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Royal Australasian College of Physicians' submission to the Ministry of Heath

Therapeutic Products Bill 2019

Introduction

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to submit feedback on the Therapeutic Products Bill 2019 (the Bill), as part of an initial sector consultation prior to be Bill being introduced in the House of Representatives.

The RACP works across more than 40 medical specialties to educate, innovate and advocate for excellence in health and medical care. Working with our senior members, the RACP trains the next generation of specialists, while playing a lead role in developing world best practice models of care. We also draw on the skills of our members, to develop policies that promote a healthier society. By working together, our members advance the interest of our profession, our patients and the broader community.

This Bill is of great significance to the health sector. It will have an ongoing impact on professional and clinical practice; patient interactions with the health sector in institution and community settings; and frame our approach as to how innovative products and devices are regulated in the future. The need for this legislation is increasingly underscored as health and other sectors grapple with new research and development, and rapid technological change including artificial intelligence, machine learning and precision medicine.

Chapter A: Key features of the new regulatory scheme

The Bill is a complex and lengthy piece of legislation, necessitated by the range of Therapeutic Products (TPs) it covers, and the complex landscape of medicines regulation. The Bill includes all categories of medicine, active medical ingredients (AMIs), medical devices and type-4 products – a category designed to future-proof legislation in the eventuation of novel TPs that are not adequately covered by the other existing categories.

Q A1. Do you support the general design of the new regulatory scheme for therapeutic products?

We are in general support of the Therapeutic Products Bill, which when implemented will replace the Medicines Act 1981. The RACP recognises the health care landscape and TP research and development sector has undergone enormous change in the time since the Medicines Act was passed. We believe the regulatory scheme as set out in the Bill does require additional review and amendment, particularly around direct-to-consumer advertising and off-label prescribing.

Other aspects of the Bill we are in agreement with are

- The inclusion of medical devices
- The Type-4 products category and recognition of future-proofing legislation
- The ability to recognise other jurisdictions' product approvals

Our concerns are around the following aspects of the Bill

- The emphasis in the Bill on products and how these will enter the market, rather than positioning these aspects in an equal partnership with clinical evidence and best practice
- The form of the Regulator
- The level of detail in the Bill compared to what will be contained in Regulations and other legislative instruments
- Introduction of Special Needs Clinical Supply Authorities (SNCSA) and tightening off-label prescribing
- The tightening of requirements for personal importation of prescription medicines
- The continued permitting of direct-to-consumer advertising

We do not support the decision for the Bill not to cover natural health products, and for these to be regulated separately. For consumers and the public, any product (whether natural or synthetic) that has a therapeutic purpose is a therapeutic product. Natural health products and category 2, 3 and 4 medicines can all be obtained at pharmacies, as can category 1 medicines with a valid prescription. Where products are available in the same settings but are governed by two overarching yet separate regulatory frameworks, confusion in health practitioners, pharmacy workers and the public may be an unintended consequence, particularly for natural health products which are purchased for a therapeutic purpose.

Chapter B: Content of the Draft Bill

Part 2 of the Bill: Interpretation

Q B2: Please provide comments on the definitions or meanings set out in the draft Bill (ss 14-50)

a. Health Practitioner Prescriber

The RACP sees changes to prescribing authority indicated in the draft Bill as a significant change from the existing Medicines Act 1981. The continued involvement of Responsible Authorities in any change to prescribing authority under Scopes of Practice (SOP) is essential, and a comprehensive consultation process must be mandated under any application to include, extend or alter prescribing authority in any manner.

