on DTCA.

Table 1: Types of respondents who sent in a submission

Type of respondent	Number	Percentage
Member of public	13	11.3
Health professional	18	15.7
Pharmaceutical company	5	4.3
Government agency	5	4.3
Educational/research organisation	11	9.6
Advertising company/agency	6	5.2
Consumer group/representative	8	7
Organisation	37	32.1
Academic	12	10.4
Total	115	99.9*

* Percentages do not add to 100 due to rounding.

See Appendix 1 for the list of submitters in each respondent category.

The Ministry is very grateful to all those who participated in the consultation process by preparing a written submission. We recognise that this is a significant commitment of time for many people, and the information provided is very valuable for informing the policy development process.

2 Level of Support and Concern for DTCA, and Common Themes

This section describes the level of support for DTCA, the overarching themes that emerged from the consultation, and other key issues raised in oral submissions.

The consultation document asked respondents to indicate their support for or concern/opposition towards DTCA. Of the respondents who explicitly stated their opinion about DTCA, 69 percent were concerned about/opposed to DTCA, while 31 percent were supportive. Table 2 shows the breakdown of concern/opposition and support for DTCA, by type of respondent.

Table 2: Concern/opposition and support for DTCA, by type of correspondent

Type of respondent	Number of submissions (n = 110)*	
	Concerned/opposed to DTCA	Supportive of DTCA
Member of public	12	1
Health professional	7	9
Pharmaceutical company		5
Government agency	5	
Educational/research organisation	9	
Advertising company/agency		6
Consumer group/representative	8	
Organisation	25	12
Academic	10	1
Total	76	34

* Not all respondents explicitly indicated their opinion towards DTCA.

From the feedback on the consultation document, the Ministry has identified the following central themes that emerged from submissions:

- the need for independent, balanced information
- the fiscal impacts and resource allocation
- confidence in the regulatory system
- the quality use of medicines
- a proposal to provide independent consumer information.

These themes provide an indication of how New Zealand organisations and the public think about DTCA, the level of support, and the level of concern for this type of advertising. In some cases these themes are in conflict. They are summarised below.

Information

The majority of respondents commented on the need for independent, balanced information for consumers, with clear risk and benefit information and discussion of alternative therapies. Many respondents raised concerns that DTCA leads to confusion, and that advertising, by its nature, cannot provide balanced information.

Respondents who support DTCA argued that it meets consumers' desire for information. Some argued that a DTCA-initiated enquiry is positive for health professionals, who can use it to discuss the reason for the request and relevant treatment options.

The New Zealand Bill of Rights Act and Health and Disability Services Consumers' Code of Rights were cited by both the critics and proponents of DTCA, setting the right to unfettered information against the right to balanced information about the range of treatment options and their respective risks and benefits.

Fiscal impacts and equitable resource allocation

Concern was raised that within a capped, publicly funded pharmaceutical budget DTCA can lead to inequitable or skewed resource allocation if the advertised medicine is subsidised. Where the medicine is partially or non-subsidised, the individual must bear the cost. These concerns relate to the unnecessary use of less cost-effective medicines over more effective, cheaper, non-advertised medicines.

The alternative view was that PHARMAC's strict cost-effectiveness criteria for subsidising pharmaceuticals and its expenditure control strategies mean that DTCA has little scope to impact on the publicly funded pharmaceutical budget. DTCA was seen to influence enquiries for medicines, but prescribers were seen as being responsible for appropriate prescribing.

Confidence in the regulatory system

A number of issues were raised about the effectiveness and robustness of the current self-regulatory system, including: the difficulty in successfully making a complaint; the ability of the public to police the system when often only those with clinical and technical expertise can judge that an advertisement is misleading; and the fact that by the time the complaint process is complete an advertising campaign is often finished.

Many respondents supported either a ban on DTCA and regulation of disease-state advertising, or a ban on DTCA and for-profit disease-state advertising. These respondents considered the overall health impact of DTCA to be negative, and felt the only effective way to regulate DTCA was to ban it.

Those respondents who supported the current self-regulatory system argued that it is cost-effective and able to respond quickly when problems are identified.

Quality use of medicines

A number of respondents were concerned that DTCA results in patients putting pressure on health professionals to prescribe drugs they would not otherwise prescribe, and that this leads to an inappropriate spread of prescription drugs. A smaller number of respondents argued that DTCA helps patients to identify conditions that are most appropriately managed by pharmaceuticals and reduces the under-treatment and under-diagnosis of conditions.

Some respondents voiced concern that DTCA generally focuses on newer, more expensive medicines, which are often marketed in a misleading way to large population groups. There were concerns about the influence of DTCA on patients switching from older, more generic medications where safety and efficacy have been established, to newer medications where the safety and efficacy data is limited. Proponents of DTCA argued that it is the prescribers' professional and ethical duty as gate-keepers for prescription medicines to prescribe only those medicines that are necessary and appropriate.

Proposal for providing independent consumer information

A number of respondents supported the provision of independent information, and a range of options for doing this were suggested. There was also support for independently funded disease-state advertising, which many respondents saw as positive in terms of identifying under-treated and under-diagnosed target groups, such as for diabetes or during immunisation campaigns.

3 The Cases For and Against DTCA

This section outlines the main arguments used by submitters to support and oppose DTCA, both in response to the questions posed in the consultation document and in additional key areas of comment. These arguments have been gathered under the following headings:

- provision of health care information to consumers
- the appropriate and quality use of medicines
- practicable and cost-effective regulation
- appropriate and proper standards for prescription medicine advertising
- medicalisation
- the impact on patient–doctor relationships
- fiscal pressures and costs to consumers.

Provision of health care information to consumers

Provision of information was set out in the consultation document as one of the key arguments used both for and against the retention of DTCA in New Zealand.

The argument that the fundamental nature and goal of advertising is to sell a product and maximise consumer demand, which makes it an inappropriate mechanism for the dissemination of quality information to consumers about pharmaceuticals, was acknowledged.

The counter-argument was also acknowledged: that DTCA may have some benefits in terms of increasing consumers' awareness of drug treatments and medical conditions, in addition to prompting consumers to discuss treatment options with their general practitioner (GP).

The consultation document sought comment on the issue of DTCA and the provision of health care information to consumers.

Concerns

Some submitters commented that DTCA is not about educating patients, but about increasing sales of particular products. Comments included:

- concern that DTCA is considered by some people to be consumer information
- the primary aim of DTCA is to sell a product – it is not a public service
- DTCA is presented in a slanted and emotive manner, playing down risks and enhancing benefits
- disease-state advertising would better achieve the claimed benefits of DTCA.

Several submitters considered that DTCA is unable to provide full and balanced information. There was strong concern that such advertising misrepresents particular products, is biased and incomplete and could result in confused, misinformed and anxious consumers. Some submitters specifically commented on the inadequate risk and benefit information provided by DTCA. The right of consumers to information was acknowledged, but these submitters did not consider DTCA provides health information, but promotes a particular brand.

One submitter commented that it is very likely that when a newer and superior cost-effective medicine becomes available, its uptake will be assured through marketing to clinicians, continuing medical education and first-hand experience, without the need for DTCA.

Several submitters commented that DTCA exaggerates or misrepresents the benefits of the advertised product. There were also concerns that such advertising misrepresents the typical impact of certain health conditions and the range of consumers who would benefit from the product. One submitter commented that it is not fair to say the prescriber is the final arbiter and use this as an excuse for providing false or misleading information through advertising.

Some submitters argued that advertising is not appropriate for prescription medicines. One claimed that drug company advertising misinforms, encourages medicine use in groups who have little to gain, and increases the risk of public harm by generally promoting the use of new medicines over older medicines that have an established efficacy and safety profile.

A number of submitters commented on the need for reliable, independent sources of medical information. It was felt by some that the provision of information by independent, not-for-profit organisations would remove the risk of consumers receiving biased or misleading information. One submitter commented that the fundamental nature and goals of DTCA make it an inappropriate way to disseminate high-quality information to the public about high-risk products.

A number of submitters were concerned about the impact of DTCA on doctor consultations when it prompts patients to erroneously believe that the advertised product is an advance on their existing treatment, or to demand the advertised medicines. One submitter felt that advertisers are only providing partial information, and are expecting health professionals – who are ethically obliged to do so – to fill in the considerable gaps.

Concerns: Key points

- DTCA is about increasing sales, not the provision of quality information.
- Advertising misrepresents the benefits of a product and downplays the risks.
- Advertising is not appropriate for prescription medicines.
- There is a need for independent sources of information.

Support

A number of submitters commented on the public's right to information and the need to protect freedom of information in a democracy. One stated that arguments that DTCA leads to confused or misinformed consumers because they do not have enough medical knowledge, or the information is unbalanced, smacks of arrogance and paternalism.

One submitter commented that unless an advertisement is actually fraudulent or offensive, any company should legally be allowed to advertise its products. Another stated that there is a need to counter the impression that the pharmaceutical industry provides biased information, and noted that most people's source of information about a new drug is from the developer anyway.

