Response ID ANON-DPZ8-G4XQ-A

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-02-03 10:46:39**

Submitter profile

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Executive summary

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question 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 imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C8 Health practitioners (including pharmacists)

Prescribers

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

Question 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?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

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

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question 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 imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question 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 view?:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question 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 view?:

I strongly oppose DTCA of prescription medications. There are good reasons why the entire developed world except for NZ and the US prohibits this practice. As an ex-pharmacist (previously working in Canada) I can see no benefit whatsoever from this, except for encouraging drug companies to promote their products with catchy slogans while failing to provide important information in intelligible language. Since the 1981 Medicines Act was implemented, the internet has taken over communications. Patients/consumers can find quality information on drugs from reliable, unbiased, third-party sources. At a time when new, costly therapies are testing the limits of our PHARMAC budgets, DTCA is of no benefit to anyone except pharmaceutical companies and is detrimental to patients who see this advertising for products they may never be able to receive. I strongly urge the government to align themselves with the rest of the world and not with the US, which has the most broken health care system in the developed world. Please stop DTCA as soon as possible.

Response ID ANON-DPZ8-G4EG-D

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-02-18 20:53:44**

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:
I have lived and worked in the UK from 2004 to 2012. This was my OE. I was a Locum for most of that time and worked for all the chains and supermarkets. In that time I was Constantly give MUR targets of 2 a day and the yearly funding was for 400 per store. If I did not meet this I was routinely asked not to come back. Boots was the biggest offender. Every pharmacist has pressure put on them to complete these MURs, which at the end of the day we're rubbish and meant nothing clinically. Some patients had no idea what they were. Profits were always put above patient care. It was remarkable as I always wishe d these people lived in NZ as coming to the same pharmacy meant consistency of treatment and care. At the end of the day that's what we studied for. Not to be dictated by a non pharmacist manger who wasn't even supervised. You may open some accessibility but that would saturate this tiny market of ours and wages for employment would decrease. Employees at all boots stores I worked in were missable and clocked watches as no one really cared anymore. I would hate that to happen to us. Please thick patent care rather than economies of scale, we are just to small a market and that's the beauty of our personalised care.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:
No, who is actually the boss here?? I have seen it happen in the UK that the supervisor pharmacist always has to fall in line or the owner , depending on who it is replaces them.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
I hope it is obvious to everyone that profits and corporate greed will be the number one driver in pharmacy, especially with increased competition. It brings the worst out in owners. Look at the Boots the chemist model. Would you really want an unqualified person in a massive discount store not communicating important information to customers as they a kids on minimum wage. To say to your staff make sure you do the Rx in 20 mins so customers can buy more. How is that helpful, when we have so many in debt that keep spending due to all the purchasing options we have now. LAYBUY etc. I have lived it for 9 years in England. Totally disengaged employees

Question C34 - Are there ways in which Option 2 could be improved?:
Don't do it!

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:
No, this would never happen in practice. I know from personal experience by working in a Corporate store that I wasn't involved or cared as much until I had some skin in the game. Any small business owner will tell you that.

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

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Question 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 imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

My name is Joel Lexchin. I taught health policy at York University in Toronto Canada from 2001 to 2016 and I have been an emergency department physician for 36 years, of which the past 30 have been at the University Health Network also in Toronto. I am the author or co-author of over 200 peer reviewed publications about pharmaceutical policy in Canada and internationally, including my book *Private profits versus public policy: the pharmaceutical industry and the Canadian state* (University of Toronto Press, 2016). In 2001, I was retained by Pharmac in New Zealand to review its policies and procedures.

Between 2015-2018, I was a paid consultant on three projects: one looking at indication-based prescribing (United States Agency for Healthcare Research and Quality), a second to develop principles for conservative diagnosis (Gordon and Betty Moore Foundation) and a third deciding what drugs should be provided free of charge by general practitioners (Government of Canada, Ontario Supporting Patient Oriented Research Support Unit and the St Michael's Hospital Foundation). I also received payment for being on a panel that discussed a pharmacare plan for Canada (Canadian Institute, a for-profit organization) and for writing a brief for a law firm. I am currently a member of research groups that are receiving money from the Canadian Institutes of Health Research and the Australian National Health and Medical Research Council. I am member of the Foundation Board of Health Action International and the Board of Canadian Doctors for Medicare.

The draft Therapeutic Products Bill, currently out for consultation (1), proposes to continue to allow direct-to-consumer advertising (DTCA) of prescription drugs subject to regulation by an independent regulator, the nature of which is yet to be decided. This submission is a response to Questions C52 and C53 and in that context focuses on the extent to which DTCA can be adequately regulated, drawing on American literature.

Studies looking at the three main forms of DTCA – broadcast advertising, print advertising and sponsored websites – have each found that the quality of information that they contain is seriously flawed. By far, the largest amount of money is spent on television advertising, about US $4 billion out of a total of $6.5 billion (2). A review of DTCA ads airing on television between 2008-2010 concluded that 46/84 (55%) of the most frequently made claims were potentially misleading (3). An earlier analysis of television ads found that while 82% made some factual claims and 86% made rational arguments for product use, only a quarter described the causes of the condition, risk factors or prevalence. Without an understanding of why health problems develop, patients are unable to develop strategies to modify lifestyle or other risk factors. In addition, more than half of the ads portrayed the product as a medical breakthrough (4) whereas in fact only about 11% of new drugs offer a substantial therapeutic improvement over existing products (5).

Two more recent papers show continuing significant deficiencies in pharmaceutical ads; one included all English-language broadcast DTC ads for prescription drugs that aired in the United States from January 2015 to July 2016 (6). No ads described drug risks quantitatively, whereas drug efficacy was presented quantitatively in 25 (26%) ads. Thirteen (13%) ads, all for diabetes medications, suggested off-label uses for weight loss and blood pressure reduction, despite off-label advertising being prohibited by the Food and Drug Administration (FDA). Few ads were fully compliant with FDA guidelines. In the most recent paper, Applequist and Ball (7) examined 61 ads that were broadcast during prime time in the US on 4 major cable television networks from July to October 2016. The ads largely showed how products can enable users to undertake more recreational activities and only 7% of ads presented alternatives to product use. Overall, despite existing regulations, televised

American DTCA continues to promote prescription drugs inappropriately; it is apparent that the purported educative and public health role of such ads has taken a back seat to companies' commercial agenda.