While there may be rationale to simplify the process in changes to prescribing authority under existing SOPs from a bureaucratic perspective (particularly in removing the need to undertake a regulation-making process) the RACP finds the draft Bill is unclear as to where the information on changes to SOPs would be published. We encourage the Ministry to include this information in a Schedule to the Bill, or at a minimum include notifying these changes through the Gazette.

m. Administer a medicine and prepare a medicine for administration

The RACP supports this new definition in the draft Bill. Both aspects (administering a medicine and preparing a medicine for administration) should be controlled activities under the Bill, and we find the Bill is light on detail, particularly regarding preparing medicine for administration. There may be situations in the future (for example, if voluntary assisted death were to be legislated in New Zealand) where these activities should entail a level of oversight and control to reduce risk of harm or unintended consequences.

s. Pharmacy business or pharmacy activity

The definitions regarding pharmacy business and pharmacy activity are intended to broaden the concept of pharmacies beyond, for example, a physical building or area within a supermarket. This could enable growth in pharmacy services for remote areas, and smaller rural settlements that do not have a pharmacy that is easily accessible – either through mobile or online services.

u. Special Clinical Needs Supply Authority (SCNSA)

The RACP finds it difficult to interpret exactly how the SCNSA would operate in practice from the text of the Bill and the consultation document, as the Bill states that the circumstances, form, content and how it will be issued will all be determined by the Regulator. This makes it challenging to comment on

this aspect of the Bill at this stage, and we recommend the Ministry of Health provides more detail regarding SCNSAs in advance of the Select Committee stage of the Bill. See our response to Q B7 regarding SCNSAs in the context of off-label prescribing.

Part 3 of the Bill: Dealing with Therapeutic Products

Q B3: Please provide any comments on product approval controls (ss 51 and 52)

As stated above, the RACP has concerns about the emphasis in the Bill on reducing perceived bureaucracy in the current legislation and opportunities for industrial influence in how TPs enter the market. We do not support changes to product approval processes which do not explicitly incorporate evidence based, clinical guidance.

Q B4. Please provide comments on the controlled activities and supply chain activity controls

The RACP supports prescribing being a controlled activity undertaken by an authorised prescriber under the Health Practitioners Competence Assurance Act 2003, meaning that the prescriber is practicing under a SOP and current practicing certificate issued by a Responsible Authority. We would support additional detail incorporated into future consultation on this Bill, as some controlled activities including the issuing of Standing Orders under the proposed Bill may be open to misuse.

TPs (including medicines and medical devices) should be accessible to people and communities who require them. Increasing the accessibility of some medicines can reduce barriers to access for some people, such as making the oral contraceptive and emergency contraceptive pill available through consultation with a trained pharmacist. The available evidence on the potential for pharmacist prescribing to reduce barriers to access for some communities and other public health impacts, including antimicrobial resistance, should be central in any future discussions on increasing pharmacist prescribing.

Q B7. Please provide any comments on the authorisations for health practitioners (ss 61-64)

SCNSAs for unapproved medicines and off-label prescribing

Although the consultation document notes that the rationale for introducing a SNCSA for unapproved medicines is intended to evidence a clinical decision-making process (whereby the issuing of the SCNSA shows that the prescriber is of the view that an approved medicine is not appropriate for the patient or there is a specific clinical need), there is little information provided as to why the Regulator would want to collect this data; what the status quo is in this area of prescribing, and what issue or problem this policy intervention would solve.

Anecdotally, off-label prescribing is common in New Zealand, with the available evidence showing it is frequently used in psychiatry – for example, the off-label use of quetiapine at low doses for insomnia,

anxiety and post-traumatic stress disorder[1] [2]. RACP Members participating in the development of our submission note that off-label prescribing is common practice in a number of specialties, including Rehabilitation Medicine, Palliative Medicine and Neurology. Members have stated that any changes to off-label prescribing from the Regulator would need to be a straightforward and minimally-invasive recording option. For example, the 'tick box' which is mentioned numerous times through the consultation document is perceived by RACP members as the most acceptable option described. Similarly to unapproved medicines, there is no information in the consultation document as to why the Regulator or the Ministry is intending to collect this information, or what it will be used for.

Q B8. Please provide any comments on the authorisations for health practitioner's staff

"Staff of a registered health practitioner" is undefined and could cover people performing a range of duties and functions within a practice. This could include practitioners covered by a Responsible Authority, including nurses, dietitians and other allied health professionals, as well as roles not covered such as office managers and receptionists.