Several submitters thought that DTCA is beneficial in ensuring consumers are informed of all available treatments, particularly new products and products that are not on the Pharmaceutical Schedule. There was support for the argument that DTCA can prompt consumers to discuss medication issues with their doctors and to raise questions about otherwise undiagnosed conditions. One submitter commented that DTCA cannot create the health condition, but it can help reduce the inertia surrounding seeking a solution.

The benefit of DTCA in terms of higher levels of compliance with medical treatments was noted. One submitter argued that medication adherence remains the greatest challenge throughout medicine, and that it is a joy to find people who have taken the trouble to seek out information about a prospective treatment.

A couple of submitters commented that the role of advertising is to inform people about the benefits and availability of products, and it is the role of the prescriber to provide full information and prescribe appropriately. A number of submitters considered that DTCA is beneficial in terms of educating and informing consumers. One noted that if the medical practitioner feels intimidated by a knowledgeable and active rather than passive client, they need to reconsider their role and skills. Another stated that if DTCA can inform someone about the benefit of a therapy such as inhaled corticosteroids (an asthma treatment), which they would otherwise not have known about, this has to be a positive benefit to society.

Several submitters commented that consumers want information, and there is an increasing expectation that they will be active participants in their health care decisions. DTCA was seen to meet the desire of consumers for information.

It was argued that information about medicines is freely available to the public through a variety of sources, and that regulated DTCA is better than unregulated information from the internet.

One submitter noted that Medsafe approval is required before any product can be marketed. This approval is given on the basis of efficacy and quality. The public is also ultimately protected by the fact that prescription medicines cannot be directly obtained by the consumer and must be prescribed by a medical professional.

A few submitters considered that the risk and benefit information in DTCA could be improved, but it was generally considered this could be addressed through existing regulatory processes.

Support: Key points

- The public have a right to information, and there is increasing consumer demand for health information.
- DTCA can improve consumer knowledge of available treatments.
- DTCA can prompt discussion of medical conditions and improve compliance with treatment plans.
- It is the role of the prescriber to provide full information and prescribe appropriately.

Code of Consumers' Rights

The Health and Disability Commissioner acknowledged that DTCA does not involve a health or disability services provider and therefore does not fall within the Health and Disability Commissioner's jurisdiction for direct action. It was noted, however, that the *Code of Health and Disability Services Consumers' Rights*¹ provides useful guidance on the informed consent requirements for the provision of prescription medicines. The Code also emphasises the importance of consumers being fully informed, and for there to be effective communication when providing any health service, including prescribing medicines.

A few submitters who were concerned about DTCA referred to the *Code of Health and Disability Services Consumers' Rights*, stating that DTCA fails or denies consumers' rights through lack of balanced information and lack of information about all the treatment options. However, one submitter who supported DTCA noted that the *Code of Health and Disability Services Consumers' Rights* explicitly states that patients are entitled to full information, and commented that it is difficult to understand how this obligation can be met if there are regulatory controls on the advertising of prescription medicines.

The appropriate and quality use of medicines

Prescription medicines are restricted items of commerce that are subject to strict controls on their availability and use because they carry significant risks if used inappropriately. It is the prescribers' professional and ethical duty as gate-keepers for prescription medicines to prescribe only those medicines that are necessary and appropriate.

¹ Available online at: <http://www.hdc.org.nz/files/hdc/code-leaflet.pdf>

The consultation document recognised that the nature of DTCA makes it difficult to provide balanced information about the complex matter of risks and benefits associated with a product, and alternative treatments. The argument that DTCA may increase patients' awareness of conditions that are most appropriately managed by pharmaceuticals and reduce the under-treatment and under-diagnosis of conditions was also noted.

The consultation document sought feedback on the impact of DTCA on the appropriate and quality use of medicines.

Concerns

A number of submitters were concerned that DTCA can lead to pressure being put on prescribers. This was of particular concern if discussions between GPs and patients and choice of treatment become dominated by the messages of a particular advertisement for a single product rather than by an assessment of the advantages and disadvantages of all treatment options. This pressure could lead to inappropriate or sub-optimal prescribing decisions. One submitter argued that the purpose of DTCA is to exert pressure on doctors to prescribe, through patients demanding products.

One submission stated that while it would seem simple for the doctor to just say no when a patient requests a medicine the doctor would not otherwise have chosen, this is at odds with the model taught within medical schools today – shared decision-making with a patient-centred approach and concordance in decisions about treatment.

Several submitters were concerned that DTCA negatively impacts on the quality use of medicines, ie, giving the appropriate medicine, to the right patient, at the right time. One submitter commented that the guiding principle of quality use of medicines is that newer medicines should not be prescribed unless there is strong evidence of additional benefit. This submitter considered that DTCA actively works against this principle in that it is designed to promote rapid uptake of newer medicines over older treatments. Another submitter stated that DTCA is likely to impair the quality use of medicines because only some are advertised, and in a misleading way.

A number of submitters were concerned about the influence of DTCA on creating rapid uptake of new medicines without established safety profiles. The following points were raised.

- On average, 3000 to 5000 people are exposed to a medicine during the pre-market period. To get a medicine to market, a manufacturer does not need to show evidence of superiority over existing treatment options, and for most new drugs there is no evidence of a treatment advantage.
- DTCA leads to rapid expansion in the use of new medicines before their safety profiles are adequately understood, often in the absence of any additional therapeutic benefit.
- Once a medicine is approved, it is used in patient populations that were not studied and problems or adverse effects come to light.
- The paucity of available data makes evidence-based decision-making impossible with regard to the merits of a new treatment.

- New medicines have less proven efficacy and safety profiles, and it would be more ethical to advertise a product with a proven safety history.
- Most DTCA is for new drugs, which are often inferior to older treatments and more expensive.
- Vioxx, a non-steroid anti-inflammatory drug used in treating arthritis pain, was cited as an example where DTCA played a major role in increasing the scale of harm from Vioxx (Vioxx was found to increase the risk of heart attacks in patients).

One submitter cited evidence from a systematic review on the effects of DTCA published in 2005,² which concluded that DTCA does influence patient demand and doctor prescribing behaviour. One submitter stated that DTCA has been found to stimulate sales and to influence prescribing decisions, including a negative effect on the appropriateness of prescribing decisions as measured by physicians' confidence or ambivalence in treatment choice.

One submitter commented that there is no evidence that DTCA leads to net health benefits. This submitter stated that DTCA is associated with market expansion within specific drug classes, and that this can translate to treatment of more people with milder health problems. It was noted that the healthier a person is to begin with, the less likely they are to experience the additional benefits from drug treatment, yet they remain vulnerable to harmful drug side effects.

A few submitters were concerned at the negative impact of DTCA on the safe use of medicines, due to the lack of risk information and the exaggeration of benefits in DTCA. It was noted that DTCA promotes prescription medicines as simply another consumer item that can be taken at will, with no serious consideration of the risks and side effects.

One submitter argued that medicines are not standard commercial products. In particular, the mechanism for the 'purchase' of the product is complex: the prescriber authorises the use of a product for a potentially misinformed second person, with a third party, the Government, paying for the medicine. This is not the usual process of people weighing up for themselves the costs and benefits of a product.

Other comments included:

- it is condescending to suggest that the average consumer does not necessarily have the skills to seek out the information they require from their health professional and to make an informed decision without DTCA
- while the evidence does not directly prove that DTCA leads to poorer health outcomes, it does raise significant concerns about its impact on patients' health and the precautionary principle should be applied
- claims that DTCA improves compliance are not supported by the evidence.

² Gilbody S, Wilson P, Watt I. 2005. Benefits and harms of direct to consumer advertising: A systematic review. *Quality and Safety in Health Care* 14(4): 246–50.

Concerns: Key points

- DTCA can lead to pressure being put on prescribers, which can result in inappropriate prescribing decisions.
- DTCA negatively impacts on the quality use of medicines by promoting the use of new medicines over older medicines with established safety profiles.
- There is no evidence of health benefit from DTCA, but there are concerns about its negative health impact.

Support

A few submitters commented that DTCA increases awareness of medical conditions, and that medical conditions are likely to be diagnosed and treated earlier where the patient is well informed.

Some considered that inappropriate prescribing (including widespread use of medicines in the community before a population risk profile is developed) was a problem of doctors not fulfilling their gate-keeping role. A couple of submitters commented that there was no evidence of DTCA prompting over-prescribing or inappropriate use of medicine, or that they did not consider this was a problem. The point was made that a patient obtaining a prescription from a DTCA-initiated enquiry was not evidence of inappropriate prescribing.

A few submitters commented on the potential benefits of DTCA in terms of encouraging compliance with prescribed medical treatments.

One submitter considered there must be a compelling case, demonstrating beyond reasonable doubt that material harm will occur, to justify increasing regulation over DTCA.

Support: Key points

- DTCA may result in earlier diagnosis and treatment of health conditions.
- Inappropriate prescribing, if it occurs, is a problem of poor prescriber 'gate-keeping'.

