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**DIRECT-TO-CONSUMER ADVERTISING FOR
PRESCRIPTION DRUGS IN NEW ZEALAND:
Time for a Radical Change?**

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Abstract

This paper deals with Direct-to-consumer advertising (DTCA) for prescription drugs in New Zealand. This kind of advertising can be defined as the business practice of pharmaceutical companies where they promote their prescription medicine directly to consumers via mass media such as television, print, radio or in recent times the Internet. Among all industrialised countries only the United States and New Zealand allow this form of drug advertising.

This paper examines if New Zealand should change its current position towards DTCA and follow the majority of countries where DTCA is prohibited.

In a first part, the paper introduces and evaluates the various existing approaches towards DTCA. Part III of the paper argues that the current regulation of DTCA in New Zealand does not provide sufficient consumer protection. Stricter regulation will be examined as one possible option, with a focus on general problems of effective regulation of DTCA. Ultimately this part concludes that a ban is justified considering the importance of health protection.

The last part of the paper argues that a ban of DTCA is one step in the right direction, but further effort is needed to enhance patient's autonomy and provide consumers with reliable health care information in the Internet.

Word length

The text of this paper (excluding abstract, table of contents, footnotes and bibliography) comprises exactly 7439 words.

Subjects and Topics

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I Introduction

When is the last time you have seen an advertisement for prescription drugs in New Zealand? Among all industrialised countries only the United States and New Zealand allow this form of drug advertising.

In general direct-to-consumer advertising (DTCA) for drugs can be defined as the business practice of pharmaceutical companies where they promote their products directly to patients via mass media such as television, print, radio or in recent times the Internet.¹

This paper will deal with product advertising for prescription drugs and will not address advertising for over-the-counter drugs available without prescription. Therefore the term DTCA in the following refers to advertisements which name a specific prescription medicine along with the condition(s) to be treated and that make claims regarding the benefits of the particular drug.²

DTCA is subject to continuous controversial political and academic discussion in New Zealand and other countries. In 2006 New Zealand's Ministry of Health carried out a public consultation on the Regulation of DTCA after ongoing public concerns. Although more than half of the submissions that indicated a policy preference, opted for a total ban of DTCA, a change in legislation was not included in the final draft of the Therapeutic and Medicine Bill 2006 due to insufficient support in the parliament.³ In the European Union, the European Commission withdrew a proposal to loosen the complete ban in 2014 after a consultation process of more than six years.⁴

¹ C Lee Ventola "Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?" (2011) 36 *Pharmacy and Therapeutics* 669 at 669.

² Other forms of drugs advertising are the so called "disease awareness advertisements" (DAA), which describes a disease or condition but does not mention a specific product.

³ See for political discussion in New Zealand: Ministry of Health *Direct-to-Consumer Advertising of Prescription Drugs in New Zealand: Summary of Submissions* (September 2006); and (12 December 2006) 636 NZPD 7067 for related discussion in Parliament.

⁴ Withdrawal of the Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use [2014] OJ C 153/57 at 3; or further information about the legislative process see DG Health and Food Safety "Information to patients-legislative approach" Public Health <www.ec.europa.eu>.

Part II of this paper introduces and evaluates the various existing approaches towards DTCA. Part III argues that the current regulation of DTCA in New Zealand does not provide sufficient consumer protection. Stricter regulation as one possible solution will be examined with a focus on general problems of an effective regulation of DTCA. Ultimately this part concludes that a ban is justified considering the importance of health protection. Part IV suggests different approaches to how consumers can be provided with reliable information.

II Evaluation of the Different Views on DTCA

A The Informed Consumer vs the Misinformed Consumer

One of the core arguments of proponents of DTCA centres on an alleged educational value of DTCA for consumers. They submit that DTCA provides consumers with information about possible new treatments for medical conditions.⁵ Consequently patients are able to engage in discussing possible new options to manage their disease with their doctor. This positive effect of DTCA is often mentioned together with the fact that consumers nowadays search actively for information and want to be involved in healthcare-decisions.⁶

On the other hand opponents of DTCA argue that DTCA does not lead to informed consumers. The basis for a real informed choice and an actual empowerment of patient's autonomy would be unbiased, complete and comprehensive information.⁷ Advertising is by nature not a medium designed to provide balanced information.⁸ Its aim is to increase consumer demand by emphasising the benefits of a particular product or brand of product.

One fundamental problem with DTCA is selected information. According to a study in the United States, which analysed print advertisements, a common advertising instrument is to name the condition and treatment. However, advertisements may not inform consumers about the prevalence of the condition or alternative treatment choices

⁵ Frank Auton "The case for advertising pharmaceuticals direct to consumers" (2009) 1 *Future Med Chem* 587 at 589.

⁶ Kanika Johar "An Insider's perspective: Defense of the pharmaceutical industry's marketing practice" (2012) 76 *Alb L Rev* 299 at 318.

⁷ Barbara Mintzes and Dee Mangin "Direct-to-consumer advertising of prescription medicines: a counter argument" (2009) 1 *Future Med Chem* 1555 at 1556.

⁸ At 1556; Ministry of Health, above n 3, at 5.

(including the option of lifestyle changes) or the actual success rate of a treatment.⁹ Additionally the advertisements often use vague terms to describe benefits, emphasise benefits over risks and rely on emotional appeals.¹⁰

Concerning the quality of information, I agree with the opponents of DTCA. It is hard to dispute that the information provided by DTCA is unlikely to be comprehensive or unbiased. However, it is less clear that this finding must automatically lead to a ban of DTCA. Consumers today are in general sceptical towards the information presented in advertisements. This applies also to drug advertising.¹¹ However, adverts may still have great influence. Therefore the consequences that DTCA has on the doctor-patient relationship and on public health in general must be examined.

B Harm to the Doctor Patient Relationship and Risk of Unnecessary Prescription vs Enhanced Relationship and the Professional Gatekeeper Function

The doctor-patient relationship is incredibly important when evaluating the risks and benefits of DTCA. To understand the vulnerability of this relationship it is crucial to understand its peculiarity.

