



Ministry of Health
PO Box 5013
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16 April 2019

**Submission to The Ministry of Health:
Therapeutic Products Bill**

1. The New Zealand College of Public Health Medicine would like to thank the Ministry of Health for the opportunity to make a submission on the draft Therapeutic Products Bill.ⁱ
2. The New Zealand College of Public Health Medicine (the College) is the professional body representing the medical specialty of public health medicine in New Zealand. We have 222 members, all of whom are medical doctors, including 185 fully qualified Public Health Medicine Specialists with the majority of the remainder being registrars training in the specialty of public health medicine.
3. Public Health Medicine is the branch of medicine concerned with the assessment of population health and health care needs, the development of policy and strategy, health promotion, the control and prevention of disease, and the organisation of services. The NZCPHM partners to achieve health gain and equity for our population, reducing inequalities across socioeconomic and cultural groups, and promoting environments in which everyone can be healthy.
4. This submission will only be addressing Section Eighty-Three of the draft Therapeutics Bill, which is concerned with Direct to Consumer Advertising (DTCA).

Background

5. DTCA refers to the promotion or advertisement of prescription medicines directly to patients, through mediums such as television, radio broadcast, social media billboards and consumer magazines.¹ DTCA is used by pharmaceutical companies to announce new products, communicate products claims and messages which exaggerate benefits and minimise risks.² DTCA is thus a marketing tool for increasing both consumer demand for pharmaceutical and the commercial success of pharmaceutical companies.
6. DTCA is a core marketing strategy used by the pharmaceutical industry. Globally spending on DTCA increased 330% between 1996 and 2005, to about US \$30 billion.³ However, only a few countries allow DTCA, including New Zealand and the United States of America (USA),

ⁱ <https://www.health.govt.nz/system/files/documents/publications/therapeutics-products-bill.pdf>

amongst developed countries. Spending on DTCA in both countries has increased significantly, from US \$12 million in the 1990's to US \$4.1 billion in 2006.²

7. DTCA has been stated to be highly effective in creating new markets in both NZ and the USA, increasing brand awareness and increasing sales of high cost medicines.⁴ Evidence suggests it leads to inappropriate prescribing, risk to the doctor-patient relationship, over-treatment and over-medicalisation of normal processes, increased costs and harm from medical misadventure.⁵

Position

8. The College opposes the inclusion of Section Eighty-Three in the Draft Therapeutic Products Bill. We are opposed to the continuation of DTCA in NZ for reasons given below.
9. The College considers the new Therapeutic Products Bill presents an opportunity for New Zealand to fall in line with other developed countries in banning DTCA.⁶ Therefore, the College supports the government in reviewing its stance on DTCA and removing Section Eighty-Three of the Bill.

Specific issues (Reasons to oppose DTCA):

DTCA does not provide objective and reliable information

10. The commercial goal behind DTCA focuses on creating demand for specific products. This makes it an inappropriate means of dissemination of information to patients.^{5,7} While DTCA is not a public service, there is concern that many consumers consider DTCA to be a reliable source of health information. In actuality, messages tend to be biased, incomplete and emotive whilst understating risks and overstating benefits. Advertising often exaggerates the efficacy of products.⁷ One study found only thirteen percent of pharmaceutical advertisements provide evidence to support their claims for efficacy.⁸
11. Arguments about patient empowerment are often cited by supporters of DTCA.⁵ They claim that advertisements increase consumer awareness of medical conditions and treatments, encourage patients to discuss treatment options with their general practitioner and facilitate patient choice.^{4,7}
12. In reality, DTCA manages and influences information in a manner that can be described as manipulative, often using the guise of information gaps as an excuse to provide deliberate misinformation to consumers. Such manipulative advertisements allow consumers to believe they arrived at their choice through a non-persuasive and rational thought process, hence undermining patient autonomy.² In these cases, DTCA conflicts with the right of patients to easily access high-quality, transparent pharmaceutical information as per the *NZ Code of Health and Disability Service's Consumer's Rights*.⁴
13. DTCA messages also have the potential to widen health inequalities by targeting more susceptible consumers. These include those with lower socioeconomic status, poorer health status, and ethnic minorities, all who may be more susceptible to deceptive messages within

DTCA and may not be able to make objectively informed decisions.⁹ Consideration of health equity should as a matter of priority be reflected in all New Zealand's health policies.¹⁰

DTCA threatens the Doctor-Patient Relationship

14. Evidence indicates that consumers are more likely to believe they need medication, to request medication from their physicians and receive prescriptions for those products advertised on television.⁵ In New Zealand General Practitioners (GPs) act as gate-keepers to further care. They facilitate the decision-making process by which patients evaluate several treatment options and select the best option for them. As gate-keepers, GPs have an ethical duty to prescribe only necessary and appropriate medicines.⁷
15. However, DTCA may challenge sensible prescribing as it has been shown to place additional commercial pressure on prescribers.⁷ DTCA encourages consumers to request advertised products, leading the consultation to become dominated by discussion of one advertised product rather than a balanced assessment of all treatment options.^{5,7} Patients may even manipulate the information they provide to their doctor in order to fit a profile as seen on a DTC advertisement, in order to be prescribed a drug not suitable for them.¹¹ This leads to sub-optimal prescribing conditions and inappropriate prescribing. One study reported that patients made inappropriate prescription requests during about forty percent of doctor's visits and were successful in about half of their attempts.¹²
16. As such, DTCA can challenge the doctor-patient relationship. Advertisements can reduce a patient's trust and confidence in their physician.⁴ It may also place pressure or increase frustration and lengthen the duration of consultations when physicians have their clinical authority challenged by evidence from DTCA.¹