Practicable and cost-effective regulation

At present the regulation of DTCA relies primarily on industry self-regulation, with an expectation that the media and advertising industries will ensure that advertising of therapeutic products is socially responsible. The consultation document outlined the regulatory requirements for DTCA under the Medicines Act and Regulations, in addition to the new requirements for advertising to come into effect under the Australia New Zealand Therapeutic Products Authority. Comment was sought on practicable and cost-effective regulation.

Concerns

The majority of respondents who commented on the regulation of prescription medicine advertising felt that the current system of self-regulation is not effective and that tighter regulation is needed.

Considerable concern was raised about the effectiveness and transparency of the self-regulatory system, which allows industry to pre-vet their own advertisements, with little oversight or monitoring. Many respondents felt that the current system encourages a conflict of interest, because the Therapeutic Advertising Pre-vetting System allows a delegated authority within either a manufacturing or media company to assess and approve their own advertisements for publication.

A number of respondents commented that self-regulation is insufficient to control inappropriate DTCA because of the commercial interest of pharmaceutical companies to promote their products and maximise consumer demand. One respondent commented that to hand over the provision of critical health information to an industry driven by profit rather than the public health is to ensure that misleading information is disseminated.

In relation to the self-regulatory system generally, a number of respondents felt that a pro-active approach to DTCA regulation was needed, and that the current complaints-based system does not adequately reflect the level of risk associated with prescription medicines. One submission questioned whether self-regulation maintains a high standard of social responsibility and whether or not the current system is accessible to complaints. Other respondents also commented on the inadequacies of a complaints-based system in an environment where drug companies are motivated to push the boundaries of that system in order to maximise profits. In particular it was noted that:

- the low success rate of complaints upheld indicates that consumers are unaware of how to complain effectively, and that the process for making a complaint can be difficult, time-consuming and pointless, with few consumers motivated to do so
- consumers are not in a position to make complaints, because they do not have the pharmacological expertise to know when the advertising claims are misleading or unbalanced
- a complaints-based regulatory system relies on action after the problem or harm has occurred – it closes the stable door after the horse has bolted
- no corrective statements are made regarding misleading advertisements that have been withdrawn, so consumers and health professionals are unaware that they have received incorrect information on a particular product
- penalties are insufficient to act as deterrents to pharmaceutical companies, because they are not severe enough to make companies comply – this compromises the robustness of self-regulatory procedures.

Some respondents commented that the only cost-effective form of DTCA regulation is a complete ban, as this foregoes the need for ongoing supervision of the self-regulatory system. A few also indicated their opposition to the United States model of central regulation, which was also seen to be ineffective and impracticable. One respondent commented that both the New Zealand system of self-regulation and the United States system of central regulation have the same problems with DTCA, including misleading advertisements containing partial, incorrect or unbalanced information; overstatement of medicine efficacy; minimisation of potential adverse effects; and inappropriate use of emotional persuasion.

Comments were also made on the inability to regulate DTCA on the Internet, and the confusion of DTCA in New Zealand with the *Family Health Diary*,³ making it unclear when advertising is indeed advertising.

Concerns: Key points

- The current system is ineffective and not transparent.
- A complaints-based system is inadequate and does not reflect the level of risk associated with the inappropriate use of prescription medicines.
- Self-regulation does not address the purported negative effects of DTCA – the only solution is a complete ban.
- Advertising on the Internet cannot be regulated.

Support

Respondents who support the self-regulatory system of DTCA commented that the current system is practicable and cost-effective, and ensures a high level of social responsibility and compliance. A few commented that the self-regulatory system balances appropriate deterrent penalties with the benefits patients receive from DTCA, which allows for consumers to receive information about new pharmaceuticals while ensuring the advertising of these products is responsible via adequate regulation. One respondent commented that the objectives of the Advertising Standards Authority adequately serve the public interest in an environment that is responsible, voluntary and free of unnecessary and costly government involvement.

Some respondents commented on the ability of the self-regulatory system to adapt to the emerging needs of consumers, and that enhancements/amendments to the system can be made relatively quickly in order to address any concerns. Comment was made that the current regulatory environment is efficient in that it allows advertisements to be pre-vetted and removed if there are any concerns about the accuracy of the information. Specifically, one respondent's view was that the industry can identify and address a problem more capably than can a government agency, and industry self-regulation is often quicker, more flexible, less adversarial, and therefore less burdensome than government regulation.

³ Family Health Diary is a "masthead" advertising format, which comes to life by way of extended length television advertisements, usually 90 seconds featuring two or three different stories, together with a bi-monthly 48-page magazine with circulation of 300,000, as well as a website.

Many of those respondents who support the current self-regulatory system noted that consumers have a right to access information about pharmaceuticals via DTCA, and that a ban on DTCA would be contrary to this right. Respondents acknowledged that legislation and a reasonable level of government protection are necessary, due to the nature of prescription medicines and their associated risks, but a complete ban on DTCA was seen as unnecessary and inappropriate given there is little evidence of harm from responsible advertising. Doubt was cast on the effectiveness of a ban on DTCA in an environment where consumers have access to DTCA via the Internet.

The following specific comments by a pharmaceutical company were made regarding their views on increased regulation of DTCA or a ban.

- DTCA has become important to pharmaceutical company subsidiaries seeking to survive New Zealand's uniquely challenging operating environment over the past decade.
- A decision to ban DTCA would be taken by the pharmaceutical industry as a discouraging signal for their further investment in New Zealand.
- A DTCA ban would weaken the ability of a local subsidiary to win support for the kind of investment that would contribute to the New Zealand government's Growth and Innovation Framework.

Support: Key points

- The current system of self-regulation is adequate and ensures a high level of responsibility and compliance.
- Industry self-regulation is flexible and can adapt easily to address any concerns.
- Consumers have a right to access pharmaceutical information via DTCA.
- Increased regulation of DTCA would be viewed as a discouraging signal for pharmaceutical companies.

Appropriate and proper standards for prescription medicine advertising

In relation to the current and forthcoming regulatory arrangements in New Zealand (outlined in the consultation document), comment was sought on appropriate and proper standards for prescription medicine advertising.

Concerns

In relation to standards for prescription medicine advertising in general, a few submitters commented about the appropriate management of the provision of information to consumers in order to maximise timely access to treatment and promote public health. It was felt that it was not possible to meet the information needs of consumers via advertising, particularly in an environment that relies on the industry to pre-vet their own advertisements and is complaints-based.

Some commented that appropriate standards for prescription medicine advertising should reflect the potential health risks from inappropriate use of DTC-advertised products, especially when other products may be more beneficial. Concern was raised by one respondent that the body that oversees the advertising regulatory regime (the Advertising Standards Authority) has a predominantly commercial interest, but should be regulating advertising in the interests of wider public health objectives.

A number of respondents commented on the need to ensure that advertisements conform to a quality standard, and that the regulatory guidelines should address concerns about DTCA such as lack of balance between benefit and risk information, poor presentation of risk data, and absence of cost information. Concern was expressed that often the information presented in DTCA is misleading and targets vulnerable people, promoting unrealistic and false expectations of medicines and possibly leading to consumers' pursuing products that may be unsuitable for their condition and/or potentially harmful to their health.

One respondent commented that many people believe that only 'safe' medicines can be advertised. Another was concerned about the times DTCA for pharmaceutical products of a sexual nature air on television, suggesting that this kind of advertising should be restricted to late in the evening.

Some respondents who support a ban on DTCA argued that it is not possible to have effective standards for prescription medicine advertising, because pharmaceutical companies will continue to 'push the boundaries' and 'identify loopholes' in any system in order to maximise consumer demand and profit. The point was also made that standards, rules and codes of conduct are worthless without meaningful incentives to comply and meaningful disincentives to prevent breaches. Other general comments included:

- the same high standards need to be applied to both advertising to health professionals and advertising of over-the-counter medicines
- if DTCA is banned in New Zealand it will help prevent the introduction of DTCA in other countries.

Concerns: Key points

- It is not possible to meet the information needs of consumers via advertising.
- Standards should be set according to public health interests, not commercial objectives.
- Advertisements should conform to a quality standard and adequately reflect risk–benefit information and cost information.
- It is not possible for advertising standards to be effective because pharmaceutical companies will continue to push the boundaries of any system in order to maximise consumer demand.

Support

There was wide agreement among those respondents who support DTCA that the current advertising standards are appropriate and ensure a high level of responsibility and compliance. It was felt that the current standards relating to accuracy of claims made in advertisements and the presentation of risk and benefit data are well covered within the existing guidelines, and that the current regulatory environment is effective, efficient and responsive to any concerns about the content of advertisements.

A couple of respondents commented that DTCA should not be considered differently to any other form of advertising, noting that consumers are well aware of the purpose of advertising and are used to being bombarded with advertising in their everyday lives. It was felt that consumers should have the right to access information about pharmaceutical products via DTCA, with one respondent commenting that consumers facing serious illnesses should have even more right to information about prescription medicines because they have the most to lose if that information is withheld and their options, in turn, are limited.