Where prescribing or dispensing activities are conducted by health practitioners (such as in the examples of pharmacist prescribers) or the staff of health practitioners, the RACP recommends that these actions are subject to ongoing monitoring, evaluation and quality activities, including audit, and practitioners having a supervisory relationship with a health practitioner prescriber.

Q B10. Please provide any comments on the approach for the personal importation of medicines or medical devices

The RACP acknowledges the current knowledge gaps for the Ministry, the Regulator and others in regard to personal imports of category one (prescription-only) medicines. We also strongly support the need to ensure medicines used in New Zealand meet standards of quality, safety and efficacy. We are concerned that this aspect of the Bill will reduce access for people with long term conditions, terminal conditions, and rare diseases to TPs that may treat their condition and improve their quality of life.

Prescription medicines imported for personal use may either be unapproved in New Zealand, or unsubsidised by PHARMAC. Unsubsidised medications are often prohibitively expensive for many New Zealanders, with courses of therapy costing tens or hundreds of thousands of dollars. Many instances are heavily publicised, particularly where there are conflicting perspectives between PHARMAC's processes to evaluate efficacy and patient advocacy groups[3] [4] [5].

There are instances where patients have formed collectives to obtain TPs from overseas – one recent example is the Hepatitis C (HCV) Buyers Club that obtained direct-acting antiviral (DAA) treatments for Genotype-3 HCV from Tasmania, as New Zealand had funded only DAAs for Genotype-1 HCV

[1] Huthwaite M, Tucker M, McBain L, Romans S. Off-label or on trend: a review of the use of quetiapine in New Zealand. N Z Med J. [Internet]. 2018; 131(1474):45-50. Available from https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2018/vol-131-no-1474-4-may-2018/7556. Accessed 16 April 2019.

[2] Monasterio E, McKean A. Off-label use of atypical antipsychotic medications in Canterbury New Zealand. N Z Med J [Internet]. 2011; 124(1336):24-9. Available from https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2011/vol-124-no-1336/article-monasterio. Accessed 16 April 2019

[3] Braae A. The politics of PHARMAC: The Bulletin. [Internet]. The Spinoff. Available from https://thespinoff.co.nz/the-bulletin/12-04-2019/the-bulletin-the-politics-of-pharmac/. Accessed 15 April 2019.

[4] McAndrew R. PHARMAC to review its practices following funding. [Internet] Stuff.co.nz. 13 February 2019. Available from https://www.stuff.co.nz/national/health/110568230/pharmac-to-review-its-practices-following-criticism-of-breast-cancer-drug-funding. Accessed 16 April 2019.

[5] Jones N. Cancer patients fight for life-extending drugs: 'everyone deserves a decent chance' [Internet] New Zealand Herald. 15 October 2018. Available from : https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=12141330. Accessed 16 April 2019

from 2016[6]. Treatment for all genotypes of HCV has since been funded by PHARMAC from February 2019[7].

The process outlined in paragraph 82 to import a prescription medicine for personal use requires greater detail in order to inform a response. While we understand this process would most likely be included in the regulatory phase of this legislation, we have concerns as to who (SCNSA issuer, pharmacist, or pharmaceuticals wholesaler) would be subject to this process; what actions the patient or person/group acting on behalf of the patient could take in the process; and what forms would be required by the Regulator. The RACP does not support complex, demanding processes or additional costs for procuring prescription medicines being put on to patients, advocacy groups or non-government organisations.

Q B11. Please provide comments on the authorisations created in sections 71-75 and sections 78-80

The RACP looks forward to further engagement from the Ministry in relation to this section, particularly on standing orders.

In terms of controlled activities in relation to a named medicine, the RACP is in support of the draft Bill incorporating a mechanism by which changes could be made, rather than making amendments to the Regulations, which is the status quo. If a future state allows for other category 1 medicines – such as other antibiotics, for example – we encourage any regulations to include a stakeholder consultation as part of this process.

