The Royal New Zealand
College of General Practitioners
Te Whare Tohu Rata o Aotearoa

7 March 2023

Tangi Utikere
Chair, Health Committee
Parliament Buildings
WELLINGTON

via email to: Health@parliament.govt.nz

Tēnā koe Tangi

Submission – The Therapeutic Products Bill

The Royal New Zealand College of General Practitioners (the College) welcomes the opportunity to comment on The Therapeutic Products Bill 2022 (The Bill).

The RNZCGP is the largest medical college in New Zealand. Our membership of 5,748 general practitioners comprises almost 40 percent of New Zealand's specialist medical workforce. The Division of Rural Hospital Medicine also sits within the College's academic remit of vocational training of doctors working in rural hospitals. Our members cover both urban and rural settings, and work in a variety of business structures. The College kāupapa is to set and maintain education and quality standards for general practice, and to support our members to provide competent and equitable patient care.

The College submission is informed by the following principles:

- any medication or device claiming a therapeutic benefit should be safe and subject to regulation,
- any natural product claiming a therapeutic benefit should be safe and safe and subject to regulation,
- patients should receive health information on therapeutic products from an independent source,
- regulations on pharmacy ownership should enable models of integrated care.

Our main points cover:

- Natural health products – Inclusion of rongoā
- Direct-to-consumer advertising
- Off-label prescribing
- Medicines classification
- Extended role of health practitioners

Natural health products – Inclusion of ronogā

The College does not support the inclusion of rongoā in the Therapeutic Products Bill. It is inappropriate for the Bill to define Rongoa. We consider the approach undermines and ignores the depth and breadth of Rongoa and its kaupapa. Our view is that rongoā is a taonga and sits within the context of Te Ao Māori. To protect rongoā from the lessons of the past[1], Māori experts must define the next steps in their role as kaitiakitanga, to protect and uphold the kaupapa of the taonga, working with Māori progress the next phase of implementation.[2]

Direct-to-Consumer Advertising (DTCA)

The College advocates that the Therapeutic Products Bill expressly prohibits pharmaceutical advertising to consumers.[3] [4]

The College is disappointed that Therapeutic Products Bill will allow DTCA.

We do not support Direct-to-Consumer Advertising (DTCA) and consider some evidence is misleading or not based on clinical trials. The use of DTCA is increasing and in some cases, there is evidence of substantial risk and harm, e.g., as in the case of Arthrem.[5] [6] [7] [8] We advocate that government has a responsibility to protect and prioritise the protection of the New Zealand public for safety and health under its obligations to the principles of the Treaty of Waitangi[9], over private industry interests.

DTCA of prescription medications cause considerable public harm through influencing the public perception of a pharmaceutical product and the stimulation of demand for unsuitable or unnecessary, costly treatment, leading to inappropriate prescribing. There is strong evidence to show that DTCA is effective for influencing public behaviour, with pharmaceutical companies (and other industries) increasingly using it as a tool to increase revenue.[10] [11] [12]

New Zealand and the USA are outliers, as the only two countries in the western world that allow DTCA, and by comparison with OECD peers where the promotion of DTCA is now prohibited.[13] 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[14] and a call to ban DTCA.[2]

Online DTCA and social media have saturated the market in the USA. Concerns raised by the Food and Drug Administration, the regulator of DTCA in the USA, warned that several pharmaceutical companies had sponsor links on search engines, and were misbranded because they did not provide statements about adverse effects[15].

The College position aligns with the Council of Medical College in not supporting DTCA:[2] [a]

1. DTCA is prohibited almost everywhere 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[b] 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.

In addition, the College strongly opposes any advertising related to medicinal cannabis. Although advertising is currently allowed under law for approved medicines, the College has reiterated its opposition to DTCA and advocates for all advertising of medicinal cannabis being made illegal.

Off-label prescribing – Clause 49

Specialist General Practitioners should be able to hold prescribing authority for approved on-label or off-label use without Ministry of Health oversight. However, unapproved medicines that do not meet the quality standards should require Ministry of Health approval.[16]

[a] As detailed in the CMC submission[2]

[b] Illness caused by medical examination or treatment

Guidance and set parameters for off-label prescribing should be developed to ensure off-label medication can be prescribed within an appropriate legal framework.

The College recommends that guidance includes:

Vocationally Registered GPs are specialists, and the proposals need to apply this understanding appropriately. Explicit wording to clarify existing sector or consumer understanding of the terms: Specialist General Practitioner, medical practitioner, and specialist.

For approved products:

- Specialists, including Specialist General Practitioners should have prescribing authority for on-label or off-label use without Ministry of Health oversight.
- Special Clinical Needs Supply Authority. Currently reads, 'Authorise all health practitioner prescribers to issue a SCNSA - We consider that this should read, 'Authorise all medical practitioners.
- Prescription medicine should not be supplied without a prescription, and prescribing should always be evidence-based to support treatment.
- Patients should be fully informed about the circumstances and be given clear direction about accepted clinical practice, their responsibility to patients and the ethical implications of off-label prescribing.

Medicines classifications

While stakeholders can comment on the classification of medicines, the proposed framework could be more inclusive to balance views of the regulator, expert community, access to medications, and risk profiles. We suggest that a way forward would be to rename the medicines groups: prescription medicines, general sales, health practitioner medicines (previously pharmacy only and pharmacist only) and according to specific scope and training.