Lastly, comment was made that DTCA is only one part of a marketing mix that is considered by a company, and that if DTCA is banned companies will find other ways of disseminating information about their products. One respondent suggested that DTCA is not the 'silver bullet' to achieve sales, as portrayed by some DTCA critics.

Support: Key points

- Current advertising standards are appropriate and ensure a high level of responsibility and compliance.
- DTCA should not be considered any differently to any other form of advertising.
- DTCA is only one part of a marketing mix – if regulations are increased, companies will find other ways to disseminate information about their products.

Medicalisation

The consultation document recognised that DTCA is often used to promote medicines for certain 'lifestyle' conditions, such as treatments for unwanted weight gain, erectile dysfunction and hair loss. The argument against DTCA on the grounds that it further medicalises normal body processes, based on the premise that lifestyle medications offer no health benefits to consumers, was also acknowledged. The consultation document briefly described some of the issues surrounding DTCA and medicalisation and sought views on respondents' concerns about or support for DTCA in this context.

Concerns

Many respondents felt that DTCA encourages people to perceive normal bodily and ageing processes as illnesses that require pharmaceutical intervention. Some submitters commented that DTCA for certain lifestyle medications may have the tendency to increase body dissatisfaction, because it promotes conformity with cultural ideals that are often unachievable or unnecessary, and does not treat underlying issues

such as self-image and self-esteem (treatments for unwanted weight gain and baldness were cited as examples in this context).

One respondent was concerned that DTCA can lead to ‘disease-mongering’ and irrational drug consumption in cases where pharmaceutical companies invent diseases to boost sales of new products. Evidence cited by one respondent in relation to this phenomenon was that a systematic review of the effect of DTCA on the sales of drugs found that in all cases DTCA seemed to increase the number of new diagnoses for a condition and increase the proportion of prescriptions specifically for the advertised product.⁴

Some respondents expressed concern that DTCA promotes pharmaceutical treatments over other alternatives that may be as, or more, effective or suitable for a condition. In particular it was noted that:

- public health and safety initiatives could be undermined in an environment that promotes the use of pharmaceuticals for conditions that may be better addressed by changes in lifestyle
- non-pharmaceutical and other alternatives are not presented in DTCA, and therefore the consumer is not equipped with the information to allow an educated assessment of the product
- DTCA creates dependency on pharmaceutical solutions, whereas medicines should be there for times of genuine need, not as a surrogate for adequate exercise, correct diet and a clean and safe environment.

Respondents also commented on the associated risks of medical misadventure that may arise as a result of medicalisation fuelled by DTCA. Concern was expressed that DTCA often targets healthy populations, people with minor or cosmetic complaints, and/or vulnerable people who do not necessarily require medical treatment. It was acknowledged that while some individuals may benefit from DTC-advertised products, this does not mean that advertising is necessarily beneficial for society as a whole. Concerns raised about ‘lifestyle drugs’ included limited safety and efficacy data, adverse effects, costs, diversion of resources, and harmful medicalisation of normal variations.

Concerns: Key points

- DTCA encourages people to perceive normal bodily and ageing processes as illnesses that require pharmaceutical intervention.
- DTCA promotes pharmaceutical treatments over other alternatives that may be more effective or appropriate.
- DTCA leads to medicalisation and the associated risks of medical misadventure.

⁴ Gilbody S, Wilson P, Watt I. 2005. Benefits and harms of direct to consumer advertising: A systematic review. *Quality and Safety in Health Care* 14(4): 246–50.

Support

The main argument given by proponents of DTCA regarding medicalisation was that DTCA often identifies underdiagnosed and undertreated conditions. Comments made included:

- DTCA serves a positive public health function by increasing patient awareness of conditions and prompting discussions between doctors and patients
- patients who consult doctors in response to a DTC advertisement for a lifestyle medicine provide doctors with an opportunity to discuss alternative treatments and lifestyle issues in general
- DTCA for certain lifestyle medications may give patients the confidence to approach a doctor about a condition they would otherwise have ignored due to embarrassment (eg, impotence).

A few respondents commented that appropriate prescribing by GPs reduces the potential for medicalisation: a competent doctor would only provide a prescription if seen as appropriate, and also advise the patient on desirable changes in lifestyle. It was also pointed out that the medicalisation argument cannot be used to support a ban on DTCA because it should be the Government and insurers' responsibility to restrain any increase in prescription medicine uptake as a result of any medicalisation that is fuelled by DTCA.

Other respondents commented that some lifestyle conditions may impact on quality of life, and that medicine treatments for these conditions are an important way to achieve better health outcomes. One submitter commented that conditions such as arthritis and incontinence may be considered to be normal diseases of ageing but can have a severe impact on employment and quality of life. One submitter noted that alleviating normal processes associated with ageing can in fact support public health and social objectives, such as independent living and positive ageing.

It was also noted that attitudes have changed over time about conditions that are normal and socially acceptable. In the case of obesity, for example, it was noted that it seemed strange to class this as a lifestyle issue given that it is linked to many serious chronic diseases and that it is one of the priority objectives in the New Zealand Health Strategy. One respondent stated that the meaning of the term 'lifestyle drug' is blurred by the perceptions of society. Medicines that treat high cholesterol or type 2 diabetes are not termed lifestyle, and are, like obesity, closely related to personal responsibility. It was also suggested that advertising has the potential to lessen the stigma associated with disease.

In the broader context of the future regulation of DTCA, it was suggested that 'lifestyle' treatments would have to be considered detrimental to public health objectives to justify a ban on this type of advertising. The Internet was also cited as an important consideration in this context: it was suggested that a ban on DTCA would be ineffective given that an increasing number of consumers access pharmaceutical information via the Internet.

Support: Key points

- DTCA identifies under-diagnosed and under-treated conditions.
- Appropriate prescribing by GPs reduces the potential for medicalisation.
- Lifestyle and ageing treatments impact on quality of life and may, in turn, produce better health outcomes.
- There has been a change in cultural attitudes towards what is classed as a lifestyle versus a medical condition.

Impact on patient–doctor relationships

The consultation document outlined the arguments around the effect of DTCA on the patient–doctor relationship. Specifically, the document acknowledged the views of both critics and advocates of DTCA, noting that while some doctors feel that advertising can create conflict in the patient–doctor relationship, others argue that advertising helps patients learn about new medicines and creates an opportunity for a partnership between patients and doctors. Views were sought on respondents’ concern about or support for DTCA in relation to the impact DTCA has on the patient–doctor relationship.

Concerns

The main concern noted by those respondents who felt that DTCA has a negative impact on the patient–doctor relationship was that DTCA places undue pressure on GPs to prescribe a particular product. It was felt that because DTCA presents unbalanced and often misleading information, this does not provide a good basis for an informed patient–doctor discussion. In addition, DTCA was seen to ‘prime’ patients to request a particular product, in many cases unnecessarily raising patients’ expectations of treatment and outcome.

The results of surveys were cited as evidence of DTCA influencing the prescribing behaviour of GPs: when a patient asks for a drug by name, they are given it more often than not, and many doctors find themselves prescribing medicines they would not have chosen had it not been requested.⁵ One respondent suggested that while the provision of background information to consumers to assist in discussions with their GPs is a good thing, the quality of information presented by DTCA is in many cases not going to provide much more than a brand name linked to a particular condition.

A couple of respondents commented on the way in which doctors are educated on how they should interact with their patients and practise medicine in an evidence-based way to optimise health outcomes. As noted in ‘The appropriate and quality use of medicines’ section (above), one respondent argued that while it may seem simple for the doctor to say no when a patient requests a medicine they would not otherwise have prescribed, this view is naïve and at odds with the model taught in medical school today, which involves shared decision-making with a patient-centred approach and concordance in

⁵ Cited but not referenced.

decisions about treatment. Another respondent commented that it is unrealistic, and perhaps unfair, to rely on doctors to counter the effect of DTCA on patient expectations.

A few submitters commented that DTCA negatively affects the consultation timeframe when GPs have to explain why an advertised medicine is not suitable for a patient. Respondents felt that GPs, already under a heavy workload, are unable to fully discuss the costs and benefits of a certain medicine in addition to discussing other lifestyle options that may be more appropriate.

A number of respondents felt that DTCA has the potential to create conflict within the patient–doctor relationship, particularly if a doctor is unwilling to prescribe a specific medicine that has been requested. It was suggested that patients may seek to find a GP who will prescribe a specific product when their request has initially been refused. There was also concern that confidence in GPs and pharmacists can be undermined when patients are encouraged to request medicines for which they may receive no benefit, or where patients are led to believe that their doctor has not prescribed the best and latest pharmaceutical.

The availability of pharmaceutical information via the Internet was also considered in this context by a couple of respondents. Comment was made that the gate-keeping role of prescribers is easily eroded by the availability of prescription medicines over the Internet, and that prescribers might be tempted to prescribe against their judgement when being pressured into prescribing a particular product, in order to maintain the patient–doctor relationship and reduce the risk that the patient will purchase a potentially unsafe medicine off the Internet.