Ads in magazines generally demonstrate the same problems as broadcasts ads. In 67 unique drug ads that appeared in 1998 and 1999, two-thirds used emotional appeals and almost 90% described the benefits of the medication with vague, qualitative terms while only 13% used hard data. None of the ads mentioned cost (8). Ads for bleeding disorders in a patient-directed magazine devoted twice the amount of text to benefits as compared to risks/adverse effects, and the information about the later was more difficult to read. Based on appraisals by experts, only slightly more than one-third of the ads presented the claims fairly and accurately (9).

DTCA websites were found to describe benefits on the homepage 82% of the time, whereas risk information was two clicks away in 75% of cases. While most websites had a direct link to benefit information in the main navigational button set on the homepage, only 8% of websites provided the same tool for risk information (10). Industry-funded mental health websites were significantly more biased toward genetic and other biological causes of illness and toward medication than were sites that were financially independent of the industry (11).

The available evidence, summarized above, shows that effective regulation of DTCA has been virtually impossible to achieve. The number of FDA violation letters is decreasing despite a growth in the volume of DTCA (2) without any evidence that the quality of DTCA has improved. The reason for this decline is unclear but possibly due to the under-resourcing of the FDA's Office of Prescription Drug Promotion which now receives nearly 100,000 promotional material submissions annually (2). In light of the vigorous and evolving promotional strategies used by the pharmaceutical industry, it is thus unrealistic to expect that a revised regulatory system in New Zealand could ensure that commercially-driven DTCA can serve the public interest by presenting a realistic and unbiased drug information.

The consultation document is equivocal about whether in sum DTCA has positive or negative effects (1), but as Gleeson and Menkes note "Drugs promoted via DTCA are often early in their product lifecycle and sometimes subsequently manifest serious harms leading to market withdrawal" (12). What happened with rofecoxib (Vioxx) is a prime example of what Gleeson and Menkes referred to. It was introduced onto the American market in 1999 and one year later, Merck spent $160 million on DTCA to drive its use (13). By the time it was pulled from the market in late 2004, the estimate is that in the US it was responsible for 88000–140000 excess cases of serious coronary heart disease (14).

Further evidence regarding the impacts of DTCA on New Zealanders indicates that these ads are commonly misinterpreted as trusted public health messages (15) and are more likely to affect vulnerable subgroups (16) and those with unhealthy lifestyles. Taken together with the international evidence that regulation has consistently failed to prevent the inappropriate promotion of prescription medicines, these findings suggest that DTCA is more likely to cause harm than benefit and should be banned.

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1. Ministry of Health. Therapeutic products regulatory scheme: consultation document. Wellington; 2018.
2. Schwartz L, Woloshin S. Medical marketing in the United States, 1997-2016. JAMA. 2019;321:80-96.
3. Faerber A, Kreling D. Content analysis of false and misleading claims in television advertising for prescription and nonprescription drugs. Journal of General Internal Medicine. 2013;29:110-8.
4. Frosch D, Krueger P, Hornik R, Cronholm P, Barg F. Creating demand for prescription drugs: a content analysis of television direct-to-consumer advertising. Annals of Family Medicine. 2007;5:6-13.
5. Lexchin J. Health Canada's use of expedited review pathways and therapeutic innovation, 1995-2016: cross-sectional analysis. BMJ Open. 2018;8:e023605.
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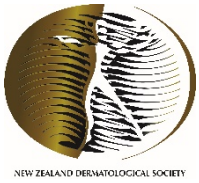
11. Read J, Cain A. A literature review and meta-analysis of drug company-funded mental health websites. Acta Psychiatrica Scandinavica. 2013;128:422-33.
12. Gleeson D, Menkes D. Trade agreements and direct-to-consumer advertising of pharmaceuticals. International Journal of Health Policy and Management. 2018;7:98-100.
13. Peters J, Nel D, Adam S. Reaching and influencing consumers in the prescription medicine market. Marketing Intelligence & Planning. 2009;27:909-25.
14. Graham D, Campen D, Rita H, Spence M, Cheetham C, Levy C, et al. Risk of acute myocardial infarction and sudden cardiac death in patients treated with cyclo-oxygenase 2 selective and non-selective non-steroidal anti-inflammatory drugs: nested case-control study. Lancet. 2005;365:475-81.
15. Every-Palmer S, Duggal R, Menkes D. Direct-to-consumer advertising of prescription medication in New Zealand. New Zealand Medical Journal. 2014;127:102-10.
16. Zadeh N, Robertson K, Green J. 'At-risk' individuals' responses to direct to consumer advertising of prescription drugs: a nationally representative cross-sectional study. BMJ Open. 2017;7:017865.



The New Zealand Dermatological Society Incorporated (NZDSI) request that sunscreens be categorised as therapeutic goods.

New Zealand has arguably the highest rate of melanoma (40.5 per 100,000 for men and 30.9 per 100,000 women((1) and non-melanoma skin cancers (estimated to affect between 1:3 and 1:2 New Zealanders before the age of 80) per population in the world, and many more New Zealanders die each year from skin cancer than on the roads 2,3). Sneyd estimated over 90,400 non melanoma skin cancers for 2018. The economic burden of skin cancers is estimated to well exceed NZ$66million (3).

Sunscreens form an important part of reducing primary and secondary skin cancer development (4-6), through providing physical or chemical reduced ultraviolet damage and immunological adverse effects to the skin (7). They are critical therapy for paediatric and adult patients with photosensitivity disorders, e.g. polymorphic light eruption, lupus erythematosus, porphyria, vitiligo etc and conditions for which the drugs they need, render them more susceptible to sunburn. Sunscreens are critical therapy for people with skin cancer precursors and skin cancers to reduce progression and further development of new lesions. Sunscreens also have a role in prevention of future skin cancer development in the outdoor population.