The physician has a fiduciary obligation in this relationship.¹² Firstly, the patient depends on the doctor to get access to medical services such as prescription drugs. Unlike over-the-counter drugs, prescription drugs are only available after medical consultation with a doctor. The reason for this is that prescription drugs are more toxic. The physician, who makes the final decision that a drug is needed, serves as a gatekeeper to prevent patients from harmful potential side-effects or drug interactions. In this regard the autonomy of patients to make their own healthcare decisions is limited. In other words,

⁹ Robert Bell, Michael Wilkes and Richard Kravitz “The Educational Value of Consumer-Targeted Prescription Drug Print Advertising” (2000) 49 J Fam Pract 1092 at 1096.

¹⁰ Alex Wellington “To ban or not to ban: direct-to-consumer advertising and human rights analysis” (2010) 3 AMJ 749 at 756, n 104; Susanna Every-Palmer, Rishi Duggal and David B Menkes “Direct-to-consumer advertising of prescription medication in New Zealand” (2014) 127 NZMJ 102 at 104, n 15; Ventola, above n 1, at 674.

¹¹ See Janet Hoek, Philip Gendall and John Calfee “Direct-to-consumer advertising of prescription medicines in the United States and New Zealand: an analysis of regulatory approaches and consumer responses” (2004) 23(2) International Journal of Advertising 197 at 218.

¹² Thomas L. Hafemeister and Richard M Gulbrandsen “The fiduciary obligation of physicians to “just say no” if an “informed” patient demands services that are not medically indicated” (2009) 39 Seton Hall L Rev 335 at 369.

once a doctor decides that a treatment is medically necessary patients have the right to be fully informed about possible treatment options and their risks and benefits. After that they make the ultimate decision about the commencement of a treatment or to choose to not get any treatment at all.¹³ However, patients have no right to demand a certain treatment.

Secondly, the doctor-patient relationship is strongly characterised by patients' trust in their physician. Even with the best access to information, a skill and knowledge disparity will remain between doctors, who have attended several years of medicine school, and patients. Hence, patients must rely on the competence and loyalty of the doctor and trust that their physician's advice for treatment options is in their best interests.¹⁴ This includes cases where the physician proposes no treatment at all or refuses a desired treatment.

Having these factors in mind, the arguments concerning DTCA are as follows:

Opponents of DTCA argue that DTCA can put a significant strain on the doctor-patient relationship.¹⁵ It can pose a risk for the gatekeeper function if it leads to unnecessary or inappropriate prescribing. Opponents refer to the common situation where patients diagnose themselves prior to a consultation and request the prescription of a specific drug. DTCA may have created unwarranted expectations regarding the efficiency of a drug or the particular drug may be inappropriate considering the particular circumstances of the patient. If the doctor refuses the prescription, the result may be, at best, improved education of the patient. But, in the worst case scenario, it can lead to unsatisfied patients who have less trust in their physician's competence and consider "forum-shopping" to get their preferred drug.¹⁶ A survey confirms that at least 25 per cent of patients would consider trying to get the drug elsewhere.¹⁷ Thus, there are concerns that physicians could feel pressured to prescribe inappropriate medicines simply to please their patients.¹⁸

The counter argument of the DTCA supporters is that DTCA has a positive influence on the communication between patient and physician. Patients see the information provided in the adverts and are more likely to discuss their questions or concerns with their doctor

¹³ The right to make a informed choice and vice versa the duty of the doctor to obtain "informed consent" are enshrined in rights 6 (2) and 7 of the Code of Health and Disability Services Consumers' Rights; Section 11 of the Bill of Rights Act 1990 also stipulates the right to refuse any medical treatment.

¹⁴ Hafemeister and Gulbrandsen, above n 12, at 371.

¹⁵ Ministry of Health, above n 3, at 12.

¹⁶ Ventola, above n 1, at 681.

¹⁷ Dominik L Frosch and others "A Decade of Controversy: Balancing Policy With Evidence in the Regulation of Prescription Drug Advertising" (2010) 100 (1) Am J Public Health 24 at 26, n 46.

¹⁸ Every-Palmer, Duggal and Menkes, above n 10, at 105; Ministry of Health, above n 3, at 13.

in a consultation. This may include questions about conditions the patient was previously unaware of, as well as specific new treatment options for existing diseases or general information about healthcare.¹⁹ In terms of potential pressure that a physician may feel, opponents argue that it is the physician's medical and ethical obligation to resist possible pressure.²⁰

When assessing the arguments on both sides it can be observed that both sides have evidence supporting their claims. Several surveys that asked patients and physicians for their personal views underpin the arguments of the DTCA supporters.²¹ Even so some scholars question the strength of the evidence, because surveys are based on subjective perceptions rather than objective measures.²² Furthermore, the ethical standards and legal provisions confirm that physicians should prescribe medicine solely on their medical judgment.²³

On the other hand it must be noted that quantitative analysis in the United States has shown that there is a direct connection between the promotion of drugs via DTCA and an increase in prescribing of the advertised medicines.²⁴ In some cases this may merely be the result of prior under-diagnosed patients. However, a clinical study with patient-actors showed the following: The actors played patients with an adjustment disorder (which is usually treated without medication). Actors who requested a brand-specific drug were five times more likely to receive a prescription compared to those actors who did not request a particular medication.²⁵

The reasons behind such unwarranted prescribing behaviour are not easily identified. Statements of physicians suggest that they take their gatekeeper role seriously.²⁶ The observed prescription behaviour may be linked to the increased financial pressures that

¹⁹ See Ministry of Health, above n 3, at 22, 23.

²⁰ At 13.

²¹ See for a compilation of several surveys on the effects of patient-physician relationship: Frosch and others, above n 17, at 26.

²² At 28.

²³ New Zealand Medical Association "Code of Ethics for the New Zealand Medical Profession" (May 2014) <www.nzma.org.nz>, at 4; Code of Health and Disability Services Consumers' Rights, right 4.

²⁴ S Gilbody, P Wilson and I Watt "Benefits and harms of direct to consumer advertising: a systematic review" (2005) 14 *Qual Saf Health Care* 246 at 247, n 16,17.