DTCA may pose risks to Patient Safety and Cause Harm

17. Rational prescribing suggests not replacing older medicines which have established efficacy and safety profile unless there is evidence to do so, and to exercise caution when recommending new medicines.⁴ DTCA tends to focus on new medicines, whose safety profiles have not been fully studied and often have rare but serious unknown side-effects or those which may be being used for off-label prescribing.⁴ This is particularly true for medicines that are anticipated to be big sellers and are heavily advertised early in their life cycle, before the long-term effects can be fully known.¹ Thus DTCA challenges the principle of rational prescribing, as it seeks to promote newer medicines over already established ones, which poses risks to patients.⁷
18. There are several examples of heavily advertised medicines gaining popularity over established medicines, only to be withdrawn once their safety profile was revealed. For example, Merck spent over \$100 million annually to promote Vioxx (used to treat arthritis pain) into a blockbuster drug, from 1999 to 2004.¹³ Despite making annual sales of \$1 billion, the drug was voluntarily withdrawn from the market after it was discovered to increase the risk of myocardial infarction in patients.¹³

19. DTCA is also more likely to exaggerate the range of consumers who would benefit from a product. Promoting the use of products in groups who have little to gain may increase the risk of harms as well as costs to the consumer.⁷

DTCA Promotes Over Medicalisation

20. DTCA tends to promote the medicalisation of normal bodily and ageing processes. Marketing of medicines with no other health benefit than to counter 'lifestyle' conditions such as weight gain (as opposed to standard dietary and exercise changes), male pattern hair loss and normal mood swings, is common practice.⁷ The pharmaceutical industry openly employs a marketing strategy of manufacturing diseases or medicalising clinically inconsequential ailments and cosmetic concerns. Common examples include erectile dysfunction medicine advertisements directed at men who may be experiencing normal variations in sexual performance, and advertisements that aim to reconceive menopause from a normal midlife experience incorrectly into a pathologic clinically consequential hormone-deficiency disease.¹¹

DTCA has Significant Financial Implications for Consumers and the Health System

21. DTCA is frequently used to promote newer more expensive drugs that have little or no evidence of additional health benefits to their generic alternatives. This places additional fiscal pressures on consumers, not only from cost of medicines but also additional doctor's visits to the GP.⁷ It may also exacerbate financial and health inequalities amongst vulnerable consumers. Cost information is also rarely revealed in DTCA.¹
22. DTCA also poses fiscal pressures for the health system. Since DTCA increases demand for certain medicines, advertised medicines that are subsidised may put pressure on the pharmaceutical budget. Advertised medicines which are not subsidised may garner public pressure on PHARMAC to subsidise them. Since these are newer, and more costly there will be significant unnecessary costs associated with them.⁷ PHARMAC, NZ's medicines etc. funder, has been successful in keeping pharmaceutical costs down through negotiations and sourcing of generics, *inter alia*. However, DTCA may challenge negotiations on medicine pricing as pharmaceutical companies raise medicine prices to offset advertising costs.
23. Unnecessary prescriptions lead to known increased costs to the taxpayer, particularly through driving demand for costly branded medicines over less expensive yet effective alternatives.^{14,15} Furthermore, as DTCA increases demand for certain medicines, and these medicines are subsidised, resources will be reallocated from other issues that need attention. This may mean a reduction in the capacity for subsidising other medicine and vulnerable members of the public may miss out on treatment,⁷ i.e. consequent opportunity costs (being the population health benefits forgone by not being able to spend those limited monies for better medicines or health services, by instead spending comparatively needlessly).
24. In addition, the promotion of unnecessary medication use misaligns with the pan-professional Choosing Wisely initiative, which encourages the mindful use of medical

intervention only when appropriate and clinically valuable.¹⁶ Without the influence of DTCA, clinicians and patients can better engage in balanced and informed discussions about treatment options, which advances quality of care for all. The College also recognises this improved quality of care as a means of advancing health equity and responsible resource-allocation, as per the NZCPHM's Choosing Wisely recommendations and explanatory statements.¹⁷

DTCA is incoherent with the NZ Antimicrobial Resistance Action Plan

25. As per the NZCPHM's policy statement on antimicrobial resistance, the College recognises AMR as a significant health threat and considers DTCA will only diminish efforts to reduce inappropriate use of antimicrobials.¹⁸ The NZ Antimicrobial Resistance Action Plan includes strengthening consumer awareness on the issue (priority action area one) as well as reviewing controls, labelling and advertising of antimicrobials including DTCA (priority action area15).¹⁹ To the extent that DTCA promotes the use of antimicrobials, DTCA contradicts the NZ Antimicrobial Resistance Action Plan, and this represents policy incoherence.⁶

The Remediation Order is insufficient to regulate DTCA

26. NZCPHM considers the penalties listed in Section 166, the Remediation Order, would be insufficient to regulate DTCA. In the United States, the FDA has been unable to confirm that it receives all disseminated advertisements for assessment or that it has been able to prevent repetitive breaches to advertising regulations. In some instances deceptive advertisements may complete their broadcast life-cycle before the FDA can issue a letter requesting their removal.⁴ This illustrates the limitation of lack of timeliness in the process of regulating advertisements. Furthermore, the college considers reprimanding any offending pharmaceutical companies as per the *Penalties for Offences* in Section 233 (maximum fine of New Zealand \$500,000) would do little to impede them as global expenditure on advertising is in the multi-billions. Therefore, the College considers the *Remediation Order* is insufficient to reprimand pharmaceutical companies, mitigate any harms that may befall consumers and to regulate DTCA.

Thank you for the opportunity for the NZCPHM to submit on The Therapeutic Products Bill. We hope our feedback is helpful and please contact the NZCPHM if we can be of further assistance.

Yours sincerely,



Dr Felicity Dumble, President, NZCPHM

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