Consumer NZ has tested numerous sunscreens available to consumers, in recent years. They have found and continue to find many fail to meet the standards the products claim (8). Our Australian neighbours, do regulate sunscreens to ensure they meet the required standard (9).

The purpose of the Therapeutic Products Act 2018 is to protect personal and community health by—
(a) ensuring acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle; and

(b) regulating the manufacture, import, promotion, supply, and administration or use of therapeutic products.

The benefit to New Zealanders if sunscreens were listed under the therapeutic products list, is that necessary regulation would then ensure quality, safety, efficacy and product performance meets the required Australian and New Zealand Sunscreen Standard (AS/NZS 2604), to protect individual patients and community health.

Please add sunscreens to the NZ Therapeutic Products register.

References:

1. Ministry of Health NZ provisional statistics for melanoma 2016 www.archive.stats.govt.nz
2. New Zealand Skin Cancer Primary Prevention and Early Detection Strategy 2017-2022 March 2017. Health Promotion Agency and Melanoma Network of New Zealand (Melnet) ISBN: 978-0-478-44901-3
3. Expected Non-Melanoma Skin (Keratinocytic) Cancer incidence in NZ for 2018. Report of for the New Zealand Health Promotion Agency. Mary Jane Sneyd (Senior Epidemiologist, Public Health Research and Consulting Services), Andrew Gray (Senior Biostatistician). March 2018

4. Daily sunscreen application and betacarotene supplementation in prevention of basal-cell and squamous-cell carcinomas of the skin: a randomised controlled trial. Green A[1], Williams G, Neale R, et al. Lancet 1999 Sep 18;354(9183):1038.
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7. Ultraviolet radiation and the skin: Photobiology and sunscreen photoprotection. Young A, Claveau J, Rossi A. JAAD 2017;76;3(Suppl 1):S100-S109.
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9. https://www.tga.gov.au/publication/australian-regulatory-guidelines-sunscreens-args

Company Response to NZ Ministry of Health Response to Therapeutic Products Regulatory Scheme Consultation

Submissions due to NZ Ministry of Health by 18-Apr-2019

Background

The Company is an innovative specialty pharmaceutical company headquartered in Melbourne, Australia (Emerge Health Pty Ltd) with an additional New Zealand entity established (Emerge Health NZ Ltd). Our primary objective is providing life-saving and/or hospital medicines. Our current New Zealand product portfolio includes only registered medicines (prescription and OTC). In the past, we have provided unapproved therapeutic products to the NZ market via Section 29 supply.

Question A1 (page 20)

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

1. ***Support***
2. ***Partially support***
3. ***Neutral***
4. ***Partially don't support***
5. ***Don't support***

Company Response

The Company wishes to express its general support (i.e. Option 1 above) of the proposed Therapeutic Products Bill. The majority of the Company's registered products are based on European and Australian dossiers. As such, the alignment of the Medsafe processes with the standardised formats and processes used overseas will also facilitate the efficiency of the submission process for future applications/variations.

Submitted to NZ Ministry of Health 19 March 2019

Therapeutic Devices Regularity Scheme Response.

My Name Is Peter Elder and I am a University of Otago graduate with a PhD degree in Chemistry. I have been employed as a Scientific Officer by Canterbury District Health Board since 1978 in the Steroid section of Clinical Biochemistry. I am also a member of the NZ Hospital Scientific Officers Assn (NZHSOA).

Executive Summary

- Stop advertising medicines. Only NZ & USA allow advertising.
- New Startup Companies subjected to same stringent requirements on staff and management that apply to current health providers. Ie DNA advice from anybody today.
- Costs associated with registration of current 'in-house tests 'carried out by IANZ. No need to duplicate and add large overheads to current and future 'in-house tests' carried out by international agency with high credentials and processes.
- Allow for diversity across NZ medical establishments, hospitals, laboratories pharmacies etc.

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

Yes with qualifications.

The new scheme (MoHa) will bring under legal control all medical services & goods to the general public. At present a large number of medical 'goods and services' are delivered by either private or public hospitals and pharmacies. These institutions are under guidelines that include operators having medical and science degrees of high standard that are overseen by colleges associated with medical degrees, (e.g. ANZ College of Pathologists) and in the case of ancillary staff the Medical Sciences Council of NZ. There is a considerable cost associated with running and maintaining these institutions born by both staff, health boards and private medical hospitals.

I assume that in future new startup companies would need to provide qualifications and experience consistent with the regulations relating to accredited groups already practicing under present guidelines. As an example at present it is possible to offer genetic medical testing using DNA to the general public with little oversight as to medical and science training of a high standard usually associated with such practices.

Australia and indeed every other country with exception of the USA prohibit advertisements w.r.t health products and services. NZ should prohibit advertising of medical devices and products similar to the Australian model.

The Australian model that has been in existence for a number of years has both positive and negative aspects that should be noted.

A huge increase in costs associated with registration and regulation of devices has occurred. Within NZ hospitals a large number of medical tests would be caught up in this new act. Private laboratories have access to funding for approximately 200 individual tests all of which are either handled by machine or readily available kits from international firms such as Bayer, Roche and Abbot. Canterbury Health Laboratories has approximately 2000 tests. Most of the tests are "in-house" and are in addition to the 200 commercial tests mentioned. All the in-house tests have been registered and approved by IANZ after demonstration that they follow established scientific principals together with quality control procedures. The costs associated with registration and regulation over and above the costs associated with IANZ regulations would prohibit the continued use of a number of tests This would give medical consultants less diagnostic options and result in lower health outcomes and a general lowering of health standards for all NZ's.

I have been employed as a scientist to assist in the analysis of endocrine diseases using a number of techniques and over the years we have made several 'in-house kits 'to analyze the steroid pathways within humans. Thus the consulting clinicians with CDHB have been able to diagnose the relevant disease state of the patients referred to them by GP's throughout the country. All this activity has been scrutinized and analyzed by IANZ (International accreditation NZ) and has conservatively saved CDHB $200 000 pa in commercial kits. Over and above these savings have been the costs associated with IANZ inspection.