²⁵ Ventola, above n 1, at 681, n 7.

²⁶ Lee Topp and others *Direct to Consumer Advertising of Prescription Drugs in New Zealand: For Health or for Profit?* (New Zealand Department of General Practice, February 2003) <www.moh.govt.nz> at 20.

physicians face today. Another reason may be that doctors are additionally influenced by parallel campaigns which target them as professionals. Pharmaceutical companies often run DTCA and advertising directed to professionals at the same time. Lastly, it has to be noted that an inappropriate prescription is not only prescription of medicine that is totally unsuitable. In fact, this will be rarely the case. More likely and equally considered as inappropriate prescribing, is for example cases where the doctor prescribes a requested new medication that is not more effective in treating the condition than older medications, but for which less is known about long- term unwanted effects.²⁷

Regardless of the reasons, it is a fact that patients are more likely to be subject to the danger of unforeseen severe side-effects from inappropriate prescriptions than from appropriate treatment, whether the appropriate treatment is no medicine or older alternatives with tried and trusted experience.

A solution should maintain the positive effects on the patient-physician relationship while minimising any negative influence of DTCA.

C Disease Awareness vs Risk of “Medicalisation” of our Society

Two other opposing positions regarding DTCA are closely linked to the part previously discussed.

There are concerns that DTCA causes a “medicalisation” of our society. Opponents argue that DTCA often heavily promotes so-called life-style drugs. These drugs treat less serious conditions or smaller ailments, which are either not perceived as a medical problems at all, or as minor medical conditions related to other conditions and not necessarily in need of medical invention.²⁸ Examples are advertisements for erectile dysfunction, obesity or hairloss. The promotion of lifestyle drugs may cause consumers to believe that there is a “pill for every ill”.²⁹ Unnecessary treatment of such lifestyle diseases results in increasing healthcare costs and additional risks of side-effects associated with drugs.³⁰ An additional concern is that “disease-mongering” may cause anxiety among consumers who are actually healthy and lead them to think that they are

²⁷ Lees Top and Dee Richards “New Zealand deserves better. Direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand: for health or for profit?” (2003) 116 (1180) NZMJ 1 at 1.

²⁸ Pooja Reddy and others “Lifestyle Drugs” (2012) 4 (5) International Journal of Pharmacy and Pharmaceutical Sciences 43 at 43.

²⁹ Johar, above n 6, at 323, n 179.

³⁰ Hafemeister and Gulbrandsen, above n 12, at 356.

suffering illness.³¹ One example is the promotion of depression drugs, which often blurs the boundary between normal temporary unhappiness in life and a pathological condition.³²

DTCA supporters disagree with the above-mentioned claims. The term lifestyle drug is vague and often conditions like obesity or sexual dysfunction can have a great impact on quality of life and therefore may need medical treatment. The role of the physician is to discuss alternative treatments and to prevent unnecessary prescription. In general, supporters claim a positive effect on healthcare because due to increased healthcare awareness, previously untreated conditions can be diagnosed earlier than they would be without advertising. Ultimately this will decrease healthcare costs. Furthermore DTCA can eliminate the taboo-effect of diseases (e.g. impotence) and prompt patients to talk to their physician when they may otherwise have been too embarrassed.³³

It is true that the line between conditions that require medical treatment is fluid and that in general the physician has the responsibility for the final decision about treatment. However, the concerns of the opponents are understandable. Pharmaceutical companies follow an economical aim to increase their portfolio by identifying potential new markets. The argument of the doctor as gatekeeper cannot serve as a general justification considering the vulnerability of this relationship (see above II B).

D Conclusion

In brief summary, the evaluation of the different approaches of DTCA has shown that DTCA is by nature not an independent source of unbiased information. The risk of negative effects on the doctor-patient-relationship and public health is particularly high. There is a risk that patients get a false impression about the particular product or are in other ways misled. Such distorted perceptions may be the result of a lack of information (e.g. alternative treatments), a lack of competence to evaluate the information included in adverts or simply the human tendency to absorb information in different ways. Without doubt, increased engagement of the public in health related questions and the treatment of undetected conditions is positive. However, it remains the question if these positive effects may be achieved in a similar manner without DTCA (see Part IV).

³¹ Ministry of Health, above n 3, at 19.

³² Ventola, above n 1, at 681; Lee Topp and others, above n 26, at 23.

³³ See Ministry of Health, above n 3, at 20.

III New Zealand - Where should we go?

After the evaluation of the different views on DTCA, this part of the essay will deal with the question of how New Zealand currently regulates DTCA in order to minimise the above mentioned risks. I will argue that the current regulation is not sufficient to effectively eliminate the risks of DTCA. Firstly, there is a structural problem in the current monitoring system. Even if the structural problem was solved, a second substantive problem would remain.

A Sufficient Consumer Protection in Current Regulatory System?

New Zealand opted for a mixture of statutory rules and industry self-regulation to regulate DTCA.

1 Statutory rules concerning DTCA

The legislation concerning DTCA can be found in the law that applies to every kind of advertising as well as provisions that specifically target advertising in the medical area.

a. Medicines Act 1981 and Medicines Regulations 1984

The two related laws that deal explicitly with medical advertising are the Medicines Act 1981 (hereinafter “Medicines Act”) and the Medicines Regulations 1984 (hereinafter “the Regulations”).

The provisions in Part Four of the Medicine Act concern medical advertisements in general, including advertising for non-prescription drugs, prescription drugs, medical devices as well as for methods of treatments.

General restrictions to any kind of medical advertising can be found in s 57 and s 58. The most important provision is s 57(1)(f) which prohibits any advertisement that is

...false, or is likely to mislead any other person, with regard to the nature, quality, strength, purity, composition, origin, age, uses, or effects of medicines or medical devices of that description, kind, or class or of any ingredient or component thereof;

Subsection 3 of the same section establishes that advertisements are deemed to mislead, if the advertising is likely to mislead in regard to “any purposes for which medicines...can be used with reasonable safety” or “any purposes for which such medicines...cannot be so used” or “any effects that such medicines ... when used, or when used in any particular way referred to in the advertisement, produce or are intended to produce”.

