ASMS

ASSOCIATION OF SALARIED MEDICAL SPECIALISTS

TOI MATA HAUORA

ASMS submission to the Health Committee on the Therapeutic Products Bill 2022

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L9, The Bayleys Building, 36 Brandon Street, PO Box 10763, Wellington 6140, New Zealand
P + 64 4 499 1271 E asms@asms.org.nz W asms.org.nz

The Association of Salaried Medical Specialists (ASMS) welcomes the opportunity to provide a submission to the Health Select Committee on the Therapeutic Products Bill 2022.

ASMS is the union and professional association of salaried senior doctors and dentists. We were formed in April 1989 to advocate and promote the industrial and professional interests of our members, most of whom are employed by Te Whatu Ora Health New Zealand as medical and dental specialists, including physicians, surgeons, anaesthetists, psychiatrists, oncologists, radiologists, pathologists and paediatricians. We have over 5,600 members.

ASMS is working for an equitable, accessible public health care system that meets the needs of all New Zealanders.

The main points of our submission are:

1. Provisions relating to off-label prescribing and products without a NZ authorisation are poorly connected within the Bill which could create ambiguity for medical practitioners and other health practitioner prescribers.
2. The failure of the Bill to end direct-to-consumer advertising of prescription medicines (DTCA-PM) is a lost opportunity to remedy the oversight made by the Medicines Act.
3. If DTCA-PM is to continue under new legislation, there should be an independent review of the practice to understand its use in the contemporary advertising and marketing context.
4. Minister-directed amendments to scopes of practice needs to be undertaken with caution.

Te Tiriti o Waitangi

ASMS welcomes the inclusion of Te Tiriti o Waitangi and mātauranga Māori in clause 4 as guiding principles in the Bill. Neither the Medicines Act 1981 nor the Dietary Supplements Regulations 1985 include any reference to Māori, Te Tiriti o Waitangi, Rongoā Māori or Hauora Māori. The health inequities experienced by whānau Māori are well-evidenced; yet Māori are less likely to receive timely, accessible health care, including access to medicines[1] [2].

Analysis and consultation by Manatū Hauora Ministry of Health and Te Puni Kōkiri on the intersections between Rongoā Māori and the Bill is welcomed, particularly with the ongoing work on the findings and recommendations from Wai 262[3].

We note that the Bill makes provision for Te Tiriti o Waitangi in relation to the functions and powers of the Regulator, and for it to have the capacity and capability in mātauranga Māori and Māori

[1] Waitangi Tribunal. Hauora: a report into Stage One of the Health Services and Outcomes Inquiry. Wellington: Waitangi Tribunal; 2019. Available from https://forms.justice.govt.nz/search/Documents/WT/wt_DOC_152801817/Hauora%20W.pdf.

[2] Hikaka J, Parore N, Haua R, Anderson A, Hudson M et al. Māori, pharmacists and medicines adherence: a mixed methods study exploring Indignoue experiences of taking medicines 'as prescribed' and mechanisms of support. Explor Res Clin Soc Pharm. 2022; 7:100175. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9465430/.

[3] Manatū Hauora and Te Puni Kōkiri. Te Pae Tawhiti: Wai 262. Wellington: Manatū Hauora and Te Puni Kōkiri; 2022. https://www.tpk.govt.nz/en/a-matou-whakaarotau/te-ao-maori/wai-262-te-pae-tawhiti.

perspectives. This latter point is key, as the Waitangi Tribunal noted regarding the now-abandoned proposal for an Australian and New Zealand Therapeutic Products Agency: if Rongoā Māori products were to be regulated under such a scheme, it would require Māori engagement, consultation and decision-making at board and expert committee levels[4].

We look forward to further information regarding the Rongoā workstream, and support the skills, knowledge and expertise of mātauranga Māori and Māori perspectives being foundational to the operation of the therapeutic products regulator.

Clause 49 Off-label prescribing

Medicines may be developed for one or several indications or uses; however there are instances where, through trials and testing, medicines are found to be effective in treating unrelated conditions. Off-label prescribing is a common feature of clinical practice and is prevalent in many medical specialities such as psychiatry, paediatrics and anaesthesia; some estimates note up to 40 per cent of adult prescribing and 90 per cent of paediatrics prescribing is off-label[5 6 7 8].