Thus if 'in-house kits and assays' were regulated further with large costs associated with extra regulations and overheads, the only outcome can be less diagnosis and large increase s of cost to the NZ health system with little or no associated benefit in terms of safety for the general public.

To date we have published all the in-house kit scientific data in medical journals of some standing so as to enable our techniques to be scrutinized and judged by other medical scientists worldwide. The cost of 'in-house kit' evaluation by MoHa would place a large and expensive addition upon CDHB and indeed all DHB's. Unless recompense for this additional cost was forthcoming from the Government, research and development would flow to the multinational companies such as 'Roche' and 'Abbot'. The consequences will be the following.

A patient sample from Auckland was sent to us to analyze a steroid and its companion protein in blood. This was due to the patient being diagnosed with a rare life threatening condition of adrenal insufficiency. The patient sample had been analyzed by two competing laboratories in Auckland each confirming a diagnosis of Addison's disease. Both laboratories were using similar equipment. CHL's analysis provided the correct diagnosis of normal hormone status using a different method of analysis saving the patient from lifelong treatment for a nonexistent disease. The use of multinational equipment by all institutions comes with unforeseen costs, sometimes with tragic outcomes.

If we as a laboratory are forced into using the same commercial kits and platforms that abound in other NZ laboratories, both hospital and private, diagnosis such as that above will continue with the same outcomes of incorrect diagnosis and treatment all with large and increasing costs to the NZ taxpayer. There are any number of worldwide quality assurance schemes that have bimodal result distributions due to differing aspects associated with analytical techniques where a significant section of results come from the use of a single commercial kit. Even when standardized controls are used other aspects still gives varying results. Reducing analytical diversity results in all having the same result even when incorrect.

The emergence of new tests has resulted in older tests being superseded in all laboratories including ours but the ability to innovate and experiment has meant the CDHB can offer the largest menu of analytical results to all NZ citizens at a fraction of the cost of commercial kits where they are available.

There are few wee drafting oddities in the draft TPB that I expect that the Council will draw to your attention in its submission, but one that is too small to bother with is s 14A(2)(a).

The bolded reference to section 11A(2) should, I think, be a reference to section 11A(2)(a). Leaving it as section 11A(2) would capture both s11A(2)(a) and (b), but s 11A(2)(b) seems redundant given the reference to the requirement for Minister's approval in 14A(2)(b).

Another oddity is that section 14B(1) (which states that, that in exercising a power under s 11A or s 14A, the Minister must be guided by the purpose and principles set out in section 3 and 4 of the TPA), essentially duplicates, and arguably renders redundant, similar provisions in s11A(6) and s14A(7).

You may already have picked these up, but just some thoughts for a sunny Friday..

Oops one more minor one I just saw..

Given s 14A(5)(a) (RA required to comply with direction within the time specified in it), shouldn't there be an addition to s14A(3) – or a new (3A) – that any direction must include a direction as to the time within which the RA needs to comply?

To whom it may concern,

On behalf of Waikato Senior Medical Staff Association, I would like to communicate our strong preference to cease Direct to Consumer Advertising, as part of the Therapeutic Products Regulatory Scheme consultation.

Our feedback on this issue is that, in an opinion which is informed by many decades of collective experience, there is an overall much greater risk of patient harm than patient benefit.
Thus while DTCA does present information, it is routinely biased. The generic nature of the advertising means that the appropriate personalised risk benefit evaluation cannot occur. The delegation of this responsibility to a medical practitioner is then devolved without direct consultation to this practitioner.
We are using this opportunity to provide this feedback.

There is a risk of inappropriate prescribing due to pressure being applied by the targeted advertising audience, when a non prescribed lifestyle modification may offer greater benefit for less harm.
Furthermore a generic substitution may offer the same benefit for less cost.
There may also be the potential for unnecessary, excessive prescribing to occur, with the associated cost implications.
The submission from the Waikato Senior Medical Staff Association is that Direct to Consumer Advertising should cease.

Yours faithfully
Margot Rumball
Chair
Waikato Senior Medical Staff Association

Responses to questions on the draft Therapeutics Products Regulatory Scheme

March 2019

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?

All prescribers should be carrying out an annual self-audit review/peer review and this should be established within the regulations within organization's who support this clinical activity. Currently Bpac carry out an audit of prescribing for clinician who choose to sign up to this system, this should be made compulsory for ALL prescribers.

C45 Please provide any comments on the approach to standing orders.

A combined primary/secondary Medicines Management Governance Group is needed in each DHB area to create standardized SO, review them, issue them to primary and secondary services, deliver training to nurses and carry out SO prescribing audits and monitor supplies of medications for SO. Each group should be no more than eight people and compromise of a pharmacist, Doctor, Nurse, Dentist, NP, Patient, PHE rep, DHB rep. a good example to look at would be the National Family Planning process around standing orders- as robust and though process and governance.

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

The off label approach will open conversations between health practitioners and services users, ensure safety of use and indulge a dialogue that includes OTC and alternative therapy medicines.

C47 What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that:

Only medical practitioners would be able to issue a special clinical needs support authority for this type of unapproved product

Other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?

Nurse Practitioners are authorized prescribers and specialist in various health conditions and SHOULD be included in this proposal NOT just GP's!

Otherwise not a problem.

C48 In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?

Where one HPP is running a clinic and a colleague is nearby and able to supply medication to that colleague for a patient who is unable to access the medication needed.

In emergency situations where lifesaving medication is needed and a HPP has medication and can supply.

C50 Do you consider health practitioners should be authorized to supply pharmacy (category 3) medicines to their patients? What are the benefits and /or risks of allowing this?

Patients with chronic disease trust their health practitioner with advice regarding cat 3 OTC medication for minor ailments. HPP should be able to provide a prescription for cat 3 medicines to reduce any risk of interaction with other medications the patient is taking.

If patients do not have a chronic health problem with polypharmacy then they should be able to go to the pharmacy to get cat 3 medicines directly.

***Benefits** –*

Patients' safety from drug interactions (many people do not carry a list of medicines they take everywhere they go and do not always use the same pharmacy).