One should also note the provisions in s 58 (1). They prohibit inter alia advertisements, which may directly or indirectly claim that, a medicine, a medical devices or method of treatment will prevent, alleviate, or cure specific diseases;³⁴ or prevent or cure specific diseases.³⁵ Furthermore advertisements cannot be advertised as panacea or infallible or contain statements that a nurse, practitioner or pharmacist or any other qualified person recommends a treatment.³⁶ Likewise any claim that a medicine has beneficially affected the health of a particular person or class of persons is proscribed.³⁷

When we consider these provisions as a whole, it can be noted that there are some specific claims that are prohibited. In these cases the legislator has seen a significant risk that consumers may be misled. One good example is the claim that a medicine is a panacea. If consumers, who maybe already suffer an illness, hear that there is a guarantee to cure their medical condition, it is likely that this kind of advertising creates unwarranted expectations.

All advertisements, which do not fall under the few specific prohibitions, are subject to the general provision in s 57 (1) f of the Medicines Act with its vague term of “misleading advertising”.

Such vague terms are often used in law and are not necessarily negative, because the legislator cannot predict precisely all potential issues in the law. Regarding the misleading character of advertising the question whether an advertisement is misleading depends on a variety of factors e.g. type of products, level of education of the average consumer, presentation of advertisement. Such an open term gives the responsible authorities the possibility to act on a case by case basis.

The Medicines Regulations complement the provisions of the Medicines Act. They prohibit any claim that the advertisement was officially approved in s 7. Section 8 stipulates mandatory information that every medical advertisement must include and distinguishes between different forms of medicine. Prescription medicine must, inter alia, include the words “Prescription medicine“, a statement that the medicine has risks and benefits and a statement about how to find further information. These provisions are more

³⁴ Section 58 (1)a; The specific diseases are contained in Schedule 1 Part 1 and include, for example, alcoholism or diabetes.

³⁵ Section 58 (1)b; The specific diseases are contained in Schedule 1 Part 2 and include, for example, asthma or obesity.

³⁶ Section 58 (1) c (i) and (ii).

³⁷ Section 58 (1) c (iii).

of a technical nature. They only require the statement to be mentioned. Apart from the obligation that mandatory statements must be clearly spoken or written, s 8 does not regulate the way information must be presented. That explains why these statements often appear in small font at the bottom of a page rather than being prominently displayed to consumers.

b. The Fair Trading Act 1986

DTCA has also to comply with the general provisions in the Fair Trading Act 1986 (hereinafter “Fair Trading Act”). Part 1 of the Fair Trading Act combats unfair conduct in trade. The relevant sections are ss 9,10 and 13 which deal with misleading conduct in trade.

Section 13 explicitly concerns the promotion for the supply or use of goods and services and prohibits specific forms of false or misleading representations. Prescription medicines are goods, which the Fair Trading Act applies to.³⁸ Hence, DTCA as a form of promotion, must comply with the rules in s 13.

Most relevant for DTCA are ss 13(a),(e) and (h) which prohibit inter alia, any false or misleading representation that goods are of a particular kind or quality, have any approval or benefits, or false or misleading representation concerning the need of the product.

Any breach of s 13 is also likely to lead to a breach of s 9, which is the most general provision in part 1 of the Act and prohibits any conduct in relation to trade that is likely to mislead or deceive.³⁹ It follows that the broad term “conduct” that is used in s 9 includes any form of advertising in trade.

Beside s 9 also s 10 can become relevant. The scope of s 10 is narrower than s 9 as it concerns misleading conduct in trade specifically in relation to goods. A company, for example, must not advertise the medicine in a way that is liable to mislead the public about the nature, characteristics or the suitability of the goods for a purpose.

2 Self-regulatory framework of the industry

Beside the legal provisions DTCA is regulated by several self-regulatory schemes designed by the industry itself. There are two relevant Codes of Practice.

³⁸ Section 2 (1) defines goods as personal property of any kind.

³⁹ See Debra Wilson “Consumer Information” in Kate Tokeley (ed) *Consumer Law in New Zealand* (2nd ed, LexisNexis, Wellington, 2014) at 143 with evaluation of case law.

The self-governing Advertising Standards Authority (ASA), an alliance of media and communication agencies and advertisers has developed the ASA Therapeutic Products Advertising Code.⁴⁰ Additionally Medicines New Zealand (MNZ), an industry association representing the pharmaceutical companies, issued a Code of Practice.⁴¹

The Therapeutic Products Advertising Code contains general principles that “advertisements must be truthful, balanced and not misleading”; “Claims must be valid and have been substantiated” and “must observe a high standard of social responsibility”. Additionally the Code stipulates eight requirements that medicine advertising to consumers has to fulfil. Apart from mandatory statements that coincide to a large extent with the provisions in the Medicines Regulations, the other requirements often use vague terms as “advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated”,⁴² or “must not unduly glamorise products or services, or prey on the vulnerability of particular audiences”.⁴³

The Code of Practice issued by MNZ contains some specific rules, e.g. one paragraph regards to the type size;⁴⁴ or the general prohibition to use a definite article to imply a special quality,⁴⁵ but in the majority of the rules vague terms prevail.

Like the law, all of these terms are open to interpretation. Exact rules for, for example when an advertisement is considered to contain “balanced” information, are missing.

3 Monitoring system and its shortcomings

To be an effective regulatory system the compliance with laws and Codes of Practice must be monitored. In the current system there are two main concerns. One is a matter of effectiveness; the second is a matter of conflict of interest.

a. Monitoring by State Authorities

In principal New Zealand Medicines and Medical Devices Safety Authority (hereinafter “Medsafe”) as a business unit of the Ministry of Health, administers the Medicines Act

⁴⁰ Advertising Standards Authority *Advertising Code of Practice* (2014) at 41 <www.asa.co.nz>.

⁴¹ Medicines New Zealand *Code of Practice* (August 2014) <www.medicinenz.co.nz>.

⁴² Requirement 3.