Concerns: Key points

- DTCA places pressure on GPs to prescribe a particular product.
- The concept of shared decision-making between doctor and patient is at odds with patient expectations fuelled by DTCA.
- DTCA negatively impacts on the consultation timeframe when GPs have to explain why an advertised medicine is not suitable for a patient.
- DTCA has the potential to create conflict within the doctor–patient relationship when doctors are not willing to prescribe the requested product.

Support

Respondents in support of DTCA and its effect on the doctor–patient relationship held the view that DTCA assists dialogue between patients and doctors, and is beneficial to consumer health and the doctor–patient relationship. The reasons given for this included:

- DTCA allows patients to have more informed discussions with their GP, not just about the medicine advertised but also about other treatment options that are available

- DTCA encourages consumers to become more involved in their health care and promotes a partnership between doctors and patients
- DTCA prompts consumers to seek further information and advice about specific prescription products and medical conditions
- DTCA increases consumer awareness of new treatments.

Some submitters noted that patients usually ask about an advertised medicine during an already-scheduled consultation, and do not make special visits in response to viewing DTCA. One GP noted that patients are usually very reasonable when enquiring about a DTC-advertised medicine, and do not put pressure on GPs to prescribe a particular product. Another GP suggested that the more informed the patient is, the better the quality of care. Evidence cited by a respondent also suggested that GPs welcome thoughtful questions from patients as a result of DTCA exposure, and that patients are better informed and educated on treatments and health care generally.

However, concerns were raised about the time taken to correct patient misconceptions as a result of unbalanced DTCA. One respondent suggested that a solution to this problem may be to improve funding models at the primary care interface so that time pressure in consultations is not the overriding factor when a patient requests a new medicine.

A number of respondents felt that consumers are becoming more empowered in today's health care system because they have an increasing amount of information available to them, and that there is a changing dynamic between doctors and patients. In this context, respondents commented that consumers are becoming more vociferous and active in decisions concerning their health care, and that the balance of power between doctor and patient is changing as patients want to know and understand the choices available to them, and be involved in the decision-making process. A few respondents noted that today's patients view their relationship with their doctor as one of a partnership, where the GP and patient work together to determine the best treatment.

A clear view expressed by a number of GP respondents was that arguing against DTCA on the basis that it encourages inappropriate prescribing and conflicts in doctor–patient relationships is counter to the fact that doctors are professionally trained with ethical and professional obligations that require them to prescribe a product only when appropriate and necessary, and with the informed consent of the patient. A few respondents noted GPs' responsibility as gate-keepers in restricting access to prescription medicines, with one stating that this is not a popularity contest: if the patient's demands are unreasonable then it is for the doctor to say so.

One respondent commented that the interests of the patient should be paramount when considering the doctor–patient argument in the DTCA debate, arguing that any regulation imposed should be for the sole benefit of the consumer, not for the *de facto* protection of the service provider.

<p>Support: Key points</p>

- DTCA assists the dialogue between doctors and patients.
- Patients usually ask about DTC-advertised medicines during an already-scheduled visit and do not exert pressure on GPs to prescribe a particular product.
- The dynamic between patients and doctors is changing, with consumers becoming more empowered and active in decisions concerning their health care.
- Doctors are professionally trained, with ethical and professional obligations that require them to prescribe a product only when appropriate and necessary and with the informed consent of the patient

Fiscal pressures and costs to consumers

The consultation document outlined the arguments relating to the fiscal impacts and costs to consumers that arise as a result of DTCA. The document noted that in cases where DTC-advertised medicines are subsidised, there is the potential to put pressure on the pharmaceutical budget. In cases where medicines are not subsidised, this may increase pressure on PHARMAC to subsidise new, higher-priced pharmaceuticals, or the cost must be borne by individuals. The alternative view was that many DTC-advertised medicines are not subsidised and that any increase in prescriptions due to DTCA should be seen as positive. Views were sought on respondents' concerns about or support for DTCA in this context.

Concerns

Respondents who were concerned about the impact of DTCA on the pharmaceutical budget and costs to consumers noted that the main purpose of DTCA was to increase sales of pharmaceuticals for the benefit of pharmaceutical companies and stakeholders. There was a worry that where newer, more expensive products are promoted, DTCA has the potential to exacerbate financial and health inequalities. Concern was raised that resource allocation distortions may result from DTCA as expenditure on newer, more expensive drugs increases as a result of increased consumer demand from DTCA.

A couple of respondents commented that DTCA is likely to cut across the Ministry of Health's objective of increasing the equity of resource allocation for pharmaceuticals, given that the purpose of DTCA is to promote increased use of new and expensive drugs irrespective of relative need for the product. PHARMAC commented that DTCA is often used to promote subsidised pharmaceuticals, and that subsidy status is often used as a selling point.

Following on from the argument above, a number of respondents felt that DTCA leads to unnecessary and inappropriate expenditure – not only in terms of increased use of pharmaceuticals, but expenditure from increased patient visits to GPs. Some also argued that DTCA has the potential to increase the cost of drugs and produce difficulties in closing negotiations on prescription medicine pricing as pharmaceutical companies increase the cost of medicines in order to recoup the costs of advertising.

A couple of respondents, including PHARMAC, commented on the clear association between DTCA and pharmaceutical consumption and expenditure. PHARMAC commented that while increased use of medicines can have some benefits, prescribing as a result of DTCA may be more related to wants (of a patient) than needs, when other treatments such as exercise may be more cost-effective.

Pressure on PHARMAC as a result of DTCA was also cited as a key argument by a number of submitters. It was felt that DTCA encourages public demand for a specific pharmaceutical (or group of pharmaceuticals), thus placing pressure on PHARMAC to fund that particular pharmaceutical or pharmaceutical group. In cases where advertised medicines are subsidised, this has the potential to divert health dollars to medicines that may not be needed or that offer little or no additional benefit over other cheaper alternatives. In addition, it was noted that in a fixed health budget, unnecessary drug use may in turn deny others the right to treatment. One respondent argued that DTCA is a threat to the sustainability of the drug subsidisation scheme.

The availability of sufficient evidence on safety and efficacy for new medicines that are advertised was also cited as a concern. A couple of respondents noted that poorly regulated DTCA may have financial implications for the Accident Compensation Corporation if consumers are misled by an advertisement and feel that there are grounds for compensation on account of either product liability or medical misadventure.

Lastly, respondents argued that when DTC-advertised medicines are unsubsidised, this shifts the cost from the Government to consumers. Considerable costs may be incurred by individuals demanding pharmaceuticals where benefit may not be proven or are of marginal value, particularly in cases where vulnerable consumers are led to believe that an advertised drug is more effective than cheaper, non-advertised alternatives.

Concerns: Key points

- Resource allocation distortions may result from DTCA.
- DTCA leads to unnecessary and inappropriate expenditure, in terms of both prescription medicine costs and the cost of GP visits.
- There is a clear relationship between advertising and increased pharmaceutical expenditure.
- DTCA increases public demand for pharmaceuticals and puts pressure on PHARMAC to subsidise those drugs that are advertised.

Support

The main area of comment among those in support of DTCA in this context was that because PHARMAC is the sole purchaser of pharmaceuticals and has strict cost-effectiveness criteria on which to base their funding decisions, DTCA has little impact on the PHARMAC budget, the allocation within the pharmacy budget or health funding priorities. The following points were cited as evidence in support of this argument.

- PHARMAC's annual expenditure over the last 10 years averages only 1.1 percent increase, which indicates either that DTCA has little impact on the pharmaceutical budget, or that the cost of DTC-advertised medicines is borne by consumers.
- In New Zealand, the average spend per head on medicines by the Government is \$141, compared to \$300 per head in Australia (where DTCA is prohibited), so there is little evidence to suggest that a ban on DTCA will prevent cost escalation.
- Results from a study⁶ that compared DTCA and price for 20 heavily advertised drugs found a weak relationship between the two, concluding that DTCA did not drive price increases.

Submitters also commented that, when considering the link between DTCA and pharmaceutical expenditure, other factors that may affect the utilisation of pharmaceuticals must be taken into account and controlled for. In addition, one respondent suggested that any decision on DTCA regulation should be taken in the broader context of the overall impact on health, rather than on the narrow perspective of balancing PHARMAC's budget.

Another area of comment was that the cost of a GP consultation is already a significant barrier to prevent overprescribing of prescription medicines as a result of DTCA. Furthermore, if GPs are prescribing appropriately, increased spending on prescription medicines should be viewed as positive, because it means that more New Zealanders are receiving treatment. It was also noted that GPs often make decisions on behalf of their patients with respect to the costs of medicines, and that there is little evidence to suggest that consumers 'doctor shop' in order to obtain a prescription for a specific medicine they have seen advertised.

A number of respondents made the point that the majority of DTCA is for medicines that are not subsidised, and it is the consumer's right to receive this information, regardless of subsidy status and cost. It was pointed out that prescribers are obliged to provide patients with information that includes all available treatment options and costs, and that consumers should be able to decide whether to privately fund their treatment or seek cheaper alternatives based on the information provided. One respondent suggested that if consumers did not have access to DTCA, this might restrict their access to information about treatment options that are only available privately. Another submitter noted that in many cases newer drugs are more effective and may lower the costs of non-drug spending.