Some patients may not be able to afford some Cat 3 medicines so being able to get this on prescription will reduce ED attendance for minor ailments.

Having cat 3 medicines available on standing orders (SO) will allow supply to patients attending rural clinics and low socioeconomic groups

***Risks** –*

Increased workload for HPP as more people will expect a prescription for cat 3 medicines unnecessarily.

Patients never tell their HPP what cat 3 medications they are taking and this may not be asked – perhaps – increasing the risk of interaction of medicines.

Margarita Bartlett – Nurse Practitioner –Primary care.

March 2019

To Whom it May Concern,

Those of you deciding how all aspects of this bill will work, will need to keep as a touchstone, that MEDICINES **CANNOT** BE TREATED AS NORMAL ITEMS OF COMMERCE. This means, you MUST build in a sufficient range of systemic controls, to prevent greed causing a range patient harms, both large and small.

1. Medicine prescribing and dispensing must be kept clearly separated by a high legislative fence:
    a. A registered doctor told me he wanted to be able to dispense like he had been able to in South Africa. There, he could buy Coversyl very cheaply; he then 'prescribed Coversyl to everyone that came in, whether they needed it or not, 89-Rand thank you very much!"
    b. Pharmacy workers in the UK, within a more open pharmacy structure, who are routinely directed by the non-pharmacist owners to sell (products) regardless of the best health advice for the individual patient, pass the blame on "the employer made me do it". The employer hides behind having no professional registration to lose. Only a registered pharmacist can take ultimate responsibility for the running of a pharmacy.
    c. Do not permit grandfathering of existing permissive interpretation of the rules. We have been lucky that GXH has effectively been under the control of pharmacists – there is no reason to prevent this changing in an instant.
    d. Any pharmacist prescribing must also remain subjugated, e.g. as part of an MDT team.

2. Pharmacist leadership and company control is vital:
    a. Pharmacists are subject to fearsome internal professional peer oversight. The risk to personal reputation within the profession is the very most effective method of controlling aberrant behaviour, on the rare occasion I have felt a more senior pharmacist was in need of a reality check, I have only had to suggest we seek clarity from a local leading colleague and the default position of what is unquestionably right was immediately adopted – no-one ever wants to look bad within the eyes of such a small profession.

3. Medicines must be kept in a controlled location
    a. If a medicine is not in a pharmacy, busy people will not store it securely (when they have to suddenly leave the room); store it safely e.g. in a controlled temperature environment or keep their stocks in date, accounted for and current, because that can only occur in a premise with the same standards as a pharmacy. This then becomes a pharmacy, so there is no advantage if medicines are not provided from pharmacies.

4. Innovation:
    a. Community pharmacies are facilitators of safe innovation. Community pharmacies have invested heavily in innovation over the last 5 years, including $10M+ in automated dispensing systems, and is not a "block" to innovation. Community pharmacists have had to balance the societal constraints of the medicines and pharmacy legislation, are routinely audited to ensure that they do so, and prevent the use of out dated medicines; second hand medicines; the introduction of imported copy medicines into the supply chain.
    b. As health professionals community pharmacies have, until the Supermarkets became involved, not been stockists of alcohol, cigarettes and sought evidence based information regarding vaping. Not all innovation is positive.

c. Community pharmacies, because they are in imbedded within their communities, take responsibility for most of their own medicine deliveries. This means potentially harmful medicines are not left to be accessed by children; are not left out of the fridge, go to the wrong address or left in the sun to degrade.

5. Supply chain
    a. The main risk New Zealanders face is failure to prevent counterfeit medicines being used. This must be prevented and therefore self-imported medicines must remain precluded with real penalties for rule breakers.

Yours sincerely

Alistair Whyte

April 2019

Consultation Feedback
Ministry of Health

To whom it may concern

RE: Therapeutic Products Regulatory Scheme Consultation

Thank you for the opportunity to provide feedback on the above named scheme. Highlighted below are the areas that we have addressed from the perspective of Registered Nurses employed by Secondary Schools.

Positives

- ✓ Clarifies that a health practitioner (non-prescriber) does not need authorisation to administer a category 2, 3 or 4 medicine. This supports the work of nurses employed by secondary schools as it clarifies in legislation that those nurses who are not prescribers, have the ability to administer a range of common treatments to their patients.

Comments/Questions

- The consultation document proposes that a health practitioner (non-prescriber) does not need authorisation to supply a category 3 or 4 medicine. With regard to the category 3 medicine this is only to 'patients of that practice'. The phrase 'of that practice' is not further defined. How does this apply to nurses working in a school setting who are providing care to students and staff?
- Appropriately trained Registered Nurses can apply for authorisation from Nursing Council to supply emergency contraception (Levonorgestrel; category 1 medicine). It is unclear if this authorisation is actually for the prescription of this medication, and how this fits with international/national/ and local guidelines recommending the use of doses and timeframes that are unapproved in New Zealand. The consultation document suggests that regulations will cover pharmacists in regards to prescribing Trimethoprim. Is this also an appropriate way to cover Registered Nurses in regards to Levonorgestrel?
- Registered Nurses as providers of primary healthcare in a nurse led service do not have the same access to medical supplies as their colleagues with prescribing rights (e.g. emergency contraception, paracetamol, pregnancy tests, condoms, spacers). This limited access to medical supplies can increase barriers to appropriate healthcare for patients, is there scope to address this issue?

Counties Manukau Health
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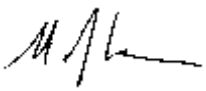
- The medicines and medical devices that are available to practitioners with prescribing rights through PSO (Practitioner Supply Order) are not kept up to date in line with patient needs and current guidelines. Is there a new process in development that will allow this to occur?
- Secondary school nurses currently administer salbutamol (category 1 medicine) as emergency treatment to students under a letter of authority from the Ministry of Health (R12700001-00). Would stipulating this in regulations be a more appropriate mechanism for this?