⁴³ Requirement 5.

⁴⁴ At 3.2.5.

⁴⁵ At 3.3.1.

and the Medicines Regulations.⁴⁶ The Commerce Commission monitors the compliance with the Fair Trading Act 1986.⁴⁷

Both institutions, Medsafe and the Commerce Commission can start any investigation of advertising themselves. They can also take a complaint by an individual as a reason to initiate investigation.⁴⁸ A breach of the Medicines Act or the Medicines Regulations is an offence and can result in a fine up of \$500. Where there is a breach of the Medicines Act there is also the possibility of a conviction to imprisonment not exceeding 3 months.⁴⁹ A breach of ss 13 or 10 (but not s 9) of the Fair Trading Act can lead to a fine of up to \$ 600,000 for the pharmaceutical company.⁵⁰

The monitoring by Medsafe and the Commerce Commission is in several ways ineffective.

First, the monitoring only takes place after the publication or release of an advertisement. Although the Fair Trading Act provides the possibility that the Court can order the company to publish a correction of the advertisement,⁵¹ the possible negative effects of DTCA may have already been caused.⁵² Often such corrections do not reach the targeted consumers in the same way as the previous advertisement did.

Furthermore it is questionable whether the maximum level for penalty constitutes a real disincentive for pharmaceutical companies. In particular, the level provided for by the Medicines Act 1981 seems to be relatively low and should at least be adapted to the level provided in the Fair Trading Act. The revenue of pharmaceutical companies is in the double digit million range. The penalty after a successful run of a campaign could be calculated into business costs.⁵³

Additionally one has to consider that Medsafe as well as the Commerce Commission have only limited human resources. They will only be able to review DTCA on a random

⁴⁶ "About Medsafe" Medsafe <www.medsafe.govt.nz>.

⁴⁷ "The legislation: A brief summary of legislation the Commerce Commission enforces" Commerce Commission New Zealand <www.comcom.govt.nz>.

⁴⁸ see Medicines Act 1981, pt 5 and Fair Trading Act 1986, pt 5 for enforcement rules; Both institutions provide information about the complaints process on their websites.

⁴⁹ Medicines Act, s 78; Medicines Regulations, s 64(2).

⁵⁰ Fair Trading Act, s 40(1) (b).

⁵¹ Section 42(1)(b).

⁵² Les Toop and Dee Mangin "Industry funded patient information and the slippery slope to New Zealand" (2007) 335 BMJ 694 at 694.

⁵³ Top and Richards, above n 27, at 3.

basis. It is likely that investigations concentrate on cases where the misleading character of the advertisement is more or less obvious. Hence, many misleading advertisements remain undiscovered.

Regarding the Commerce Commission, an additional point is that the Commission have even less incentive to spend a lot of time on DTCA because the Commission takes into consideration that Medsafe is the more appropriate institution to deal with this special kind of advertising. For example, investigators of Medsafe certainly have more medical knowledge than general investigators of the Commerce Commission.

The aim of the complaint system is to call attention to a greater number of possibly misleading DTCA. However, only two groups exist that can lodge a complaint. Consumers are one group. They are unlikely to complain because they do not have the competence to scrutinise the advertisement.

The other group are rival pharmaceutical companies. They may have the necessary competence, but any rival company will have in mind that a successful complaint will limit its own possibilities to advertise.

One may argue that no monitoring system can reach a hundred per cent safety. However, while misleading the public about normal consumer goods may result in unwanted purchasing decisions, in relation to prescription drugs this might ultimately affect consumers' health.

Ultimately, the fact that penalties are rarely issued suggests that responsible state authorities largely rely on the self-regulatory monitoring-system by the industry.⁵⁴

b. Monitoring by self-regulatory bodies

A drawback of the self-regulatory monitoring system is a potential conflict of interest. The system is based on a mixture of complaint-based monitoring and pre-vetting of advertisements.

ASA has implemented the separated Advertising Standards Complaints Board (ASCB);⁵⁵ MNZ provides a Code of Practice Standing Committee (COPSC).⁵⁶ The above-mentioned general disadvantages of a complaint-based monitoring apply here in the same way. Additionally unlike Medsafe the ASCB is not able to impose any penalty on

⁵⁴ Toop and Mangin, above n 52, at 694.

⁵⁵ Advertising Standards Authority, above n 40, at 9.

⁵⁶ Medicines New Zealand, above n 41, at 10.

advertisers.⁵⁷ Concerning COPSC the incentive to lodge a complaint is further weakened by the fact that a complaint costs \$ 7,500 (for non-members of MNZ).⁵⁸ Even if the rules provide for the possibility to request a waiver, members of the public are reluctant to start the process.⁵⁹

Due to concerns about the efficiency of the complaint-based system, since 2000 an additional mandatory therapeutic advertising pre-vetting system (TAPS) exists. The Association for New Zealand Advertisers (ANZA) administrates this system.⁶⁰

The media will refuse the publication unless the advertisement has a TAPS approval number.⁶¹

To understand the concern about a possible conflict of interest, one may look at the composition of the ASCB and the TAPS examiners. As a starting point one has to bear in mind that members of ASA and ANZA are the advertising industry itself. Although half of the members of ASCB are public members with no connection to the industry, they are mostly selected after recommendation by ASA members.⁶² There is no information on how the adjudicators of TAPS are selected, but as ANZA is the “representative of the major therapeutic advertisers in New Zealand” it is not unlikely that adjudicators will interpret the vague terms in an industry-friendly way.⁶³ Additionally ANZA creates the possibility to register a delegated authority, which means that a person within the advertising company itself to approve the company’s own advertisements. This possibility is restricted, but here the conflict of interest is most obvious and causes most concern.⁶⁴

B Stricter Regulation - General Problems with Effective Regulation

To eliminate the structural problems in New Zealand’s current system one option is to shift completely to a state-regulation system. Although it would be desirable to have a strict pre-vetting by a state authority of all advertisements before they are published or broadcasted, this option is unlikely to be implemented in practice due to the immense state expenses it would require.