Currently, Medsafe approves medicines for a specific purpose, use, duration, dose and administration route; anything beyond these parameters is considered an off-label use. Practitioners may prescribe any medicine (approved or unapproved) within their scope of practice and professional ethical obligations under s 25 of the Medicines Act. Medicines which have not been approved for use in Aotearoa can only be prescribed and supplied by a medical practitioner under section 29.

We note that clause 49 of the Bill describes off label use as being the undertaking of a controlled activity (for example, prescribing) of a medicine or device for an unauthorised use; that is, the New Zealand authorisation of the medicine or device does not include that particular purpose, indication, route, dose, or administration. The guidance note on this clause specifies "*a person is allowed to supply, administer, or use it for an off-label use only if they are allowed to do so with products that do not have a NZ authorisation*".

While the Medicines Act did distinguish between unapproved *use* of a medicine and *unapproved medicines* (s 25 and s 29), the new Bill emphasises a "NZ authorisation" for therapeutic products. A NZ authorisation is required to undertake all controlled activities, although if no NZ authorisation is

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[4] Waitangi Tribunal. Ko Aotearoa Tēnei: This is Aotearoa New Zealand. Vol 2. Wellington: Waitangi Tribunal; 2011.

[5] Wilkinson S, Mulder RT. Antipsychotic prescribing in New Zealand between 2008 and 2015. N Z Med J 2018; 131(1480): 61-67. Available from https://assets-global.website-files.com/5e332a62c703f653182faf47/5e332a62c703f6392b2fd33d_Mulder-FINAL.pdf.

[6] Upfront: unapproved medicines and unapproved uses of medicines: keeping prescribers and patients safe. BPJ 2013 (updated 2021); 51. Available from https://bpac.org.nz/bpj/2013/march/unapproved-medicines.aspx

[7] Julian KA, Stapelberg F. A survey of the use of unapproved medicines in anaesthesia practice in New Zealand. Anaesth Intensive Care 2008; 36:102-06. Available from https://journals.sagepub.com/doi/pdf/10.1177/0310057X0803600118.

[8] Allen HC, Garbe MC, Lees J, Aziz N, Chaaban H et al. Off-label medication use in children, more common that we think: a systematic review of the literature. J Okla State Med Assoc. 2018; 111(8):776-783. Available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6677268/.

in place, the "special case requirement" (covered in clause 65) must be met. The special case requirement clause is necessary for any controlled activity where a medicine or device is used off-label or does not have a NZ authorisation, yet it is poorly referenced and connected to other clauses in the Bill. There are several points in the Bill where clarification would augment the Bill's readability and accessibility, notably clause 49 (off-label use); clause 83 health practitioners, where the mention of special case requirements in 83 3(e) should cite clause 65; and potentially clause 128, covering the scope of market authorisations which specify product indications.

Clause 65 states the potential for additional criteria or requirements pertaining to products without a NZ authorisation under future regulations in the Therapeutic Products Regulatory Scheme. Without detail regarding the intended regulatory scheme for off-label and unapproved medicines, it is difficult to ascertain what additional requirements may be imposed and if this will add to an existing administrative burden for medical practitioners and other prescribers.

Comment on Clause 54 standing orders, and products without a NZ authorisation

There are currently instances when health practitioners will administer a medicine under a standing order where the medicine is being used for an off-label or unapproved indication. To our reading of the Bill, this would be prohibited under clause 54 (1), as standing orders would only apply to products with a NZ authorisation. This restriction could have significant unintended consequences for prescribers, health practitioners, patients and whānau. ASMS supports greater clarification and detail regarding standing orders.

Clause 193 Advertising

ASMS is disappointed that the Bill continues to permit DTCA-PM in Aotearoa.