Sincerely,

Julia Burgess-Shaw
Youth Service Development Manager

Dianne Dawson
Clinical Nurse Specialist-Youth Health

Kate ChiTar
Nurse Practitioner-Youth Health



Heather Laxon
Clinical Nurse Specialist-Youth Health

New Zealand Hospital Scientific Officers' Association Inc
Home of the Specialist Medical Scientist
NZHSOA

Submission on Therapeutic Product Bill

To The Ministry of Health,

The New Zealand Hospital Scientific Officers Association (NZHSOA) was incorporated in 1985 and is the professional association for Specialist Medical Scientists employed as Scientific Officers in either the private or public sector. Hospital Scientific Officers provide highly specialised scientific and medical resources to other health practitioners and their patients. We have a strong and demonstrable history of providing medical devices in medicine and improving the patient journey. We would like to consult on the draft therapeutic product bill to ensure we continue to provide high quality medical devices and maintain our reputations as lead players in clinical diagnostics within New Zealand.

Medical Devices-IVD

Exemption for in-house IVD

If the bill sets out the boundaries for the scope and development of the subordinate legislative instruments then we believe the proposed exemption for in-house IVD is dealt to in the bill. An exemption for in-house IVD used within DHB laboratories is crucial to Hospital Scientific Officers providing high quality medical devices and maintaining our expertise in clinical diagnostics for the wellbeing of New Zealand population.

Under the Health Practitioners Competence Assurance Act 2003 ("HPCAact") the practice of medical laboratory science is a **restricted activity**. Furthermore, under the HPCAact the scopes of practice for Medical Laboratory scientists are gazetted to include medical laboratory science **research and development** (1). These conditions within the HPCAact allow medical laboratory scientists scope to make in-house IVD. Given the protection within the HPCAact for medical laboratory scientists to develop in-house IVD we believe this activity can be exempted from the TPB. Encompassing this is also the situation where in-house IVD is supplied to other medical laboratories for the practice of medical laboratory science by registered medical laboratory scientists.

The following is an excerpt from a document circulated from the Pathology Roundtable where it was proposed that health institution laboratories would not require a licence under the TPB but went on to propose definitions within the TPB as a consequence.

"The regulations would need to define what is meant by health institution laboratory (for example to cover hospital laboratories and other pathology labs, and possibly also other laboratories such as ESR). The regulations would also have to spell out the nature of the caveat relating to accreditation by a recognised third party accreditation body."

We believe these definitions are unnecessary as all medical laboratories are accredited under ISO15189:2012 to meet the Essential Principles that ensure IVD are fit for purpose, furthermore all medical laboratory practitioners are regulated by the HPCAact.

All other IVD

For all other IVD used in medical laboratories we believe the TPB is subordinate to the HPCAact. This will allow health practitioners surety of purpose. For example, the use of a medical device that meets the conformity criteria set out by the TPB is not sufficient in terms of the HPCAact, as under our scope of practice further validation and verification of medical devices is required. Furthermore, a medical device that meets the conformity criteria of the TPB and is subsequently found to fail in the clinic provides health practitioners scope to refer the product to the TPB regulator. If the HPCAact has superiority over the TPB we help ensure protection of personal and community health.

Under ISO15189:2012 all medical devices used in medical laboratory testing are done within quality management systems. As such all medical devices in medical laboratories are validated for use and there is ongoing verification that they are fit for purpose. The ongoing verification of medical devices performance could be included in the regulators post market surveillance with health practitioners to submit reports on clinical performance to the

regulator. While mandatory reporting of issues is required of sponsors post market surveillance should also be expected from health practitioners.

Another point to consider is the emergence of diagnostic consumer devices for example smartphone-based monitors for sleep, glucose, blood pressure etc. They are beneficial as a clinical resource promoting a virtual diagnosis outside traditional structures and while individual devices may conform to the essential principles of a good IVD manufacturer the ability to make a diagnosis comes under competence of health practitioners and the HPCAact.

Bioinformatics is also increasingly used in diagnosis. For example, in genetic testing databases are interrogated by software applications to aid diagnosis. Many of these databases are not domiciled in NZ and thus not within reach of the TPB regulation. However, as the diagnosis is performed by a health practitioner the activity is regulated by the HPCAact.

Feedback loop

The risk matrix is a useful means of assessing the conformance requirements of a new medical device, however it is possible that a device may be wrongly classified and cleared for use with reduced assessment on conformance. It can only benefit personal and community health if those who use IVD to make diagnosis have the ability to interact with the regulator. In quality management systems it is referred to as the feedback loop.

Therapeutic products

At the time of preparing this submission we came upon the case in Europe of babies with foetal valproate syndrome (FVS). Their mothers are demanding public enquiries into why they were not warned of the risks of taking an anti-epilepsy drug while pregnant. Studies had indicated there was an increased risk of neural tube defects when women took sodium valproate however it was not until February 2018 that the European Medicines Agency

recommended that sodium valproate should not be used during pregnancy. The following is a pertinent quote from Carl Heneghan, professor of evidence-based medicine at the University of Oxford, who said by 1992 it was "clear with some certainty...there were increased risks of neural tube defects". "It's very clear to us that everybody acted too late – regulators, governments, drug companies, journal editors, prescribers. The most important issue here is that the commercial complex seems to override patient safety." (2)

That the commercial complex was perceived to override patient safety is worrisome when legislation was in place. The medical device industry is a strong economic driver and we need to ensure the regulation implemented by this bill truly protects personal and community health. One countermeasure we believe is that health practitioners should have an interactive role with the regulation system adopted in New Zealand under the TPB. With the ever increasing repertoire of new medicines and devices it will be hard for a regulator to keep pace with conformance assessments, adopting conformance reports from other authorities is a sound approach. We believe the most prudent approach for NZ is to implement an improved post market surveillance system that integrates with health practitioner assessments.

Regulatory Independence

We also suggest that the funding agency for therapeutic agents in NZ is independent of the TPB regulator. In the example quoted above commercial interests trumped patient safety and this must be considered under this legislation.

Cost and flexibility of Regulation

Another aspect is the cost of regulation. We do not wish to see commercial IVD providers leaving the NZ market due to regulatory costs. Such a scenario will affect the overall service. Furthermore, the regulations must be flexible and support timely availability of therapeutic products, hence we favour the adoption of conformance assessments from regulator approved bodies.