Vending machines and other forms for access to and delivery of medicines should be included in the draft Bill as a future-proofing mechanism. Again, the RACP encourages the Regulator to develop a robust set of criteria for authorisation and use of a vending machine to supply medicines, and consult widely with the health and consumer sectors prior to implementation.

Q B12. Please provide any comments on the offenses created in sections 81-84

The RACP does not support the continued permission of Direct-to-Consumer Advertising (DTCA) of prescription medicines under the draft Bill. Please see our further comments in our response to Question C53.

Part 4 of the Bill: Product approval

Q B14. Please provide comments on the sections covering conditions on approvals and cancellation of approvals (ss 105-113)

The Regulator will need to be well-resourced to administer the approvals process, particularly if significant changes proposed by the Bill are to be made to the existing methodology. The regulation of medical devices – until this point not adequately covered by regulation – is welcomed.

[6] Sheerin I. Potential for public health success in tackling the Hepatitis C virus epidemic. [Internet] N Z Med J; 2017; 130(1467): 73-77. Available from https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2017/vol-130-no-1467-15-december-2017/7447. Accessed 15 April 2019.
[7] PHARMAC. Hepatitis C treatments. [Internet] PHARMAC 1 February 2019. Available from https://www.pharmac.govt.nz/medicines/my-medicine-has-changed/hepatitis-c-treatments. Accessed 15 April 2019.

The emphasis on a single person (the 'Sponsor') in the approvals process may encounter issues in implementation. The RACP contends that it may be more appropriate for a single entity to hold 'Sponsor' designation: over time, people will change roles, leave organisations or industries. Further detail around how the Regulator intends to administer an efficient Sponsor arrangement as part of product approvals requirements would be beneficial in the next stages of the Bill. There may be difficulties in acquiring sponsors for product approvals if the process is perceived as too onerous or places an individual at undue risk or liability.

In instances where a product approval has been declined, the RACP recommends an appeals process is developed for situations where a product may not have been approved but medical practitioners believe there is a demonstrable clinical need for the product.

Special Clinical Needs Supply Authorities and approvals

SCNSAs would be required for all unapproved medicines used in New Zealand, which would include the off-label use of a medicine for a therapeutic purpose. As stated elsewhere in this submission, the RACP has concerns regarding SNCSA and how this might be implemented for unapproved medicines, namely how an 'unapproved' therapeutic use of a medicine would be recorded, and what this information would be used for by the Regulator.

Part 6 of the Bill: Regulator

The RACP notes that the specific form of the Regulator under the draft Bill is still to be determined. Options for consideration include an independent Crown enterprise, or a business unit of the Ministry of Health as is with the existing regulator Medsafe. The RACP favours maintaining the current arrangement, given the excessive cost, time and resources required to establish a new entity.

The Regulator will require expert technical advice from individuals or groups to inform its decision-making. The current Regulator has three standing expert advisory committees, the Medicines Classification Committee, the Medicines Assessment Advisory Committee, and the Medicines Adverse Reactions Committee. Although the existing committee structure may not be retained under the new Regulator, the RACP encourages the Ministry to include provision for standing committees in the new Regulator structure, as well as the ability to seek technical advice from a variety of sectors on an ad-hoc basis.

Q B24. Please provide any comments on the Regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss160-182)

The responsibilities and functions of the Regulator under the proposed Bill may require a significant scaling-up of resources to enable

- A system to continuously monitor the safety of approved, approval-exempt, and lawfully-supplied unapproved products (s 160)
- Administrative systems and processes to issue regulatory orders (as defined in ss 162 – 182).

