Te Kaunihera o Ngā Kāreti Rata o Aotearoa
COUNCIL OF MEDICAL COLLEGES
NEW ZEALAND

PO Box 58
NZ Post House
Wellington 6011

enquiries@cmc.org.nz
www.cmc.org.nz

5 March 2023

Tangi Utikere
Chair, Health Committee
Parliament Buildings
Wellington

By email to: Health@parliament.govt.nz

Tēnā koe Tangi,

Re: Therapeutic Products Bill

Thank you for the opportunity to provide feedback on the Therapeutic Products Bill. The Council of Medical Colleges (CMC) is the collective voice for seventeen medical colleges in Aotearoa New Zealand, and through its members aims to improve, protect and promote public health via a well-trained medical workforce providing high-quality medical care. Our member colleges provide support to over 9000 specialist medical practitioners working in a range of disciplines in the Aotearoa New Zealand health system. All colleges have an interest in decisions that impact the wellbeing of patients, whānau and communities throughout Aotearoa New Zealand – making this Bill of significant interest.

There are many areas that CMC could focus on, however our greatest concern is on the harm caused by Direct to Consumer Advertising (DTCA) of pharmaceutical products in New Zealand, and as such, this is what our submission will focus on.

The CMC strongly recommend the Therapeutic Products Bill expressly prohibit pharmaceutical advertising direct to consumers.

For decades, doctors have been concerned that DTCA presents a biased, overly optimistic picture of advertised medicines and prompts patients to request treatments they do not need. Prescription medications (and indeed many non-prescription substances) can cause considerable harm if used

PO Box 58
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inappropriately – this is why the barrier of a prescription exists in the first place. The stringent regulation of how prescription medications are accessed proves they are not normal commodities, and their advertising should be similarly restricted.[1]

CMC does not support DTCA for ten main reasons. They are:

1. DTCA is prohibited almost everywhere else in the OECD
2. DTCA is inconsistent with efforts to improve New Zealanders health literacy
3. DTCA targets the most vulnerable
4. DTCA leads to increased costs for the health system
5. DTCA leads to inappropriate prescribing and overtreatment
6. DTCA leads to iatrogenic[2] harm
7. DTCA puts the doctor-patient relationship at risk.
8. DTCA regulation options are flawed
9. DTCA does not provide patients with useful information
10. DTCA perpetuates power imbalance in pharmaceutical companies favour

We have included more information on each of these reasons below.

DTCA is prohibited almost everywhere else in the OECD

Over the last few decades, all other counties in the OECD apart from the United States of America have outlawed the promotion of DTCA. There have been repeated attempts to remove DTCA in the US, including in 2015 when the American Medical Association cited concerns that a growing proliferation of advertisements was driving demand for expensive treatments despite the clinical effectiveness of less costly alternatives[3] and called for a ban on DTCA.

The Food and Drug Administration is the regulator of DTCA in the USA. Online DTCA and social media can saturate the market - the FDA in the USA has warned several pharmaceutical companies that their sponsored links on search engines were misbranded because they did not provide statements about adverse effects[4].

[1] Health Practitioners Competence Assurance Act 2003. No 8. Available from: http://www.legislation.govt.nz/act/ public/2003/0048/latest/DLM203312.htm
[2] illness caused by medical examination or treatment
[3] American Medical Association Website (Accessed February 2018) https://www.ama-assn.org/press-center/press-releases/ama-calls-ban-dtc-ads-prescription-drugs-and-medical-devices
[4] *The Role of Direct-to-Consumer Pharmaceutical Advertising in Patient Consumerism,* AMA Journal of Ethics, November 2013, Volume 15, Number 11 http://journalofethics.ama-assn.org/2013/11/pfor1-1311.html

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DTCA is inconsistent with efforts to improve New Zealanders health literacy

DTCA prompts patients to request advertised drugs - this is the purpose of advertising, to increase brand awareness, increase product sales - and is most frequently used to promote new products. Increasingly DTCA is targeted at the most vulnerable populations and those with low health literacy.

In Aotearoa New Zealand, low health literacy is a significant issue[5]. Health literacy has been defined as 'the capacity to obtain, process and understand basic health information and services to make informed and appropriate health decisions'[5]. The determinants of health literacy are multiple and include personal factors such as age, education and language, and system factors such as fragmentation of care and signage. On average, New Zealanders have poor health literacy skills, with both Māori and non-Māori males and females scoring on average less than 275, which is the minimum required score for individuals to meet the complex demands of everyday life and work in the emerging knowledge-based economy.