Direct-to-consumer advertising (DTCA)

The NZHSOA does not support DTCA of therapeutic products and devices. Marketing of prescription medicines is unnecessary and may conflict with Pharmac's role.

The NZHSOA is happy to assist further with this regulation should you require our input.

Yours sincerely,

Paula Keating, Secretary NZHSOA

References:

1. NEW ZEALAND GAZETTE, No. 135 — 10 DECEMBER 2015 Notice of Scopes of Practice and Prescribed Qualifications for the Practice of Medical Laboratory Science

2. The Irish Times Fri, Mar 22, 2019, Mothers of children with foetal valproate syndrome demand public inquiry https://www.irishtimes.com/news/social-affairs/mothers-of-children-with-foetal-valproate-syndrome-demand-public-inquiry-1.3835645

New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

9 April 2019

Ministry of Health

By email: therapeuticproducts@moh.govt.nz

Therapeutic Products Bill Exposure Draft and Proposed Regulatory Scheme

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. The NZMA is New Zealand's largest medical organisation, with more than 5,000 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our response has been informed by feedback from our members, Advisory Councils and Board.

General Comments

1. The NZMA welcomes the development of the Therapeutic Products Bill and accompanying regulatory scheme which are intended to replace the Medicines Act 1981 and associated regulations. We agree that the Medicines Act 1981 is dated, inflexible and prescriptive, and has significant gaps in coverage. To address current weaknesses, we note that changes in three broad areas are proposed: i) shift to a principles-based legislative framework; ii) coverage expanded to include a range of products (including devices); iii) regulator to be provided with a set of tailored and responsive regulatory tools. We are generally supportive of these high level changes. However, we have a number of concerns relating to specific aspects of the regulatory scheme that are being proposed. We elaborate on these concerns in the following paragraphs.

2. We are generally supportive of the objectives for the regulatory scheme. In particular, we welcome the objective to provide assurance of acceptable safety, quality and efficacy or performance of therapeutic products. We also welcome the objectives to provide regulation that is efficient and cost-effective, flexible, durable, up to date and easy to use, and that ensures high-quality robust and accountable decision-making. However, we have some concerns at the objective to 'support New Zealand's trade and economic objectives' and seek clarification on what this entails. We would be concerned if safety, quality and efficacy or performance of therapeutic products are in any way made, or at risk of being made, subordinate to trade and economic objectives. It is our view that a regulatory scheme for therapeutic products should be insulated, as far as is possible, from possible obligations that could ensue from trade and

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investment agreements that could undermine the primary objectives of ensuring safety, quality and efficacy or performance. Equally, it is important, when negotiating trade and investment agreements, to ensure that such obligations do not restrict the government's ability to regulate for health, including in the arena of therapeutic products.

Specific Comments

Exclusion of natural health products

3. The New Zealand Medical Association (NZMA) is very disappointed that complementary and alternative medicine products are not being brought under the Therapeutic Products Bill and associated regulatory scheme. We consider this to be a missed opportunity. We have long been concerned about the array of natural health products on the market, with consumers making uninformed choices based on unproven health claims, with no assurance of product safety, quality or efficacy. While the Natural Health and Supplementary Products Bill would have gone some way towards addressing our concerns,[1] this Bill was not reinstated following the change of Government in 2017 with no satisfactory explanation provided.

4. We note that definitions of therapeutic purposes that are made in the exposure draft of the Bill are broad and include purposes such as "alleviating or compensating for a disease or ailment"—purposes that are similar to claims that are sometimes made by natural health products. Given this overlap, it is difficult to understand the logic behind developing exclusion provisions for natural products from this Bill. Health literacy in New Zealanders is often insufficient for many people to know the important differences between approved medicines and complementary and alternative medicines. Furthermore, the currently permitted practice of co-locating complementary and alternative medicine products and evidence-based medicines in pharmacies, with both categories being sold by pharmacists, gives inappropriate legitimacy to natural health products.

5. It is the NZMA's view that natural health products should fall under the regulatory scheme for all therapeutic products, such as is the case in Australia. We believe that complementary and alternative medicine products must also be subject to evidence-based scientific testing. This includes ensuring an adequate assessment of safety, with specific consideration given to post marketing surveillance and adverse reaction monitoring. We have previously called for a two-tier regulatory system to be considered for natural health products, which would provide appropriate safeguards, with pre-market assessment as a requirement for higher-risk products. We note that such a two-tier system operates in Australia. We seek an explanation as to why natural health products are to be excluded from the Therapeutics Products Bill and associated regulatory scheme. We would also like to know more about the options the Government is considering for regulating natural health products, including specific timeframes.

Medical devices

6. We are supportive of more robust regulation of medical devices than is currently the case. At present, medical devices in New Zealand are not subject to any pre-market regulatory scrutiny to assess safety and performance, and post-market controls are minimal. We note that under the

[1] NZMA. The regulation of natural health products. Submission to the Ministry of Health. 15 February 2016. http://www.nzma.org.nz/__data/assets/pdf_file/0009/47079/NZMA-Submission-on-the-regulation-of-natural-health-products.pdf; NZMA. Natural Health Products Bill. Submission to the Health Committee. 23 February 2012. http://www.nzma.org.nz/__data/assets/pdf_file/0014/1607/sub-naturalproductsbill.pdf

scheme that is being proposed, the intention is to apply the full range of pre- and post-market controls for medical devices in accordance with the risk-based model developed initially by the Global Harmonisation Taskforce and continued and maintained by the International Medical Device Regulators Forum. We support this approach and believe it will bring New Zealand into line with international best practice. However, it will be important to ensure that regulation does not adversely impact the availability of, and support for, medical devices. We also contend that it is necessary to better define the scope of devices that are to be covered as well as build in exceptions to the usual regulatory requirements for certain situations (eg, devices used to diagnose rare conditions or emerging epidemics).