Product prohibition orders (s 170) and medicine access limitation orders (s 173) may provide additional policy settings to reduce levels of prescription pharmaceutical addiction in New Zealand,

particularly in relation to opioids which may be obtained through repeated and frequent visits to dispensing pharmacies[8] [9].
The definitions in s 172 of the draft Bill require a level of clinical judgement and understanding which may be difficult to obtain easily. Designing a system which can keep pace and effectively monitor drug-seeking behaviours of people who are known to misuse opioids may be challenging, and will rely heavily on prescribers, pharmacists and other health workers to be on alert. The RACP would support the Regulator exercising powers under s 172(3) only once having sought advice from medical practitioners who have a clinical relationship with the individual thought to be an oversupplied person.

Part 8 of the Bill: Administrative matters

Q B32. Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256-274)

Section 267 of the draft Bill outlines proposed requirements for consultation with persons and organisations that the Minister considers appropriate in relation to regulations, rules or notices. Subsection 3 states that "however, a failure to comply with this section does not affect the validity of the regulations, rules, notice, or exemption."

The RACP strongly supports all persons or organisations affected by proposed regulations, rules and notices under the Bill having an opportunity to comment on proposed changes that may affect how patients receive health care or affect health practitioners. Consultation is an important part of democratic process, and rationale as to why consultation is not undertaken in any instance under the Bill should be communicated to the sector. We support the amendment of this section to reflect this.

Chapter C: What the new scheme would mean for different sectors and health practitioner groups

C3: Medical device sector

The RACP has concerns regarding the regulation of tests and diagnostic procedures as medical devices. We see this being a significant area of interest for medical laboratories and find it is not adequately outlined in the Bill or the consultation document. For example, does the Ministry intend for regulation to cover existing products manufactured in laboratories and in-vitro diagnostic procedures, and how would the compliance be determined? The RACP believes that the cost of compliance with new regulations should be modelled across the health sector, given the variety of contexts and settings it covers, from tertiary hospitals to community-based general practices, and from pharmacies to laboratories.

[8] Best Practice Advocacy Centre. Unintentional misuse of prescription medicines. [Internet] Best Practice Advocacy Centre; 2018. Available from https://bpac.org.nz/2018/misuse.aspx. Accessed 16 April 2019.
[9] Health Quality and Safety Commission. Atlas of health care variation: Opioids. [Internet] Health Quality and Safety Commission; 2017. Available from https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/opioids/. Accessed 16 April 2019.

Medical devices cover a vast and diverse range of products. We find a clear difference, for example, between medical devices implanted or inserted into a person, devices that may be a component of first aid (bandages, splints etc.) devices that may be specifically manufactured for an individual (such as artificial limbs), and diagnostic testing in-vitro. As medical devices include in-vitro tests and software under the Bill, there is a need to determine how devices might be grouped together (as medicines are) to ensure that persons with the appropriate levels of skill, knowledge and expertise would be operating or using these devices for a therapeutic purpose. If tests are to be included as medical devices, there is a need to understand how regulation of this category would reduce patient harm.

If approvals are perceived to be complex and compliance costs significant, there may be unintended consequences arising from reductions in the availability of diagnostic testing or treatment options.

The regulation of software as medical devices is another area where more information around what the Ministry would be seeking to regulate would be desirable – for example, would the intention be to regulate any software (including applications) used in clinical practice, such as software which acts as an interface between an MRI machine and a smartphone device allowing a clinician to view and interpret results.

The exponential growth in health technology and applications for personal health is evidenced by the numbers of applications to measure and monitor personal health and wellbeing, and the definitions for software medical devices should align with internationally-accepted standards, such as those used by the United States' Food and Drug Administration (FDA)[10] [11]. Under regulation, software developed locally to meet the needs of antibiotic prescribing, as described in the Australasian Society of Infectious Diseases (ASID) submission on the Therapeutic Products Bill, could be less accessible to non-specialists or academics outside the hospital system[12].

Q C11. Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose should be regulated? If so, are there particular products you are concerned about and why?

The RACP supports regulation for products that have similar features and risks to medical devices or are understood by the public to have an association with health, medicine or medical practitioners. This would include products used in the cosmetic or appearance medicine industries. While we recognise that the intention for these products is in appearance rather than a therapeutic purpose, many of these products are used in the patients that have requested them in an operation performed by a medical or health practitioner who is has a current practising certificate.