A couple of submitters commented that DTCA increases demand for a particular class of product, as opposed to a specific brand, and the fact that an advertisement is branded does not diminish interest in generic discussion of the condition. A possible explanation for this phenomenon was that often DTCA prompts consumers to discuss their condition with their GP regardless of their desire for a particular product, and that prescription choice is still decided primarily by the GP. The point was made that DTCA merely drives public enquiry. The driver of pharmaceutical expenditure is entirely in the

⁶ Anantharaman R, Parthan A, Shepherd M. 2005. Examination of the relationship between direct-to-consumer advertising expenditure and price. *Drug Information Journal*.

hands of the prescriber, and the key issue should not be about DTCA but about the decision-making responsibilities of prescribers.

In regard to the use of a fiscal argument to justify imposing stronger regulations on DTCA, one submitter noted that public pressure is an essential and necessary component of a funding decision, and it would be inappropriate to prohibit DTCA to provide protection for the funder. A couple of submitters also commented that pharmaceutical companies have a right to advertise their products, particularly if they are unsubsidised. Another respondent noted that the government is not a neutral party in this debate, and that any decision to increase regulation of DTCA should be taken in the interests of public health and not from a financial position.

Support: Key points

- DTCA has little impact on pharmaceutical expenditure due to PHARMAC's strict control of the pharmaceutical budget.
- Increased spending on medicines should be viewed as positive, because it means that more New Zealanders are receiving appropriate treatment from their GP.
- Consumers should have access to information about treatment options, regardless of subsidy status.
- The key factor in the DTCA debate should be public health, not the financial position of the funder.

4 Further Information or Arguments that Support or Oppose DTCA

The consultation document sought feedback from respondents on any further information or arguments that support or oppose DTCA.

Some respondents made suggestions for further research or analysis. These suggestions included:

- general research and analysis of the effect of DTCA on the uptake of prescription medicines and affordability to consumers
- meta-analysis of the international evidence on DTCA in relation to the Ministry's and the Minister's strategic priorities
- monitoring the effects of DTCA on health and health care
- critical examination of the flaws in and operation of the current self-regulatory system
- examination of the problems with central regulation of DTCA in the United States
- research on DTCA in other jurisdictions.

Many respondents made comments on further evidence and arguments that support or oppose DTCA. These points have been covered under the main cases for and against DTCA outlined previously.

One submission cited evidence from *Family Health Diary* research, noting a number of key points with respect to consumers' and GPs' attitudes towards DTCA and the usefulness of information presented via DTCA. In general, the research found that a number of consumers and GPs have favourable attitudes to DTCA, both in terms of increasing awareness of conditions and treatments and improving compliance with medical treatment.

5 Section 14 of the New Zealand Bill of Rights Act 1990

The consultation document outlined the relevance of the New Zealand Bill of Rights Act 1990 to any proposal to restrict DTCA and the justifiability of such a proposal under section 5 of the Bill of Rights Act. While comment from respondents was not specifically called for on this matter, a number of submitters gave their views on DTCA with respect to the Bill of Rights Act.

Those opposed to DTCA argued that a ban is justified under the New Zealand Bill of Rights Act 1990. General comments were made on reasons for justifying a ban on DTCA and on purported infringements made by DTCA to the Bill of Rights Act, including the following.

- DTCA is misleading and can lead to inappropriate prescribing, resulting in medical misadventure and harm to consumers.
- DTCA encourages increased uptake of new prescription medicines that do not have established safety profiles.
- DTCA targets consumers, who cannot access prescription medicines without a health professional – any advertising should be aimed at these professionals who are able to understand and evaluate it.
- Legislative controls over the sale and advertising of tobacco products, liquor and firearms provide a precedent for DTCA in the context of protecting the interests of consumers. The nature of the risks associated with prescription medicines warrant a restricted approach to advertising.
- Commercial expression is on the fringe of the freedom of expression protected by section 14 of the Bill of Rights Act: ‘advertising is a profit-driven type of expression, far from the “core” of freedom of expression’.
- A rational connection exists between a prohibition on DTCA and the objective of reducing the risks associated with such advertising.

One respondent noted that DTCA is banned in Canada despite the same provisions in the Canadian Charter of Rights and Freedoms (including the same provision regarding justified limitations on the rights as in section 5 of the Bill of Rights Act), on which the New Zealand legislation is based. In addition, the comment was made that the New Zealand Parliament is free to enact legislation that is inconsistent with the Bill of Rights Act by reason of section 4 of the Act.

Respondents in support of DTCA argue that a ban on DTCA is not justified under the New Zealand Bill of Rights Act 1990. General comments were made on reasons that a ban on DTCA would not be able to be justified under section 5 of the Act, and sections that a ban on DTCA would purportedly contravene, including the following.

- Individuals have a right to receive information via DTCA, and pharmaceutical companies have a right to advertise their products to consumers.
- Consumer health and safety are better served if product-specific and related material is able to come directly from the regulated pharmaceutical industry.

- There is a lack of evidence to show that DTCA is harmful to consumers, so an argument for restricting DTCA cannot be made.
- In order to constitute a justifiable limitation, a total prohibition on DTCA must be rationally connected to the public health objective the Government wishes to pursue. Ensuring consumers and doctors have access to information about medicines supports the public health objectives of early intervention and treatment, resulting in better outcomes for patients.

6 Options for Regulating DTCA in New Zealand

The consultation document took a neutral perspective to DTCA regulation, reviewing the costs and benefits and seeking feedback on three options for the regulation of DTCA in New Zealand:

- 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).

Many of the submissions called for a ban on both DTCA and disease-state advertising (other than that provided by independent information sources). The support for an option 4 – to ban DTCA and for-profit disease-state advertising – warranted its addition to the regulatory options to be considered in the context of the current review of DTCA regulation.

Table 3 shows the number and percentage of submissions that supported each policy option. Note that a number of respondents indicated that they supported an option, but with slight variations to that option. These variations are not indicated in the table below.

Table 3: Preferred policy option for DTCA regulation

Preferred policy option	Number of submissions*	Percentage
Allow DTCA to continue with more stringent regulation	20	24.6
Allow DTCA but with stricter requirements than specified by the Therapeutic Products Advertising Code	6	7.4
Ban DTCA and regulate disease-state advertising	44	54.3
Ban DTCA and ban for-profit disease-state advertising	11	13.6
Total	81*	99.9**

* Forty submissions did not indicate a preferred policy option for the regulation of DTCA, and six submissions indicated more than one option (and are counted under both).

** Percentages do not add to 100 due to rounding.

Option 1: Allow DTCA to continue with more stringent regulation

As outlined in the consultation document, option 1 is to allow DTCA to continue but with more stringent regulation under the Therapeutic Products Advertising Code.

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 Australia New Zealand Therapeutic Products Authority. This option was therefore considered as the status quo, against which the other options could be measured.

Of the 81 (70 percent) submissions that indicated a policy preference, 24.6 percent supported Option 1 (status quo).

Supporters of option 1 felt there was little evidence available to support a strengthening of the regulatory requirements for DTCA, and that the current system is working well. Following are some of the general comments made on the current approach to the regulation of advertising in New Zealand.

- New Zealand's system of self-regulation is highly regarded internationally and ensures a high standard of responsibility and compliance.
- The current approach of legislation supported by industry self-regulation is practicable and cost-effective.
- The complaints-based system is transparent and efficient in responding to any concerns.
- The Advertising Standards Authority is the authorised body to regulate advertising in New Zealand.
- Appropriate and proper standards for advertising prescription medicine already exist in the current Researched Medicines Industry (RMI) Association and Advertising Standards Authority codes of practice.
- The RMI code of practice is achieving a high level of compliance against an effective and appropriate set of standards that align with community expectations and needs.
- Members of the Advertising Standards Authority are highly motivated to self-regulate therapeutic advertising in a responsible manner. Indeed, there is an economic imperative to operate a successful self-regulatory regime, and the media rely on income from advertising to sustain their business.
- The Advertising Standards Authority has established a culture of respect. If a punishment system were introduced the whole structure would be undermined, the support for the Advertising Standards Authority self-regulatory system would diminish, and a culture of resistance, exploitation of loopholes and vastly increased expenditure would develop. In short, it would be self-defeating.

One respondent commented that the advantage of the Advertising Standards Authority having already adopted the Australia New Zealand Therapeutic Products Advertising Code is that it gives the Advertising Standards Authority's complaints board the authority to apply the more detailed and stringent RMI code of practice to the pharmaceutical advertisements of all companies that advertise medicines in New Zealand, not just those who are members of the Research Medicines Industry Association.

In addition, respondents commented on their support for this option in relation to the new advertising arrangements to come into effect under the Australia New Zealand Therapeutic Products Authority. General comments in this context included:

- the Therapeutic Advertising Pre-vetting System should continue under the Therapeutic Products Authority
- the current draft Australia New Zealand Therapeutic Products Advertising Code takes into account the differing approach taken to DTCA in Australia and New Zealand.