Aotearoa New Zealand remains one of two developed countries (the other being the United States) to allow the advertising and marketing of medicines and medical devices, including prescription-only pharmaceuticals, to consumers via mass media platforms. This practice was initially permitted by omission in the Medicines Act 1981, and despite reviews of the practice in 1998, 2000 and 2006, it was proposed to continue under the previous iteration of the Therapeutic Products Bill, as well as the current Bill[9].

The Cabinet paper provides extensive commentary on DTCA-PM. It proposes that the existing framework of government regulation, industry self-regulation, and the wider health regulation under

[9] Lexchin J Menkes DB. Can direct-to-consumer advertising of prescription drugs be effectively regulated? N Z Med J. 2019; 132(1496):59-65. Available from https://journal.nzma.org.nz/journal-articles/can-direct-to-consumer-advertising-of-prescription-drugs-be-effectively-regulated. Accessed 11 January 2023.

the Code of Health and Disability Services Consumer's Rights strikes an appropriate balance to establish DTCA-PM settings. The Cabinet paper contends that DTCA-PM creates negligible levels of harm in the community, evidenced by the lack of complaints investigated by Medsafe or made to the Advertising Standards Authority[10].

The Ministry of Health's thematic analysis of submissions on the 2018 Bill notes

> "Generally speaking, submitters from the advertising sector, industry sector, and parts of the pharmacy sector supported DTCA whereas health practitioners and their representative groups did not. Consumers were both for and against but were generally opposed to it"[11].

DTCA-PM benefits those who can derive a profit from its existence: the pharmaceutical industry, the advertising industry, and pharmacy businesses. Health practitioners, health professional associations and consumers have continued to call for the practice to be banned in Aotearoa New Zealand, stating that the health claims in DTCA-PM are often unsubstantiated and based on weak evidence; in its most basic form, the priority of advertising is sales and profits; and the triangulation and imbalance of power between the industry, prescribers, and patients places the latter at a distinct disadvantage[12] [13].

DTCA-PM has been scrutinized through the 2018 and 2022 iterations of the draft Therapeutic Products legislation, but no specific review of the practice in Aotearoa New Zealand has been undertaken since 2006[14]. The Cabinet paper also notes the absence of more contemporary studies; however there has been analysis undertaken on the influence of DTCA-PM, marketing and

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[10] Cabinet paper. Therapeutic products and natural health products regulatory scheme: establishing a new regulator and funding settings, offences and penalties; direct-to-consumer advertising of prescription medicines. Released November 30 2022. Available from https://www.health.govt.nz/system/files/documents/pages/therapeutic_products_and_natural_health_products_regulatory_scheme_1_redacted.pdf. Accessed 11 January 2023.

[11] Ministry of Health. Key themes from submissions to the Therapeutic Products Bill. Available from https://www.health.govt.nz/publication/therapeutic-products-regulatory-scheme-consultation. Accessed 11 January 2023.

[12] Jochem H. Direct-to-consumer advertising for prescription drugs in New Zealand: time for radical change? LLM Research Paper, Faculty of Law Victoria University of Wellington; 2015. Available from http://researcharchive.vuw.ac.nz/xmlui/bitstream/handle/10063/5110/paper.pdf?sequence=1. Accessed 11 January 2023

[13] Toop L, Richards D. DTCA in New Zealand: the challenge of finding an acceptable balance. Br J Gen Pract. 2002 52(477):341. Available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1314283/pdf/11942460.pdf. Accessed 11 January 2023

[14] Ministry of Health. Direct-to-Consumer advertising of prescription medicines in New Zealand: Summary of submissions. 2006. Available from https://www.moh.govt.nz/notebook/nbbooks.nsf/0/51F2DBB3E4305D83CC2576BD0078A1F1/$file/Direct-to-Consumer.pdf. Accessed 11 January 2023.

advertising approaches and its impact on the opioid crisis in the United States, looking at consumer behaviour and health practitioner prescribing practices[15] [16] [17].