⁵⁷ Hoek, Gendall and Calfee, above n 11, at 208.

⁵⁸ Medicines New Zealand, above n 41, at 10.2.4.

⁵⁹ At 10.2.6.

⁶⁰ See Therapeutical advertising prevetting system <www.anza.co.nz>.

⁶¹ Hoek, Gendall and Calfee, above n 11, at 205.

⁶² Advertising Standards Authority *First schedule: Rules of the Advertising Standards Complaints Board* (February 2015) at 3.5.

⁶³ Association of New Zealand Advertisers “TAPS Pre-Vetting System” (2014) <www.anza.co.nz> at r 3.1.

⁶⁴ Ministry of Health, above n 3, at 14.

A more reasonable option is an active enforcement of the law by Medsafe after the publication of DTCA, combined with the implementation of more precise guidelines for DTCA.

A look towards the United States of America with the Federal Drug Authority as the central state monitoring authority for DTCA suggests that the implementation of more detailed rules will play a decisive role for an effective regulation, because the shift to state monitoring itself is not sufficient. The experience in the US shows that even without pre-vetting personal resources are not enough to guarantee time-effective monitoring.⁶⁵ Toop and Mangin raise similar concerns in their recent article suggesting that “it would be impractical in a country the size of New Zealand to centrally vet all advertising claims”.⁶⁶

Therefore, the purpose of the rules should be to enhance the quality of information for the consumer and provide the industry with exact rules in order to minimize any “grey zones”. These rules would exist in addition to the general prohibition of misleading advertising in the current regulation and would concern the content itself and its actual presentation in advertisements. TAPS could be retained as an additional cost-effective checkpoint, but would become more reliable, because the examination would no longer only depend on mostly vague terms. In the end the industry would also benefit from increased legal certainty.

The idea of precise rules is attractive, but to put the idea into practice comes with challenges.

To enhance the quality of information and minimise the risk of misleading advertising, several scholars propose that advertisements should provide more quantitative data to support claimed benefits of the drug instead of “emotional driven portrayals”. This would contain evidence from clinical trials (including placebo studies) about absolute risk reduction, a comparison to the success of a life style change without medical treatment and information about available (cheaper) generic alternatives.⁶⁷ The educational value of the information certainly would be improved.

But how practical is this approach? First, companies would still have the possibility to pick the “best cherries” out of clinical trials and to mention only the favourable results.

⁶⁵ Jaqueline West “National Marketing gone unintentionally global: Direct-to-consumer advertising of pharmaceutical products and the Internet” (2012) 11 J Int Bus & L 405 at 413; Ventola, above n 1, at 671.

⁶⁶ Les Toop and Dee Mangin “The art and science of marketing medications” (2015) 128(1421) 1 at 11.

⁶⁷ Frosch and others, above n 17, at 29.

Furthermore, one may not forget that DTCA is advertising and the promotion of cheaper and as effective rival products is at odds with the primarily goal of advertising. Imagine for example an advertisement for Viagra. The advertiser includes (as may be required) possible other treatment options as a vacuum constriction device or medication patches or gels. However the company does this in a way, that these other options are received as more invasive or less effective. This can happen by the simple wording or by combining the statement about the Viagra pill with a smiling man on the TV screen while the other options are mentioned in a box at the bottom of the screen. This example shows that it is difficult to establish a concrete dividing line between permissible promotional nature and misleading promotion.

The threshold for DTCA to be misleading is likely to be relatively low. One may not forget that the particular nature of the products plays a decisive role. Prescription medicine is not comparable to any other consumer good. Consumers do not have the knowledge to question claims. In this regard it should be noted that even in advertisements which targeted health care professionals, a recent study showed the following: In only eight per cent of the evaluated advertisements the advertised claims were supported by clinical trials with a low risk of bias and in 19% the cited published paper did not support the cited claim.⁶⁸ Additionally it can be noted, that in the cases examined by the study, TAPS did not prevent the advertisements from being published. Health professionals may in some cases detect these shortcomings; consumers will not be able to do so.

Lastly there remains the question whether pharmaceutical companies are the right entities to empower consumer rights in this particular field. Pharmaceutical companies will always try to test the boundaries and find potential loopholes in regulations in order to increase their market share.⁶⁹ All in all it can be concluded that the proposals from different commentators constitute a good basis for improvement. A prerequisite to this, however, is that pharmaceutical companies fully comply with proposed changes. In practice this view is a very optimistic one. In his essay Wellington gets right to the point saying by that “the “ifs” relating to quality assurance are very substantial ifs, and we seem to be rather a long way from those concerns being adequately addressed”.⁷⁰

⁶⁸ Alison Ma and Lianne Parkin “Randomised controlled trials cited in pharmaceutical advertisements targeting New Zealand health professionals: do they support the advertising claims and what is the risk of bias?” (2015) 128 (1421) NZMJ 22 at 22.

⁶⁹ Ministry of Health, above n 3, at 17.

⁷⁰ Wellington, above n 10, at 759.

C Ban on DTCA

The above-mentioned findings lead to a third possibility for regulating DTCA: A complete ban of this form of advertising. This option is the most radical one, but on the other hand obviously the most effective to impede any negative effects on DTCA on public health and the doctor-patient relationship.

The effectiveness goes hand in hand with the fact that a complete ban constitutes the biggest interference with the pharmaceutical companies' right of freedom of commercial speech.

Section 14 of the Bill of Rights Act 1990 guarantees that everyone has the right to freedom of expression. Regarding businesses nowadays it is undisputed that freedom of expression includes also commercial expression by companies, for example via advertising.⁷¹ However rights guaranteed in the Bill of Rights Act 1990 are not absolute. In fact the existence of s 5 of the Bill of Rights Act 1990 demonstrates that rights may be subject to reasonable limits if the limitation can be demonstrably justified in a free and democratic society.

Hence, it has to be examined whether a complete ban of DTCA can be considered as a reasonable limit that can be demonstrably justified. Tipping J described the New Zealand approach in the leading decision *Hansen v R*, taking the *Oakes* test developed in Canadian case law as a basis.⁷²

The first question is, if the limiting measure serves a purpose sufficiently important to justify impairment of the right or freedom.