High literacy demands are created by the way health conditions are explained, managed and resourced. For many, living in an environment that requires a higher level of health literacy than they are equipped with will contribute to premature morbidity and mortality, poorer access to health care, inequity, treatment/medicine safety concerns, informed consent and quality of care issues[6].

Historically, people have been described as having 'low health literacy' – which ignores the role of the health system in creating health literacy demands and how these demands set people up to fail. In 2015, the Ministry of Health developed a Health Literacy framework to *reduce* demands on people and *build* health literacy skills of its workforce, patients and whānau who use its services. Focusing on this microcosm - just the patient and health workforce – but ignoring the reality of operating within a broader environment alongside the poor quality information provided by pharmaceutical companies direct to patients is setting the health system and patients up to fail.

If our aim in Aotearoa is to improve health outcomes, we need to improve health literacy of individuals and reduce the high literacy demands within our health system so that individuals and whānau can obtain, process and understand health materials, make informed decisions, and navigate appropriate, quality and timely health services. This shift requires an environment free from poor quality, persuasive and biased

[5]Ministry of Health. 2010. Kōrero Mārama: Health Literacy and Māori. Wellington: Ministry of Health, February 2010
[6] Health Navigator New Zealand, *Health Literacy.* Retrieved February 2023 from https://www.healthnavigator.org.nz/clinicians/h/health-literacy/

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NZ Post House
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information from pharmaceutical companies. There is no doubt that medications are essential for improved health care but that does not mean that our environment should be controlled by those who manufacture them.

DTCA targets the most vulnerable

The current legislative approach leaves the door wide open for pharmaceutical influencers to micro-target and persuade vulnerable New Zealanders. Research commissioned by New Zealand On Air in 2014 found that television reaches 83 percent of New Zealanders daily and is still the most received form of media[7] Those aged 65+ were found to have higher daily reach than average. Understanding this daily reach is important, as older persons are also more likely to be experiencing a decline in health status, a key indicator of declining health literacy, and are therefore more vulnerable to help-seeking advertisements.

The current legislative settings do not consider the increased channels by which DTCA might reach or influence consumers. The internet has changed the advertising landscape so significantly that it is almost unrecognisable from the one described in the Medicines Act 1981. With the rise of new communications channels – including podcasting, streaming, Instagram, YouTube, Facebook, Snapchat, TikTok etc – social media influencers are becoming an increasingly popular strategic communication tactic used by pharmaceutical companies to build relationships directly with patients or prospective patients[8]. Some of the more attractive social media influencers for pharmaceutical brands are micro- or nano-influencers: those with a small number of followers with high engagement rates and strong psychosocial relationships with very specific audiences who have been primed for health messaging[9]. This DTCA is widespread, it reaches the public effectively, and it reaches specific health-seekers with low health literacy with increasing accuracy[10].

It is for this reason that DTCA is not the same as pharmaceutical advertising to clinicians. Specialist clinicians have many years of rigorous medical training and ongoing education that provides a knowledge base against which to compare claims made by pharmaceutical companies. They can assess the appropriateness of advertised therapeutic products from a clinical perspective and withstand the more persuasive tactics used to target direct consumers. This is not true for patients or prospective patients:

[7] Brunton C. *Where are the audiences? Benchmark survey of New Zealanders' media consumption.* Colmar Brunton/NZ On Air; 2014. Available from: https://www.nzonair.govt.nz/research/where-are-audiences/
[8] Willis E, Delbaere M *Patient Influencers: The Next Frontier in Direct-to-Consumer Pharmaceutical Marketing.* J Med Internet Res 2022;24(3):e29422 URL: https://www.jmir.org/2022/3/e29422 DOI: 10.2196/29422
[9] Zuppello S. *The latest Instagram influencer frontier? Medical promotions.* Vox. 2019. URL: https://www.vox.com/the-goods/2019/2/15/18211007/medical-sponcon-instagram-influencer-pharmaceutical [accessed 2021-07-29]
[10] J Med Internet Res. 2022 Mar; 24(3): e29422.Published online 2022 Mar 1. doi: 10.2196/29422 PMCID: PMC8924782
PMID: 35230241 Patient Influencers: The Next Frontier in Direct-to-Consumer Pharmaceutical Marketing Monitoring Editor: Amaryllis Mavragani Reviewed by Mohammad Amin Bahrami and Emil Chiauzzi Erin Willis, PhD, MPH#1 and Marjorie Delbaere, PhD#2

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their expertise is often limited to their lived experience, their use of 'Doctor Google', and they do not have the same rigorous framework to analyse claims[11].