Since the time of the last review of DTCA-PM in Aotearoa, the media landscape has undergone transformative changes, including the increased globalisation of media, the dominance of digital, web-based and streaming services, and social media channels. Further, DTCA increasingly encompasses medical procedures, diagnostics and testing, such as patient-requested blood tests. When not requested as part of a health practitioner's diagnostic or treatment plan for a patient, these forms of DTCA may contribute to poor health resource stewardship, which contrasts with health system-level approaches such as Choosing Wisely – a clinically-led campaign to reduce harm from low-value and unnecessary treatment[18] [19].

Comment on terminology and the Health Practitioners Competence Assurance Act 2003

The Medicines Act 1981 was highly specific in its delineation of practitioner roles and responsibilities. The new Bill differentiates between 'Health Practitioner' and 'Health Practitioner Prescriber', with the latter acknowledging the prescribing of medicines as part of a scope of practice under the Health Practitioners Competence Assurance Act 2003 (HPCAA).

We note the specificity of the 1981 Act created difficulties as Health Practitioner roles and responsibilities changed over time. We find the updated terminology to be more consistent with the goal of future-proofing legislation.

As anticipated, the Therapeutic Products Bill necessitates changes in other legislation, including the HPCAA. Proposed changes to the HPCAA relate to scopes of practice, particularly to the prescribing of therapeutic products and the issuing of standing orders.

While we support the continued requirements for responsible authorities to consult with affected classes of practitioners and representative organisations regarding changes to scopes of practice, we note the Minister of Health will have the power to direct a responsible authority to amend scopes of practice, including prescribing therapeutic products.

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[15] Yukubi H, Gac B, Appollonio DE. Industry strategies to market opioids to children and women in the USA: a content analysis of internal industry documents from 1999 to 2017 released in State of Oklahoma v. Perdue Pharma, L.P. et al. BMJ Open 202212(11):e052636. Available from https://bmjopen.bmj.com/content/12/11/e052636.long

[16] Humphreys K, Shover CL, Andrews C M, Bohnert ASB, Brandeau ML et al. Responding to the opioid crisis in North America and beyond: recommendations from the Stanford-Lancet Commission. Lancet 2022; 399(10324):555-604. Available from https://thewellnews.com/wp-content/uploads/2022/02/OpioidCommission.pdf. Accessed 12 January 2023.

[17] Beilfuss S, Linde S. Pharmaceutical opioid marketing and physician prescribing behaviour. Health Econ. 2021; 30(12):3159-3185. Available from https://pubmed.ncbi.nlm.nih.gov/34562329/. Accessed 12 January 2023.

[18] Shaked M Levkovich I, Adar T, Peri A, Liviatan N. Perspective of healthy asymptomatic patients requesting general blood test from their physicians: a qualitative study. BMC Fam Pract 2019; 20(51). Available from https://bmcprimcare.biomedcentral.com/articles/10.1186/s12875-019-0940-9. Accessed 12 January 2023.

[19] Health Quality and Safety Commission. Choosing Wisely. Available from https://www.hqsc.govt.nz/resources/choosing-wisely/. Accessed 10 February 2023.

As Ministers are political appointments who may or may not have clinical experience, there are risks that such amendments may be motivated by perceptions of efficiency or cost savings.

Any amendment to prescribing of therapeutic products in scopes of practice of any health practitioner should be subject to a robust and rigorous process guided by quality, safety and clinical expertise, as well as consultation with the sector. The balance of evidence should be on the need to *enable* the change, not to prove the change is unnecessary (14A (4)) The Bill should be amended to reflect this process.

Conclusion and recommendations

The Bill includes provision for off-label prescribing and the use of unapproved medicines, both of which are frequent activities within the scope of clinical practice. How the regulations and other legislative instruments provide for these activities within everyday practice will be key, as we see a risk for significant unintended consequences with the lack of detail in the current Bill.

We strongly recommend the Committee endorses the prohibition of DTCA-PM under the new legislation, but if the practice is to continue, an independent review should be undertaken as a priority.

We believe caution is needed regarding the role of the Minister of Health and the amending of scopes of practice. While we support future-proofing the legislation, the need for a balanced and evidence-formed process, including sector consultation is needed.

Nāku noa, nā

Sarah Dalton
Executive Director

M +64 27 210 2234
E sarah.dalton@asms.org.nz