Australasian College
for Emergency Medicine

34 Jeffcott Street West Melbourne Victoria 3003, Australia
+61 3 9320 0444 | admin@acem.org.au | ABN 76 009 090 715

Draft Submission to the Ministry of Health: April 2019

DRAFT THERAPEUTIC PRODUCTS BILL

The Australasian College for Emergency Medicine (ACEM) welcomes the opportunity to provide feedback to the Ministry of Health on the draft Therapeutic Products Bill (the Bill).

ACEM is the peak body for emergency medicine in New Zealand and Australia, with responsibility for training and educating emergency physicians and advancing professional standards in emergency medicine. As the trusted authority for emergency medicine, ACEM has a vital interest in contributing to a sustainable emergency medicine workforce that provides high quality patient care for all patients and upholds the highest possible professional standards in emergency medicine. Fellows of ACEM (FACEMs) are specialist emergency physicians working in emergency departments (EDs) across New Zealand and Australia.

In general, ACEM welcomes a regulatory regime for therapeutic products that would align New Zealand with international standards, ensure patient safety and offer effective regulatory control over evolving technology. However, ACEM identifies a range of issues that could arise from the Bill, either as unintended consequences from the proposed regulatory regime or gaps that the Bill needs to address. These issues include:

- Direct to Consumer Advertising
- Definitions for post-market activity
- Recognised authorities
- Regulation of natural products and rongoā Māori

Direct to Consumer Advertising

Direct to Consumer Advertising (DTCA) is the advertising of pharmaceutical products directed towards consumers rather than medical professionals. New Zealand is one of only two nations in the OECD to allow DTCA, with the other being the United States of America. The Bill, as it is currently drafted, allows for DTCA to continue to occur.

In New Zealand, industry advertising for pharmaceutical products is largely managed through self-regulation by the pharmaceutical industry with oversight from the Advertising Standards Authority and industry codes of practices. In other OECD nations, the pharmaceutical industry has its advertising regulated through robust statutory bodies responsible for protecting consumers, such as the Food and Drug Administration in the United States, or the Therapeutic Goods Agency in Australia.

ACEM does not support Direct to Consumer Advertising (DTCA) of pharmaceutical products in New Zealand, and calls for the Government to bring its position on DTCA into line with the overwhelming majority of other nations in the world, including Australia, Canada and the whole of Europe. Allowing DTCA to continue to occur would not align New Zealand with international regulatory standards or offer sufficient regulatory control over evolving technology. We note that permitting DTCA to occur contradicts the intent and purpose of the regulatory regime proposed within the Bill.

There is overwhelming evidence demonstrating the harms of DTCA, with strong consensus on the issue from within the health sector and consumer groups.[1]DTCA frequently over-represents benefits and understates harms, leads to increased costs, inappropriate prescribing, overtreatment and iatrogenic harm and puts the doctor-patient relationship at risk.[2] A survey[3] of GPs regarding DTCA showed that:

- Approximately 90% of GPs reported consultations being generated as a result of DTCA (of which 68% were unnecessary consultations)
- Approximately 44% of GPs reported switching a patient to a DTCA medication at their request, despite no evidence of benefit over the non-advertised alternative
- Only 12% felt that DTCA could be useful for patients
- Only 4% felt that the information provided was balanced.

Recent research demonstrates that vulnerable populations are particularly susceptible to the negative effects of DTCA, such as those with self-reported poor health, the elderly, those with low educational attainment, having lower incomes and those belonging to ethnic minority groups.[4] At-risk populations are more vulnerable to overestimating the potential benefits form medications advertised to them, particularly when advertisements are deliberately vague and provide biased advice.[5] In some cases, medications with prescriptions driven by DTCA such as COX-2 inhibitors, have been withdrawn due to patient safety concerns.[6]

To address the issue, ACEM proposes that the Bill be amended to prohibit directly advertising pharmaceutical products to consumers, in-line with the overwhelming majority of OECD nations. Additionally, the proposed regulatory body responsible for administering the Bill must also have a role as being the regulator responsible for overseeing advertising (whether direct to consumer or to health professionals) activities as defined in section 82. The regulatory body should have the role of review and regulating advertising of pharmaceutical advertisements, upheld by surveillance and enforcement powers. Independent consumer advice could be provided to the public, free from any commercial interest, by a government regulatory body such as MedSafe.