DTCA leads to increased costs for the health system

DTCA can lead to increased costs to patients because branded medications often cost significantly more than generic medications or non-drug therapy[12]. Therapeutic products directly advertised to consumers are usually new, branded medicines that carry a premium price tag; and for this reason, DTCA has also been linked to increases in pharmaceutical expenditure[13]. The resulting demand from patients for branded medications ultimately imposes a disproportionate cost on the health-care sector – more often than not the prescribing doctor is unaware the cost of.

In 2011, GSK phased out the asthma inhaler Becotide and replaced it with the more expensive but generally equivalent Flixotide. GSK developed a million-dollar promotional campaign targeted at consumers that generated sales of $3 million[14] demonstrating how DTCA can increase pharmaceutical costs.

DTCA leads to inappropriate prescribing and overtreatment

DCTA can lead to inappropriate prescribing as doctors may feel pressured by patients to prescribe certain medications to the detriment of tried-and-true drug options or other non-drug modalities such as lifestyle modifications[12][15]. There is considerable evidence that patients' requests for a specific product can be a key cause of unnecessary prescribing (i.e., medicinal wastage) with little benefit and often higher cost to the patient and health system[16].

Studies conducted in the United States found that consumers exposed to DTCA were more likely to believe that they needed medication, to request products advertised on television, and to receive prescriptions for these products[17]. There are also examples where significant harm has arisen from under-reporting of safety risks. For example, in 2012, Glaxo Smith Kline promoted the safe use of an antidepressant in a paediatric setting despite established concerns about the risk profile in this population[18]. DTCA also

[11] Friestad M, Wright P. The Persuasion Knowledge Model: How People Cope with Persuasion Attempts. Journal of Consumer Research 1994 Jun;21(1):1-31 [FREE Full text] [CrossRef]

[12] Every-Palmer, Susanna et al, Direct to consumer advertising of prescription medication in New Zealand, New Zealand Medical Journal, Volume 127, No 1401: August 2014

[13] Gellad ZF, Lyles KW. *Direct-to-consumer advertising of pharmaceuticals.* Am J Med. 2007 Jun;120(6):475-80. doi: 10.1016/j.amjmed.2006.09.030. PMID: 17524744; PMCID: PMC3967783.

[14] [14] Toop L, Richards D, Dowell T, Tilyard M, Fraser T, Arroll B. *Direct to consumer advertising of prescription drugs in New Zealand: for health or for profit?* Report to the Minister of Health supporting the case for a ban on DTCA. Dunedin, 2003. Available from: https://www.otago.ac.nz/christchurch/otago628243.pdf

[15] Bond B 2013. The pharmaceutical industry and the profession. Chapter 26 in St Georg IM (ed.). Cole's medical practice in New Zealand, 12th edition. Medical Council of New Zealand. Wellington.

[16] Ashworth M, White P, Jongsma H. *Antibiotic Prescribing and patient satisfaction in primary care in England*. British Journal of General Practice, 2015. Available at: http://bjgp.org/content/early/2015/12/04/bjgp15X688105.full.pdf+html

[17] Gilbody S, Wilson P, Watt I. *Benefits and harms of direct to consumer advertising: a systematic review* (2005) Quality and Safety Health Care 14: 246-50.

[18] Keller MB, Ryan ND, Strober M, Klein RG, Kutcher SP, Birmaher B, Hagino OR, Koplewicz H, Carlson GA, Clarke GN, Emslie GJ, Feinberg D, Geller B, Kusumakar V, Papatheodorou G, Sack WH, Sweeney M, Wagner KD, Weller EB, Winters NC, Oakes R, McCafferty JP. Efficacy of paroxetine in the treatment of adolescent major depression: a randomized, controlled trial. J Am Acad Child Adolesc Psychiatry. 2001 Jul;40(7):762-72. doi: 10.1097/00004583-200107000-00010. PMID: 11437014.

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NZ Post House
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www.cmc.org.nz

encourages health professionals to engage in prescribing off-label uses of pharmaceutical products where the potential to cause consumer harm may increase further[19].