If there is concern from the Regulator or the Ministry regarding the emphasis on the 'non-therapeutic' nature of these products, then one option for regulation could be under the Hazardous Substances and New Organisms Act 1996. Another could be augmenting and strengthening the Health (Protection) Amendment Act 2016, which sought to restrict the use of artificial UV tanning services to people aged 18 years and over[13].

[10]Dorsey ER, Chan Y, Yu-Feng MD, McConnell MV, Shaw SY, Trister AD, Friend SH. The use of smartphones for health research. [Internet] Acad Med. 2017; 92(2):157-60. Available from https://journals.lww.com/academicmedicine/FullText/2017/02000/The_Use_of_Smartphones_for_Health_Research.15.aspx. Accessed 16 April 2019.

[11] Food and Drug Administration. Global approach to software as a medical device. [internet] Food and Drug Administration; 2017. Available from https://www.fda.gov/MedicalDevices/DigitalHealth/SoftwareasaMedicalDevice/ucm587925.htm. Accessed 16 April 2019.

[12] Australasian Society for Infectious Diseases. Submission to the Ministry of Health on the Therapeutic Products Bill 2019.

[13] Health (Protection) Amendment Act 2016. p 5.

The RACP supports the regulation of any device that requires insertion, injection or implantation subcutaneously, and the regulation of machines that emit high-intensity electromagnetic radiation for cosmetic and appearance purposes.

C8: Health practitioners (including pharmacists)

Q C43 Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioner's scope of practice (subject to approval from the Minister of Health)?

The RACP considers the Responsible Authorities under the Health Practitioners Competence Assurance Act 2003 to be the bodies through which any alterations or amendments to scopes of practice are raised.

In terms of prescribing authority the balance between patient safety mitigating risks of polypharmacy and public health threats such as antimicrobial resistance, while increasing access and availability to health care and services is a key consideration. Where changes to a prescribing authority are proposed, the RACP supports a process of consultation with other responsible authorities and professional organisations within the sector.

Q C44 Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?

The RACP supports the standardisation of regulation for a consistent approach for form and content of prescribing provisions. Where prescribing authority is approved in the instance of a broader range of scopes of practice, such as Nurse Practitioner or Pharmacist scopes of practice, the RACP supports the following training, supervision and professional development requirements applying in these instances:

- Training in the area of prescribing – for example, pharmacists prescribing the antibiotic trimethoprim for uncomplicated urinary tract infections should have training in antimicrobial stewardship and antimicrobial resistance (including patterns of resistance in New Zealand)
- A supervisory relationship with a health practitioner prescriber
- Undertake a mandatory annual clinical audit as part of professional development activities

Q C46 What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?

Please see our responses in Q B7 and B14 for the RACP's views on the approach for the off-label use of medicines.

Q C18 What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines from overseas would need to be sourced by the issuer of a special clinical needs supply authority, a pharmacy, or a wholesaler?

Please see our responses in Q B10 for the RACP's views on the personal importation of prescription medicines.

Q C53 Do you have a view on whether direct to consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your views?

The RACP does not support direct-to-consumer advertising (DTCA) of prescription medicines, nor direct-to-consumer advertising of medical devices, such as blood tests. The RACP has endorsed the New Zealand Medical Association's position statement calling for the prohibition of direct-to-consumer advertising of laboratory testing in New Zealand[14].

New Zealand, along with the United States of America, remain the only two jurisdictions in the developed world where prescription medicines can be actively marketed to consumers. Both countries have different health systems, with New Zealand having a public health system and self-regulated advertising for prescription medicines, while the US has a majority private-funded health system and advertising regulated by the FDA.