A couple of respondents commented that providing an increased level of regulatory oversight will benefit drug companies more than consumers, because stronger regulation increases the credibility of advertising and can lead to a misplaced level of trust. It was suggested that consumers, relying on the regulatory oversight by the Government, may be less cautious of such advertising than they would of more general advertising messages from unregulated sources. In addition, it was argued that doctors may be less inclined to contradict messages portrayed in strongly regulated DTCA, in comparison to the current regime, where doctors can simply argue that advertising is merely a means by which self-interested drug companies sell their products.

Many respondents in support of the status quo option commented that consumers have a right to access information via DTCA. It was also noted that the key question to consider is not whether regulation of DTCA should be strengthened, but whether health professionals, as gatekeepers to prescription medicines, have an inability or unwillingness to exercise their professional responsibilities and prescribe appropriately.

There were many suggestions for potential improvements to this option, such as:

- ongoing revision of the RMI and Advertising Standards Authority codes of practice to enhance patient-friendly disclosure of the risks of advertised medicines and consistently meet consumers' evolving needs
- more formal and specific recognition of the RMI code of practice within the Australia New Zealand Therapeutic Products Advertising Code
- providing the ability for the RMI, Advertising Standards Authority or the Therapeutic Products Authority to initiate independent challenges against breaches of advertising codes or regulations
- providing the ability for the Advertising Standards Authority or the Therapeutic Products Authority to impose a range of financial sanctions against companies whose advertisements breach advertising codes or regulations.

Support for this option by some respondents was conditional on:

- clear disclosure of risk information in DTCA, or information on how to access risk and benefit information
- additional comprehensive consumer information on pharmaceuticals being available.

A couple of respondents commented on the undesirability of having disease-state advertising in New Zealand in place of DTCA. Specific comments included:

- the experience with disease-state advertising in Australia suggests that more often than not consumers are completely aware that a disease-state advertisement pertains to a particular product
- disease-state advertisements fail to provide vital information to consumers to assess whether the medicine is suitable for their condition
- DTCA is inherently better than the promotion of prescription medicines via disease-state advertisements.

Although many respondents did not specifically indicate a preferred option for the regulation of DTCA (40 submissions), a number of comments made in support of DTCA could be construed to indicate support for option 1. For example:

- drug companies' freedom to advertise products should be continued in its present form
- DTCA should be retained now, and when the trans-Tasman agreement comes into force
- if the claims drug companies state in advertisements are accurate, then they have every right to publish them.

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

As outlined in the consultation document, option 2 is to allow DTCA in New Zealand but with stricter requirements than specified under the Therapeutic Products Advertising Code. The consultation document noted that criteria for stricter regulatory requirements on DTCA would be developed in consultation with the sector.

Of the 81 (70 percent) submissions that indicated a policy preference, 7.4 percent supported option 2. This option received significantly less support than the other two options identified by the consultation document.

A number of supporters of stricter requirements for DTCA than specified by the Therapeutic Products Advertising Code felt that this option was likely to address a number of concerns held about DTCA, including:

- the risk to patients from medicines that are newly marketed and that do not have established safety profiles
- variable standards of DTCA due to low-level regulation.

Many respondents commented on how the regulatory requirements for DTCA could be strengthened, as follows.

- Advertisements should be strictly pre-vetted by facilitators for misleading content.
- DTCA for new products should be prohibited until the product has been on the market for some time, allowing the possibility of a serious problem to have shown up.

- The regulatory regime for advertising should ensure a fair balance of information and encourage the communication of both benefits and risks of products.
- Advertisements should give greater emphasis to the role of health practitioners in making final decisions about the appropriateness of an advertised medicine and in assisting patients to understand whether or not a medicine is appropriate for them.

A few respondents rejected the proposal that mandatory pre-vetting of advertisements should be undertaken by the Therapeutic Products Authority. A couple felt this responsibility should continue to sit with the Therapeutic Advertising Pre-vetting System, under delegation from the Therapeutic Products Authority. However, one respondent was in support of moving the pre-vetting of advertisements from the RMI and Advertising Standards Authority to the Therapeutic Products Authority.

One respondent argued that if DTCA is prohibited in New Zealand, efforts to influence prescribers with advertising will be increased. Another commented on the effect of a prohibition on DTCA on consumers, suggesting that consumers are more likely to be provided with a variety of treatment options if they have requested a specific product. It was also felt that DTCA is a strong motivator for physicians to seek out information on a variety of medicines (both advertised and non-advertised) so that they can make an informed prescribing decision.

One respondent strongly recommended that DTCA be limited, but they did not indicate a preferred option for DTCA regulation.

Option 3: Ban DTCA and regulate disease-state advertising

As outlined in the consultation document, under this option DTCA would be prohibited and disease-state advertising would be regulated. This would allow for-profit disease-state advertising, but advertisements would be pre-approved. 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.

Of the 81 (70 percent) submissions that indicated a policy preference, 54.3 percent supported Option 3. The option received the highest level of support from submitters who indicated a preference.

Many respondents felt that this option was the most appropriate in the face of inconclusive evidence to show that DTCA provides a public health benefit, and that any purported benefits of DTCA are outweighed by its harms. General comments included that this option:

- provides the best policy for both providers and customers in the New Zealand health sector
- provides a higher level of protection for the consumer

- will take away the bias towards pharmaceutical manufacturers and advertising agencies
- may lead to reduced investment in advertising by drug companies, which may in turn reduce medicine costs.

A number of respondents commented that allowing disease-state advertising in place of DTCA is beneficial in that this form of advertising still retains the benefits of providing pharmaceutical information to consumers via advertising, without specifically pushing a branded product, and also removes the negative aspects associated with DTCA. It was felt that disease-state advertising could continue to be used as a mechanism for raising awareness of under-treated and under-diagnosed conditions, and for early assessment, diagnosis and treatment of chronic conditions.

One consumer commented on the desirability of having consumer medicine information mandatory under this option, allowing instructions and contraindications to be provided to consumers together with a medicine when the need for that medicine is deemed appropriate by their GP.

A number of respondents commented further on the purported problems with DTCA and DTCA regulation in New Zealand to provide justification for the decision to implement a prohibition. Comments in this context included the following.

- DTCA is a threat to the health of people of New Zealand.
- DTCA interferes in the decision-making process between doctor and patient.
- DTCA cannot be controlled either by central or self-regulation.
- The Therapeutic Advertising Pre-vetting System is ineffective because it fails to identify misleading advertising claims, and the complaints process is long and difficult.
- There is inadequate protection of consumer interests in the current self-regulatory system.
- Currently, advertisements provide partial information or misinformation, overstate efficacy, minimise adverse effects, use emotional persuasion, and fail to mention alternative treatments.

Many supporters of this option indicated that if it were to be implemented, disease-state advertising would need to be strictly regulated in order to ensure that information provided via this form of advertising is balanced and appropriate, and to avoid exploitation of this form of advertising by pharmaceutical companies.

A couple of respondents made suggestions as to how this option could be improved.

- Disease support organisations should not be sponsored by industry, because they are in a position of conflict of interest.
- Regulation of disease-state advertising should support only disease awareness campaigns and information about public health issues.

- Disease-state advertisements should be produced non-commercially – companies could provide funding, if desired, through a publicly administered blind trust or other mechanism that removes individual manufacturers’ need to expand product sales through the provision of disease information.
- The option for industry self-regulation of disease-state advertising should be removed.
- Reliance by drug companies on direct-to-doctor advertising of prescription medicines should be discouraged.

A couple of respondents also commented that this option should be implemented together with the establishment of an independent health information service to provide comprehensive pharmaceutical information to consumers that is free of commercial interest.

A few respondents commenting on this option felt that insufficient information was provided in the consultation document on what harmonisation with Australia’s policy entailed. One suggested that if a similar model to Australia is adopted in New Zealand, DTCA will continue to occur but in less obvious ways, as is currently the case in Australia. Another noted concern that the draft advertising code accommodates different approaches taken toward DTCA and disease-state advertising by New Zealand and Australia.

One respondent felt that the argument that banning DTCA may result in the pharmaceutical industry reducing investment in New Zealand is, while valid in principle, overstated. The respondent suggested that the industry could instead divert investment into direct-to-doctor advertising, and that while non-DTCA approaches may be less profitable for individual companies, they may have a beneficial effect in the long run, particularly where clinically effective and cost-effective pharmaceuticals are available.

For many respondents support for this option was conditional on banning for-profit disease-state advertising by pharmaceutical companies. As noted above, these respondents are therefore included in the summary of submissions that supported option 4 (ban DTCA and for-profit disease-state advertising), outlined below. A couple of respondents indicated that they supported option 3 out of the choice of options provided in the consultation document, but they were more in favour of a ban on both DTCA and for-profit disease state-advertising.

While many respondents did not specifically indicate a preferred option for the regulation of DTCA (40 submissions), a number of comments could be construed as indicating support for option 3. For example:

- banning DTCA works elsewhere and is there for a purpose
- DTCA should be banned
- DTCA should not continue.