DTCA leads to iatrogenic harm

By reducing the hype of newly promoted products, and only prescribing those pharmaceutical products that are clinically indicated and informed by the evidence, New Zealand can expect to see a reduction in the prevalence of previously unknown and significant side effects. When introducing new medicines, pharmaceutical companies can never fully understand the range of side effects that new product will have on a wide population after often only being tested on a small group. Some intensively advertised drugs, such as the painkiller *Vioxx*[20], have later been withdrawn from the market when they were understood to produce serious side effects - for example elevated rates of heart attacks (when risk of cardiovascular events was not detected in the pre-marketing clinical trials) and even death. Removing artificially generated patient demand for new pharmaceutical products by prohibiting their promotion will allow cautious use of new pharmaceuticals when clinically indicated and save lives.

DTCA puts the doctor-patient relationship at risk.

DTCA contributes to deterioration in the doctor-patient relationship[4]. Many specialists, especially General Practitioners, find themselves being asked to prescribe medications that they do not consider are clinically indicated[21]. Research shows that DTCA highlights benefit information more effectively than risk information[22], and Doctors who find themselves resisting patients' requests may place the therapeutic relationship under stress. Similarly, Doctors can find themselves trying to re-educate patients about inappropriate treatment options which strains the therapeutic relationship and lengthens the duration of consultations.

DTCA regulation options are flawed

Currently, the advertising of therapeutic products is regulated by the Medicines Act 1981, the Medicines Regulations 1984, and guided by industry codes that set out the minimum standards. These industry codes are the Advertising Code of Practice[23] set by the Advertising Standards Authority (ASA), the New Zealand

[19] Humphreys G (2009) Direct-to-consumer advertising under fire. Bulletin of the World Health Organization 87(8): 576–577.
[20] Medsafe, *COX-2 Inhibitors – where to from here?* 2004. Retrieved 2023 from https://www.medsafe.govt.nz/profs/PUarticles/COX2info.htm
[21] Robinson AR, Hohmann KB, Rifkin JI, Topp D, Gilroy CM, Pickard JA, Anderson RJ (2004) *Direct-to-consumer pharmaceutical advertising: physician and public opinion and potential effects on the physician-patient relationship*. Archive of Internal Medicine 164(4): 427-32.
[22] Hoek J et al. (2001) *Could Less be More? An Analysis of Direct to Consumer Advertising of Prescription Medicines*. Marketing Bulletin 12, Article 1.
[23] Advertising Standards Authority website (accessed February 2023) https://www.asa.co.nz/codes/codes/therapeutic-and-health-advertising-code/

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Code of Practice[24] from Medicines New Zealand, and the general complaints process established by Medsafe.

None of these industry standards have any legal effect. Not only are they not fit to regulate, but they are also not fit to effectively monitor DTCA as they are retroactive rather than proactive and complaint based. To lay a complaint, one first must know that the advertisement is misleading, and without expert knowledge, a patient may not be aware of how an advertisement misleads.

The ASA is a self-governing, self-regulatory industry body which provides a Code of Practice specifically for the advertising of therapeutic products by its members. Penalties for breeches of the Advertising Code of Practice are infrequent and minimal: ASA has set up the Advertising Standards Complaints Board to handle complaints about DTCA but the Board has no authority to impose penalties on advertisers[25].

Similarly, organisations or members of the public who are not members of Medicines New Zealand and wish to lodge a complaint, they are required to include an administration fee of $7,500 (plus GST) which is forfeited if the complainant is unsuccessful and refunded if successful[26].

It would be impractical in a country the size of New Zealand to centrally vet all advertising claims against even the cited “evidence”, and without having access to the complete trial data, it is—and would remain—very difficult to ensure that claims are both evidence-informed and balanced. Instead, the solution surely lies with legislation, and prescribers distancing themselves from biased industry sources of information, and for regulators, professional bodies, medical journals and academic funding institutions to support and incentivise this distancing[27]

DTCA does not provide patients with useful information

DTCA does not exist to support patients in their pursuit of accurate information about their health care - in fact, DTCA primarily serves to promote products and in doing so obfuscates and misdirects patients in their treatment options.