Advertising can be in a range of formats and contexts, including television commercials, print media, radio commercials and internet advertising. Advertisers will deliberately use well-known personalities to front these commercials, giving the impression of authority while maintaining a friendly, personal connection. The fact that the New Zealand government as well as pharmaceutical companies have used such advertorials as the "Family Health Diary" shows the significant brand recognition associated with this marketing channel[15].

A wide range of medicines may be advertised to consumers, with not all being prescription only, as some will be available as pharmacist-only or pharmacy-only medicines. Since 2000, advertisements in New Zealand have included the now-withdrawn Sibutramine (Reductil); medicines for managing diabetes (Lantus insulin); medicines for smoking cessation (Champix); and serotonin norepinephrine reuptake inhibitor Venlafaxine[16].

The RACP finds that DTCA has the potential to compromise patient safety and increase harm. Given New Zealand's self-regulatory approach, to DTCA, there is greater risk for incorrect information to be promulgated to consumers. A 2016 analysis of DTCA for prescription medicines found that fewer than one in four advertisements stated the biologic nature or mechanism of the disease, around 16 per cent identified risk factors or causes, and around 15 per cent stated the prevalence of the condition[17].

In New Zealand, a recent cross-sectional study reported a positive association with DTCA for people who were less physically active, consumed unhealthy diets, and had higher alcohol intakes[18]. Along with previous findings, which found that women, people with lower income, lower levels of education and ethnic minority groups were more susceptible to the messages in DTCA, the authors raise concerns regarding the ethicality of DTCA in New Zealand, particularly its self-regulated status[19].

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[14] New Zealand Medical Association. Direct-to-consumer laboratory testing position statement. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0007/84418/Direct-to-Consumer-Laboratory-Testing-Position-Statement_FINAL_August-2018.pdf. Accessed 16 April 2019.

[15] Brandworld. Family Health Diary. [Internet]. Available from http://www.brandworld.co.nz/family-health-diary.html. Accessed 16 April 2019.

[16] Every-Palmer S, Duggal R, Menkes DB. Direct-to-consumer advertising of prescription medicine in New Zealand. [Internet] N Z Med J. 2014; 127(1401):102-10. Available from https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2014/vol-127-no-1401/6278. Accessed 16 April 2019.

[17] Applequist J, Gerard Ball J. An updated analysis of direct-to-consumer television advertisements for prescription drugs. [Internet] Ann Fam Med. 2018; 16(3):211-16. Available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5951249/. Accessed 16 April 2019.

[18] Zadeh NK, Robertson K, Green JA. Lifestyle determinants of behavioural outcomes triggered by direct-to-consumer advertising of prescription medicines: a cross-sectional study. Aust N Z J Public Health. 2019; 43(2):190-96. Available from https://onlinelibrary.wiley.com/doi/full/10.1111/1753-6405.12883. Accessed 15 April 2019.

[19] Zadeh NK, Robertson K, Green JA. 'At risk' individuals responses to direct-to-consumer advertising of prescription drugs: a nationally representative cross-sectional study. [Internet]. BMJ Open. 2017; 7(12):e017865. Available from https://bmjopen.bmj.com/content/7/12/e017865. Accessed 15 April 2019.

The RACP strongly recommends the prohibition of DTCA for prescription medicines and medical devices in New Zealand.

Conclusion

The RACP supports the intentions of the Therapeutic Products Bill in general but notes there are many important decisions to be made about the operation of the Regulator, and how the various instruments that sit under the Act (once passed) will be determined. The format of this consultation (releasing a draft of the Bill to consult directly with the health sector initially) signals to the College and other groups commenting on the Bill that there is an interest from the Ministry in getting the balance right before the Bill goes to the House.

The RACP thanks the Ministry of Health for the opportunity to provide feedback on this consultation and looks forward to commenting through the Bill's next stages. This is an important change to the health sector in New Zealand, and ongoing consultation with all health practitioners is essential. To discuss this submission further, please contact the NZ Policy and Advocacy Unit at policy@racp.org.nz.

Nāku noa, nā

Dr Jeff Brown
New Zealand President
The Royal Australasian College of Physicians