Option 4: Ban DTCA and for-profit disease-state advertising

As noted above, this option was added to the options for regulating DTCA in New Zealand due to the considerable amount of support it gained from a number of submitters. Under this option, both DTCA and for-profit disease-state advertising would be banned. Disease-state advertising by independent information sources would continue to be allowed.

Of the 81 (70 percent) submissions that indicated a policy preference, 13.5 percent supported a full ban on DTCA and for-profit disease-state advertising. However, it should be emphasised that as this option was not included in the DTCA consultation document, it may not have been considered by the majority of respondents.

Respondents who supported this option were opposed to all forms of for-profit prescription medicine advertising. Many felt that there is little difference between DTCA and disease-state advertising, and that disease-state advertising merely allows pharmaceutical companies to promote their products in a covert and less transparent way.

Respondents argued that this form of advertising:

- risks entrenching early innovators and could potentially reduce competition within a therapeutic class, because a pharmaceutical company has to dominate a therapeutic class in order to engage in disease-state advertising
- provides little information to consumers – in some cases it simply directs consumers to their doctor or to where they can find additional information
- due to its lack of specificity, may cause a large number of unnecessary visits to doctors, resulting in unnecessary costs to the patient.

Perceived benefits of a complete ban on both DTCA and disease-state advertising included:

- there will be no misunderstanding of what is permissible, and no conflicts of interest arising in the health profession
- such a ban is clear and definitive, and so would make the regulator's position much easier.

A number of respondents commented that in the absence of for-profit pharmaceutical advertising, public health and disease awareness campaigns should be independent from industry, and access to quality pharmaceutical information for consumers should be improved. With regard to public health campaigns, one respondent commented that priorities should be identified on the basis of public health need and the emergence of truly innovative treatments.

Many respondents who supported this option wanted to see an independent pharmaceutical information source established to provide reliable and balanced information on the variety of treatment options available to consumers, and which is free from commercial interest. Following are a few of the suggestions given for how such a system could be implemented.

- Health information and awareness campaigns should be carried out by parties with no vested interest, such as non-government organisations (NGOs), community organisations and health professional bodies.
- Extensive resources currently spent on regulation can be redirected to ensuring a consumer-friendly drug database and effective monitoring of other undesirable activities relating to pharmaceutical promotion.

7 Further Options for the Regulation of DTCA

The consultation document sought suggestions for and views on further options for regulating DTCA in New Zealand.

Only a handful of submitters responded to this question. Suggestions for further options for DTCA regulation, aside from respondents' support for the other options for DTCA regulation, included:

- all types of drug promotion targeting health professionals and the public should be banned in all countries – drug promotion should be banned or restricted as much as is politically achievable
- regulation of DTCA should apply to any 'health product' – there should be consistency in the regulatory approach to advertising across all prescription medicines, over-the-counter medicines and complementary and alternative medicines
- allow DTCA to be regulated under the more general provisions that govern all advertising.

A number of respondents commented on how the regulation of DTCA could be improved.

- Involve pharmacists in the pre-vetting of advertisements.
- All advertisements could be made to comply with a requirement to state where the consumer can obtain additional information about the product.
- More explicit warning statements should be required.
- Pharmaceutical companies that breach advertising guidelines should be required to publish retraction statements.
- Advertisements should include equal risk and benefit information at the beginning of the advertisement rather than in small print at the end.
- An independent review board should be established to peer review the content of advertisements to ensure they comply with international standards for consumer information and don't make misleading claims.
- Advertisements should be required to contain information about other treatment options and the cost to the Government.

8 Other Views on Achieving the Purported Benefits of DTCA Without Experiencing the Purported Costs of DTCA

The consultation document sought respondents' views on how to achieve the purported benefits of DTCA without experiencing the purported costs of DTCA.

Respondents' feedback to this question focused on the following key areas.

- An independent pharmaceutical information service should be established to ensure transparency and easy access to pharmaceutical and other related information about a condition or treatment that is free from commercial interest.
- Information presented via DTCA could be improved to achieve a balance between the interests of pharmaceutical companies and the need for consumers to receive accurate and comprehensive pharmaceutical information.

A number of respondents suggested ways in which an independent pharmaceutical information system could be established and how it would operate. One commented that there is an abundance of consumer health information already available in New Zealand, but the quality of this information is variable and there are issues relating to its appropriateness and accessibility.

General comments and suggestions included:

- provision of independent drug information via an 0800 number
- the Ministry of Health should fund independent consumer and patient advisory groups to produce and distribute pharmaceutical information
- the establishment of a central repository of independent pharmaceutical information
- the Government should establish an independent health and information service
- the possibility of linking a pharmaceutical information service to 'Healthline'
- adapting/collaborating with current not-for-profit information sources to provide pharmaceutical information
- providing consumer access to the Cochran Library website for information on health conditions and best practice treatments.

Appendix 1: Participants in the Consultation

Member of public

Amanda Zukerman
Individual*
James Owen
Heather Barker
Gwen and Gordon Wardlaw
Trevor I McIntosh
Dr Janice Ann Prest
Wilton and Helene Willis
Borislau Dacic and Georgina Mussen
Juliet Yates
Michael Taylor
Individual*
Sandra Coney

Health professional

Paul Corwin
Dr Jon Scott
Individual*
Clare O'Donnell
Ian Packer
Viv Bath
Neville Cameron
Peter Barron
Victoria Perry
Hamid Ikram
Dr Mike Inskip
Euan Galloway
Dr Jennie Connor
Evan Begg
John Grigor
Dr Shaun Holt
Dr Leo Revell
Dr Cameron Grant

Pharmaceutical company

GlaxoSmithKline New Zealand
Merck Sharp & Dohme New Zealand
AstraZeneca Limited
Roche Products (New Zealand) Ltd
Pfizer New Zealand Ltd

Government agency

Northland District Health Board
Otago District Health Board
Lakes District Health Board
PHARMAC
Waitemata District Health Board

Educational/research organisation

Michael Harker and Debra Harker, Social Marketing and Advertising Research Team,
University of the Sunshine Coast, Queensland, Australia
Australian and New Zealand College of Anaesthetists
Royal Australasian College of Physicians
Pegasus Health
Joint Faculty of Intensive Care Medicine, New Zealand National Committee
College of Nurses Aotearoa (NZ) Inc
Royal New Zealand College of General Practitioners
The Informed Prescriber, Japan
Four New Zealand Departments of General Practice and Primary Care
University of Otago and University of Auckland Schools of Pharmacy
New Zealand College of Chiropractic

Advertising company/agency

Advertising Standards Authority
Athena Marketing Research
Marketing Association
Association of New Zealand Advertisers
Insight New Zealand Ltd
Brandworld Ltd

Consumer group/representative

Patients Rights Advocacy
Frances Acey
Palmerston North Women's Health Collective
National Council of Women of New Zealand
Consumer Advisory Committee of PHARMAC
Public Citizen's Health Research Group, USA
Consumers' Institute
Australian Consumers' Organisation

Academic

Douglas Ball
Joel Lexchin
Catherine Collings
Dr Nick Wilson
Peter Crampton
Barbara Mintzes
Individuals*
Ann Richardson
Agnes Vitry
Dr Anna Stevenson
Janet Hoek
Dr Rhema Vaithianathan

Organisation

Public Health Association of New Zealand
New Zealand Federation of Graduate Women (Auckland Branch) Inc Public Issues Committee
Medicines in Europe Forum
South Link Health Inc
New Zealand Medical Association
International Society of Drug Bulletins
Healthy Skepticism Inc
Pharmacy Council of New Zealand
Family Planning Association
DHBNZ Safe and Quality Use of Medicines Group
Japan Institute of Pharmacovigilance
Medwatcher Japan
Federation of Women's Health Councils Aotearoa New Zealand
Infant Feeding Association of New Zealand
New Zealand Health Care Pharmacists' Association Inc
Women's Health Action Trust
Health Action International Europe
Clinical Advisory Pharmacists Association
Public Health Association of New Zealand Inc (Canterbury Branch)
Grey Power New Zealand Federation Inc
Hamilton Labour Women's Branch
Medical Council of New Zealand
Health and Disability Commissioner
Health and Disability Advocacy
New Zealand Nurses Organisation
Balance NZ – Bipolar and Depression Network
Pharmacy Self Care – Pharmaceutical Society of New Zealand
Pharmacy Guild of New Zealand
Pharmaceutical Society of New Zealand
New Zealand Self Medication Industry Association Inc
Arthritis New Zealand
Television New Zealand Ltd

Radio Broadcasters Association
Foundation for Advertising Research
Researched Medicines Industry Association of NZ Inc
New Zealand Organisation of Rare Disorders
Access to Medicines NGO Coalition

* Four submitters did not give permission for their personal details to be released.

Appendix 2: Questions from the Consultation Document

- 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?
- Q3. Which of the arguments outlined in Section 5, 'The Cases For and Against DTCA', do you find the 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.
- 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.