A clearer concept would be to have four categories of medicines, with no reference to a location / environment:

- Category 1 medicines - General sales medicines as currently classified.
- Category 1A (e.g., previously Pharmacy Only medicines) – all pharmacists and all nurses or other named groups of health practitioners can provide.
- Category 2 medicines - Health practitioner medicines – requiring additional training to supply, as per Health Practitioners Competency Assurance Act / regulatory authorities. This would be a 'limited prescriber' activity, with named medicines.
- Category 2A (previously Pharmacist Only medicines) with individual health practitioners having a list of medicines that they may supply for this list.
- To avoid confusion, we believe the term should be Supply / provide and **not** prescribe.
- Category 3 medicines - Prescription medicines requiring a specific scope of advanced training and qualification.
- Category 4 medicines - Controlled drugs.

The terminology is confusing, and this is emerging between prescribers due to associating medicines with a location (pharmacy) when they could be available elsewhere or linked to a particular profession (pharmacist-only, e.g., a clinical pharmacist attached to a general practice). We suggest changing the terminology to, supply or provide, unless the medication is a prescription medicine. This would reduce the differentiation and confusion between: pharmacists prescribing, pharmacist-only medicines, prescribers, and the prescription medicine list.

A main area of contention is the lack of clarity around authorised vs delegated prescribing. We endorse the 'prescriber - interest in a pharmacy' clause, and which would be allowed only through exemption from the Ministry of Health, and that pharmacist prescribers, still not being able to prescribe Class B controlled drugs.

In summary

Thank you for the opportunity to provide comment on the proposed Therapeutic Products Bill.

In particular, our submission supports the call by other professional Colleges and organisations to introduce legislation prohibiting DTCA of prescription medicines directly to the public, through print and broadcast media or any other form, in favour of an independent health and medicines information service that is free of commercial interest. Implementation of these would move New Zealand from its current anomalous position to one of world leadership in the promotion of the appropriate and rational use of medicines.

The College notes that the regulations and rules will be a significant part of the new Therapeutic Products regime and we indicate an interest in providing advice during ongoing development and implementation.

We welcome the opportunity to meet with you to present in person to the Select Committee.

For further clarification, please contact Maureen Gillon, Manager, Policy Advocacy Insights - maureen.gillon@rnzcgp.org.nz

Nāku noa, nā

Dr Bryan Betty
ONZM, FRNZCGP (Dist.), FACRRM, MBChB
Medical Director | Mātanga Hauora

References

[1] New Zealand Parliament. Tohunga Suppression Act 1907. https://en.wikipedia.org/wiki/Tohunga_Suppression_Act_1907

[2] Ka Mua – Wai 262. The Symposium, the first WAI 262 claimant whānau (Taumata Whakapumanu) led korero in the history of the WAI 262 Flora and Fauna claim - https://www.wai262.nz/

[3] The Royal New Zealand College of General Practitioners. Position Statement. Prohibition of direct-to-consumer advertising of prescription medications. 2017. Available at: https://www.rnzcgp.org.nz/gpdocs/New-website/Advocacy/Position-Statements/2017.03-DTCAPositionStatement.pdf

[4] The Council of Medical Colleges. Joint submission on the Therapeutic Products Bill. March 2023.

[5] Medsafe (2018) Arthrem – potential risk of harm to the liver – statement under section 98 of the Medicines Act 1981 Early Warning System – Alert Communication. Available at: https://www.medsafe.govt.nz/safety/EWS/2018/Arthrem.asp

[6] Medsafe (2018) Artimesia annua (Sweet wormwood, Sweet Annie, Qing hao) extract marketed as Arhrem: risk of harm to the liver – statement under section 98 of the Medicines Act 1981. https://www.medsafe.govt.nz/safety/EWS/2018/ArthremNov2018.asp

[7] Ministry of Health (2018) Warning of potential harm to liver associated with the natural medicine Arthrem – Privileged Statement 19 February 2018. Available at: https://www.health.govt.nz/news-media/media-releases/warning-potential-harmliver-associated-natural-medicine-arthrem

[8] Ministry of Health (2018) Renewed Warning of Liver Harm – Privileged Statement 27 November 2018. Available at: https://www.health.govt.nz/news-media/media-releases/renewed-warning-liver-harm

[9] Ministry of Health. Treaty of Waitangi principles. https://www.health.govt.nz/our-work/populations/maori-health/he-korowai-oranga/strengthening-he-korowai-oranga/treaty-waitangi-principles

[10] Donohue JM, Cevasco M, Rosenthal MB. A decade of direct-to-consumer advertising of prescription drugs. N Eng J Med. 2007;357:673–81. Available from: https://www.nejm.org/doi/full/10.1056/NEJMsa070502#t=articleBackground

[11] Kravitz RL, Epstein RM, Feldman MD, et al. Influence of patients' requests for direct-to-consumer advertised antidepressants: a randomized controlled trial. JAMA. 2005;293(16):1995–2002. [Erratum in JAMA. 2005;294(19):2436.]

[12] Toop L, Richards D, Dowell T, Tilyard M, Frazer 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. 2003. Available at: https://www.otago.ac.nz/christchurch/otago628243.pdf

[13] Toop L, Mangin D, Tilyard M, Stokes T, Dowell T, McBain L, Arroll B, Goodyear-Smith F. Submission for Therapeutic Products Regulatory Scheme consultation. Direct to Consumer Advertising of prescription medicines (DTCA). 2019. University of Otago, Christchurch, Dunedin, Wellington; University of Auckland. April 2019.

[14] 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

[15] 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

[16] The Royal New Zealand College of General Practitioners. Medicinal Cannabis Scheme Submission. 2019. https://www.rnzcgp.org.nz/gpdocs/Submissions/Medicinal-cannabis-submission-Final7-August-2019.pdf