[24] Medicines New Zealand Code of Practice (Accessed February 2019) https://www.medicinesnz.co.nz/our-industry/code-of-practice
[25] Toop L, Richards D, Dowell T, Tilyard M, Fraser T, Arroll B. *Direct to consumer advertising of prescription drugs in New Zealand: for health or for profit?* Report to the Minister of Health supporting the case for a ban on DTCA. Dunedin, 2003. Available from: https://www.otago.ac.nz/christchurch/otago628243.pdf
[26] *Medicines New Zealand. Code of Practice.* Edition 16: Medicines New Zealand, cited March 11, 2019]. Available from: http://www.medicinesnz.co.nz/fileadmin/user_upload/Ed-16-Final-Updated-22-Sept-2015.pdf
[27] Toop, L.& Mangin, D. (2015) *The art and science of marketing medications* NZMJ 4 September 2015, Vol 128 No 1421 ISSN 1175-8716

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The pharmaceutical industry argues that the benefits of DTCA include disseminating health information about illnesses and treatment, and empowering consumers by providing information and encouraging choice. However, research suggests that information provided to consumers by the pharmaceutical industry is likely to be biased in favour of benefits over potential harms. A 2013 study found that only 13% of pharmaceutical advertisements provided any evidence to support their claims about efficacy[28]. Where evidence is made available, the data tends to exaggerate the magnitude of the benefits[29]. Advertisements for pharmaceuticals in New Zealand focus on particular disorders - which can serve to de-stigmatise those disorders - but inconsistent quality of promotional materials and inappropriate citations to bolster claims[30] can see patients self-diagnosing incorrectly.

DTCA perpetuates power imbalances in pharmaceutical companies favour

It is clear the DTCA playing field is not level: patients and companies are not equal parties with relationship-centered two-way information exchange, within a supportive and inclusive environment, where power is more equalised and health literacy is supported.

When balancing the rights and freedoms of individuals and groups, DTCA does not adequately compare the financial interests and 'freedom of speech' of industry with patients' right to freedom of information and does not consider how subconscious persuasion by predatory DTCA denies patients' right to freedom of thought. Prohibiting DTCA supports patients' rights to receive appropriate care, with benefits and risks explained clearly, and never be pressured into anything, or taken advantage of[31].

CMC strongly recommends the interests of the public be prioritised ahead of the financial interests and 'freedom of speech' of pharmaceutical industry. Under the guise of consumer awareness and empowerment, arguments that DTCA should continue in Aotearoa so that 'patients have access to information' are strawman fallacies. Patients in almost every other developed country in the world who have prohibited DTCA still have access to information about therapeutic products. Patients will continue to seek and find information about available treatment options for their conditions.

For these reasons, CMC believes New Zealanders should be free from predatory DTCA pharmaceutical advertising. In Aotearoa, successive governments have taken a 'watching brief' of DTCA since the

[28] Schwartz LM and Woloshin S (2013) The Drug Facts Box: Improving the communication of prescription drug information. National Academy of Science USA 110: 14069-74.
[29] Every-Palmer S, Duggal, R, Menkes, DB (2014) *Direct-to-consumer advertising of prescription medication in New Zealand.* New Zealand Medical Journal 127: 102-110.
[30] Ma A. & Parkin L. *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?* Wellington: NZMA, 2015. 128(1421): 22-29. Available at: https://www.nzma.org.nz/journal/read-the-journal/allissues/2010-2019/2015/vol-128-no-1421-4-september-2015/6637
[31] Medical Council of New Zealand, *Your rights as a patient* (Accessed February 2023) https://www.mcnz.org.nz/support/support-for-patients/your-rights-as-a-patient/

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Medicines Act 1981 did not specifically prohibit the practice. Since then, a number of reviews have taken place, and despite opposition by clinicians, health professionals, colleges, and consumer advocacy groups, DTCA remains legal and increasingly common in New Zealand. Now is the time to prohibit DTCA.

The collective agreement by leaders of the health sector is a clear indicator that legislative change is in the best interests of public wellbeing. In the interest of effective, safe and cost-effective healthcare, CMC is strongly opposed to DTCA. We want to protect patients by prohibiting poor quality, persuasive and biased information from companies who wish to target vulnerable New Zealanders and push to purchase their products.

Choices about a patient's treatment should be made by the patient and their doctor on the basis of the best evidence - not on the craftiest or most compelling marketing campaign.

To reiterate, the CMC recommend the Therapeutic Products Bill expressly prohibit pharmaceutical advertising direct to consumers. We welcome the opportunity to present in person to the Select Committee.

Nāku noa, nā

Dr Samantha Murton
Chair