Post-market monitoring

The definition of advertising (section 82) refers to advertising as meaning: "An advertisement for a therapeutic product means a communication made to the public or a section of the public for the purpose of promoting the product."
ACEM considers this definition to be too vague as it may not include claims on social media which may always be considered to be advertisements by the public. We propose this definition be amended to read: "An advertisement for a therapeutic product means a communication made to the public, a section of the public, *or a statement to a customer*."

Recognised authority

We note that in section 207, the regulator proposed by the Bill "will be able to rely on recognised authorities to draw on work by overseas regulators and assist in efficiency". We note that the Bill does not define what a "recognised authority" is, or the nature of the criteria that would be included in additional regulations. In the interests of clarity this should be defined.

We note also that recognised authorities may rely on information sourced from overseas regulators. ACEM considers this provision to be sensible, however we caution that the Bill or any regulations ensure that a wide range of overseas regulators are considered. Advice should not be solely sourced from the Food and

[1] Ministry of Health. (2006). Direct-to-Consumer Advertising of Prescription Medicines in New Zealand: Summary of Submissions.
[2] Ma, A. and Parkin, L. (2015). 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? NZMJ.
[3] Maubach, N., and Hoek, J. (2005). New Zealand general practitioners' views on direct-toconsumer advertising (DTCA) of prescription medicines: a qualitative analysis. NZMJ.
[4] Zadeh, N., Robertson, K., and Green, J. (2017). 'At risk' individuals' responses to direct to consumer advertising of prescription drugs: a national representative cross-sectional study. BMJ.
[5] Every-Palmer, S., Duggal, R., and Menkes, D. (2014). Direct-to-consumer advertising of prescription medication in New Zealand. NZMJ.
[6] Toop, L. and Mangin, D. (2006). The impact of advertising prescription medicines directly to consumers in New Zealand: Aust Prescr.

Drug Administration in the United States of America; regulators such as those in Australia, the United Kingdom, Canada and the European Union must also be considered to avoid a narrow focus within external advice.

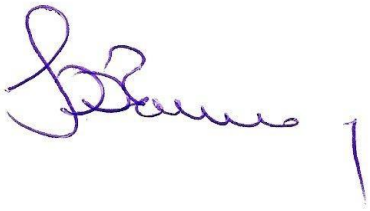
Regulation of natural products and rongoā Māori

ACEM wishes to raise the issue of regulating natural health products and rongoā Māori intended for therapeutic use. Given the size of the natural health product industry and the risk to individual and public health without adequate regulation, we believe the Government must prioritise the development of a regulatory regime. Regulation of natural health products and rongoā Māori must ensure that products are safe, meet international standards for quality and evidence for efficacy, and do not make false representations to consumers. The approach to regulating these products in Australia through the Therapeutic Goods Act is an example that the Government should consider.

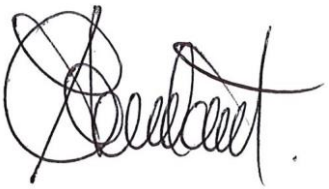
Thank you for the opportunity to provide feedback to the draft Therapeutic Products Bill. Should you require clarification or further information, please do not hesitate to contact Ryan Angus (ACEM Policy Officer) on (+61) 03 9320 0452 or via email at ryan.angus@acem.org.au.

Yours sincerely,

Dr Simon Judkins
President



Dr John Bonning
President-Elect



Dr Andre Cromhout
Chair, New Zealand Faculty