This question can be answered in the affirmative. The example of provisions for tobacco packaging shows that in general the protection of public health is considered to be a sufficiently important purpose to justify the limitation of freedom of expression.⁷³

Secondly, the limiting measure must be rationally connected with its purpose.

This means that on an abstract level a ban must be able to assist the purpose. A ban of DTCA in New Zealand would logically minimise the risk of unnecessary prescribing because consumers are no longer exposed to DTCA. Some argue that a ban of DTCA is ineffective because consumers continue to be exposed to DTCA on the Internet due to the fact that national laws are difficult to enforce in the online environment. To this regard it can be stated, that the requirement of rational connection does not require a hundred per

⁷¹ Andrew Butler and Petra Butler *The New Zealand Bill of Rights Act: A Commentary* (2nd ed, LexisNexis Wellington, 2015) at 539.

⁷² *R v Oakes* [1986] 1 SCR 103 (SCC); *Hansen v R* [2007] NZSC 7, [2007] 3 NZLR 1 at [104].

⁷³ Andrew Butler and Petra Butler, above n 71, at 539.

cent effectiveness. Often laws may not be able to solve problems completely. That is why the term “minimise” is used above. Online advertising is only one kind of DTCA. The absolute amount of DTCA will be reduced and consequently the number of targeted consumers.

The third question is, if the impairment of freedom of expression is not greater than reasonably necessary for the sufficient achievement of its purpose. In other words it must be examined if milder measures exist that would achieve the purpose as effectively. The requirement that alternatives must be as effective is important, because this limitation recognizes that the legislator has a zone of discretion within different possibilities. A milder measure would be stricter regulation of DTCA, but this approach is not as effective as a ban of DTCA.

The question if the ban can be justified compared to a milder but less effective measure of stricter regulation has to be answered by applying the last requirement. A justified limitation of the right requires that the limit is in due proportion to the importance of the objective. This means that the more severe the harmful effects of a measure, the more important must be the objective.⁷⁴

The objective of a complete ban is the protection of public health.

This aim is to be considered of high importance especially in the field of prescription drugs. The decision to restrict the access to prescription drugs shows that the legislator saw a great danger for public health and a need to intervene and to limit patient autonomy in this regard. Whereas with other goods, even harmful substances such as tobacco, consumers can evaluate the risks and make informed decisions, this is different with prescription drugs. This is why the legislator implemented the obligation of a medical prescription. Considering the vulnerable situation of ill consumers and severe unforeseen side effects of prescription drugs, consumers should not be able to medicate themselves with this kind of drugs. I would like to stress that DTCA has its impact exactly at the implemented gatekeeper function of the doctor.

Additionally even if the potential dangers of inappropriate prescribing are realized only in a few cases of DTCA, these cases may have an impact on a large number of consumers because DTCA is mass advertising.

Lastly, considering the importance of the gatekeeper function, it is not sufficient protection to ban DTCA only from certain communication channels and to allow it on others. Some may argue that consumers perceive information in a different way if they actively seek for it (e.g. claims on a company websites assessed after a google search)

⁷⁴ *R v Oakes* [1986] 1 SCR 103 (SCC) at 140.

compared to the situation where they are exposed to it unpredictably (e.g. on television).⁷⁵ Assuming that this is right, consumer can still be misled. Furthermore such a piecemeal approach to a ban can even have a worse effect. Consumers could wrongly conclude that information on websites must be pre-vetted by an official authority, because they will notice the ban of DTCA on other communication ways.

As regards to the gravity of interference with the freedom of commercial speech, it can be concluded that advertising is an important part of business and commercial companies will be completely barred to use this tool to promote their products if DTCA is banned. Furthermore, a ban of DTCA will deprive consumers from being informed through this source. One reason why commercial expression is protected is that advertising provides information to consumers and is of value for their decision making in the market.⁷⁶ However, in regard to the companies, it can be argued that still have the right to promote their products to health care professionals. Furthermore, when assessing the proportionality it has to be considered that commercial expression mostly serves an economic interest rather than a contribution to public debate in a democratic society.⁷⁷ Regarding the right of the consumers to be informed by DTCA, the assessment in the preceding parts of this essay has shown the little value of this information in the current system.

All in all the importance of the protection of public health in this particular field of medicine justifies the limitation of the freedom of commercial speech. Due to the high risk of such mass advertising an extensive protection and precautionary approach is proportionate.

IV Consumer protection via education

A ban of DTCA is one step in the right direction. However, of the previous parts of this essay it can be concluded that valuable consumer information in the health sector is a fundamental goal.

⁷⁵ Timothy S Hall “The Promise and Peril of Direct-to-Consumer Prescription Drug Promotion on the Internet” (2003) 7 DePaul J Health Care L 1 at 2.

⁷⁶ Caroline Reid “Freedom of Expression, Commercial Expression and Tobacco in Canada” (2008) 39 VUWLR 343 at 352.

⁷⁷ One factor why the freedom of expression is considered as one of the most important and valuable freedoms in democratic societies.

First of all, the possible positive effects of DTCA should be retained. The dissemination of information can improve awareness for health care questions among consumers and ultimately lead to enhanced efficiency of the public health system.

Additionally consumer education can also be considered as an important part of consumer protection.

The Internet has become one of the first sources for consumers who seek information about conditions or possible treatments. Unfortunately the quality of information a consumer can find is currently of little value. Blogs and health-forums often solely stir up fear rather than any objective information. Cyberchondria is the definition for “the unfounded escalation of concerns about common symptomatology, based on the review of search results and literature on the Web”.⁷⁸ And even regarding websites that appear to present information in an objective way, consumers often do not have a possibility to identify how reliable this information is. To counter cyberchondria on one hand, but also to provide patients with the necessary information for an informed choice regarding health care decisions on the other, the government should continue efforts to increase the quality of information and provide reliable information, which consumers can recognise as such.

A Disease Awareness Advertising

Because the ban of DTCA only affects product related drug advertising, many countries where DTCA is correctly banned allow another form of advertising, disease awareness advertising (DAA). DAA must not name any product or brand, but can contain information about a certain disease or condition and its treatment. DAA can be sponsored by the pharmaceutical companies themselves, independent disease-support groups or the government.

An advantage of DAA is that this kind of advertising could retain the potentially positive effects of DTCA. DAA can heighten consumers’ awareness for conditions, encourage those who are potentially at risk to see their doctor and in this way combat underdiagnosis of conditions.

If pharmaceutical companies sponsor this kind of advertising it is likely that the concerns about disease mongering and a medicalisation of our society remain (see above II C).

⁷⁸ Ryen W White and Eric Horvitz “Cyberchondria: Studies of the Escalation of Medical Concerns in Web Search” (2009) 27 (4) ACM Transactions of Information System 23 at 1.

Nobody can dispute that pharmaceutical companies will concentrate their budget on DAA on the diseases they have invented new treatments for.

A look towards Australia, where DAA is often industry sponsored, reveals further reservations:

One issue is that the commercial character of DAA is often veiled. One cited case is the large donation of Pfizer (a leading pharmaceutical company for arthritis drugs) to the Arthritis Foundation, an independent disease group, which shortly afterwards ran a community service announcement encouraging arthritis patients to ask for a new treatment.⁷⁹

Another concern is that companies circumvent the prohibition of DTCA via DAA. In Australia companies became creative to invent methods to communicate the identity of the product by other means. One example is the Pfizer tiger used in DAA for erectile dysfunction for representing Pfizer's product Viagra.⁸⁰

State funded DAA has the advantage that the decision which disease the advertisement will cover does not depend on sales targets. Often state funded DAA will consider those diseases where studies show a tremendous strain for the public health care system, may it be in long term or short term.

In the last public consideration of DTCA in New Zealand a high per cent of the submissions opted for a ban of DAA undertaken by pharmaceutical companies additionally to a ban of DTCA.⁸¹ If a ban of DAA could be justified is not easy to answer, especially because the promotion of a particular product in DTCA is a key factor for the inappropriate prescription behaviour.

A milder measure could be that Medsafe strictly monitors the claims made by DAA, for example concerning the prevalence of a condition, and that Medsafe could try to counteract any lack of balance regarding the coverage of different diseases by state funded DAA.

Additionally measure should be implemented to impede that companies use their influence on disease support groups to obscure the commercial interest of DAA. One

⁷⁹ Danika Valerie Hall, Sandra Carol Jones and Janet Hoeck "Direct to consumer advertising versus disease awareness advertising: consumer perspectives from down under" (2011) 11(1) *Journal of Public Affairs* 60 at 61.

⁸⁰ At 61.

⁸¹ Ministry of Health, above n 3, at 36.

proposal is to implement so called blind-trusts where donations can only be made anonymously to ensure that consumer groups retain their independency.⁸²

B Healthcare Information on the Internet

Ultimately in regard to consumer information on the Internet, it was mentioned that the primary goal is to enhance the quality of information and to promote the accessibility to trustful sources of information.

At the moment the official website of Medsafe provides approved medical data sheets for prescription drugs. Data sheets must be submitted as a part of mandatory documents in the approval process for prescription medicine.⁸³ Hence, data sheets have the advantage that they are pre-vetted documents, but they are prepared for health care professionals, not consumers. Because of this, Medsafe also provides Consumer Medicine Info (CMI). Those documents are supposed to be a consumer friendly summary based on the content of data sheets.⁸⁴ In contrary to data sheets CMI sheets are not officially approved, but written by the pharmaceutical companies on a voluntary basis and afterwards published on the Medsafe website with the company's permission.

Medsafe informs consumers about the fact that CMI sheets are not pre-vetted, but nevertheless it is likely that for consumers the mere publication of an official website implicates that there is some sort of official evaluation. Because both documents concern the same content, it should not cause significant extra work for Medsafe to evaluate the CMIs. CMI could be a mandatory requirement equally submitted to Medsafe as part of the approval process.

This amendment would be not only useful to enhance reliability but also necessary to draw a clear dividing line between the prohibition of DTCA and the dissemination of information by pharmaceutical companies.

A comparison with the provisions in the European Union can provide guidance:⁸⁵ Companies should still be able to provide officially approved documents such as data

⁸² FJ Mackenzie and others "Direct-to-consumer advertising under the radar: The need for realistic drugs policy in Australia" (2007) 37 *Internal Medicine Journal* 224 at 227.

⁸³ *Medicines Regulations*, s 52.

⁸⁴ New Zealand Medicines and Medical Devices Safety Authority *Guideline on the Regulation of Therapeutic Products in New Zealand: Part 10: Requirements for information for prescribers and consumers* (Edition 6.0, June 2013) at 3.4.

⁸⁵ see Directive 2001/83/EG on the Community code relating to medical products for human use [2001] OJ L 311/67 at art 86 (2).

sheet on their websites. Furthermore they should be allowed to publish informative announcements such as adverse reaction warnings or pack changes and to answer concrete individual questions of consumers.

A further improvement of the current system could be to implement a separate website to Medsafe to deal solely with consumer information. This website would be administered by the Ministry of Health and contain all information currently available on the official website of Medsafe. However, additionally the Ministry could provide links to other independent sources as for example disease support foundations. In this way existing sources could be combined and consumers would have an easier access. Additionally, the Ministry could actively promote the existence of such a portal . This may include public campaigns and cooperation with health care professionals.

V Conclusion

This paper has shown that DTCA may have benefits, but is considered as a potential hazard for the doctor-patient relationship and public health due to unnecessary prescribing. Because prescription medicine can have serious unexpected side-effects the gatekeeper function is of particular importance. An effective regulation of DTCA remains difficult even if New Zealand tightens up the current regulatory scheme. Concerning the possible risk of misleading DTCA, the legislator should opt for a complete ban of DTCA. This does not mean stepping back to a “doctor-knows-best” culture. Patients’ participation in their healthcare management is desirable and should be promoted. Therefore government should actively work towards a better quality and easy access to healthcare information especially on the Internet.

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