7. While our view is that the additional benefits to public health and safety conferred by stronger regulation of medical devices must remain the main priority, there is a need to give particular consideration to the potential impacts of the proposed regulation on the cost and availability of products. We note that while the split between the costs of regulation recovered from industry and those met by the government has not yet been decided, it is expected that a significant proportion of the costs would be recovered through industry fees or charges. We are aware that PHARMAC, as the funding agency, is expanding its role to assume responsibility for the procurement of medical devices. We would be concerned if these separate, but parallel, developments led to the reduced availability of necessary medical device products in the New Zealand market due to commercial considerations—particularly given the small size of the New Zealand market and the funding environment in which industry operates. We are encouraged that the regulatory scheme that is being proposed would allow the regulator to rely on work done by other recognised authorities. For medical devices, we note that these authorities are expected to be a mix of third-party conformity assessment bodies, such as those designated under the EU system, and national regulatory bodies.

8. We have some concerns that the range of medical devices that would fall under the Bill would be too wide and potentially impractical. Given the definitions of therapeutic purposes that are proposed, a medical device could be anything that is used for "preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury". As such, this could be taken to include any piece of laboratory equipment or reagent used for a laboratory test. It could also be taken to include the use by a health practitioner of bathroom scales, or a tape measure (used to measure girth or head circumference). We believe that it would be useful to have a clearly defined limit to the scope of what is covered by the Bill.

9. The proposed regulation of *in-vitro* diagnostic medical devices may be problematic for specialised diagnostic laboratories that provide 'in-house testing' for rare conditions for which no commercial kits are available. Often such assays clearly provide clinical benefit and yet cannot reasonably be validated and rigorously evaluated to the standard that would be expected of a commercial product. Another area where this could cause problems is when new in-house assays need to be developed quickly, for example in response to an epidemic of an emerging infectious disease (eg, SARs, MERs, Ebola, pandemic influenza). Accordingly, it is essential to build clear provisions allowing for exceptions in these situations into the legislation. In addition, diagnostic tests for rare but important conditions will never be commercially attractive but are of course needed. Imposing overly rigorous and onerous constraints on specialised laboratories may make compliance practically unfeasible and this would pose a risk of harm / reduce the quality and scope of diagnostic services, particularly in highly specialised areas and for rare conditions. While protecting safety is the paramount consideration, it is important to keep in mind the principle of beneficence. There is a risk that unduly high regulatory requirements could ultimately reduce access to specialist testing and treatments.

Direct-to-consumer advertising of prescription medicines.

10. We are strongly opposed to the draft Bill continuing to permit direct-to-consumer advertising (DTCA) of prescription medicines. Currently, New Zealand and the United States are the only countries in the developed world to allow DTCA of prescription medicines. We believe that the development of the Therapeutics Products Bill represents an important opportunity to end this practice and bring New Zealand in line with the rest of the developed world. Research signals that DTCA provides information that is likely to be biased in favour of benefits over potential harms, leads to unnecessary prescriptions, iatrogenic harm, and increased costs to the taxpayer (particularly through driving demand for costly branded medicines over cheaper effective alternatives).[2] DTCA may also adversely affect the doctor-patient relationship.[3] We refer officials to our position statement on DTCA of prescription medicines for further details.[4]

11. A specific issue which is of particular importance with respect to DTCA is the development of antimicrobial resistance. We draw attention to the New Zealand Antimicrobial Resistance Action Plan,[5] specifically priority action areas one (strengthening public understanding of appropriate antimicrobial use) and two (reviewing and, if needed, amending regulations on advertising of antimicrobials, including DTCA). We contend that continuing to allow DTCA of antimicrobials in light of these critical priority action areas makes no sense and represents policy incoherence.

Authority to prescribe to be established in, and bounded by, scopes of practice under the HPCAA

12. We have major concerns with changes to the approach to authorising which practitioner groups may prescribe. Rather than listing practitioner groups in the Act or regulations, we note that authorisation to prescribe would be established via relevant profession's scopes of practice under the Health Practitioners Competence Assurance Act (HPCAA) with the draft Bill defining a 'health practitioner prescriber' as a health practitioner whose scope of practice includes prescribing. We understand that this approach would require amendments to the HPCAA in order to make it explicit that a scope of practice can include prescribing, and that the Minister of Health's approval would be required before a scope of practice could include a new or amended authority to prescribe. We note that the new scheme would no longer have categories of prescribers (such as authorised, designated and delegated prescribers). Where a prescribing authority includes particular restrictions or requirements, this would be reflected in the scope of practice. Where particular health practitioner groups are restricted to prescribing certain medicines, we are aware of a proposed shift away from lists of named medicines to "other logical groupings". We are very concerned that a shift away from formal gazetting of lists of medicines

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[2] Every-Palmer S, et al. Direct-to-consumer advertising of prescription medication in New Zealand. N Z Med J. 2014 Aug 29;127(1401):102-10. https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2014/vol-127-no1401/6278; Metcalfe S. Changes to time trends for inhaled corticosteroid use and costs in New Zealand since April 2002. Draft 5, 29 September 2003. Unpublished report for PHARMAC. Available from https://www.pharmac.govt.nz/assets/changes-time-trends-inhaled-corticosteroid.pdf

[3] Robinson AR, et al. Direct-to-consumer pharmaceutical advertising: physician and public opinion and potential effects on the physician-patient relationship. Arch Intern Med. 2004 Feb 23;164(4):427-32. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/216701

[4] Direct-to-consumer advertising of prescription medicines. NZMA position statement. June 2018. http://www.nzma.org.nz/__data/assets/pdf_file/0005/83480/Direct-to-Consumer-Advertising-of-Prescription-Medicines_June-2018.pdf

[5] Ministry of Health and Ministry for Primary Industries. Antimicrobial Resistance: New Zealand's current situation and identified areas for action. 2017. Wellington: 2017. https://www.health.govt.nz/publication/new-zealand-antimicrobial-resistance-action-plan

(as is currently the case with designated prescribing) towards "other logical groupings" under a scope of practice (or even outside a scope of practice as has been suggested) represents a retrograde step—both in terms of a weakening of transparency/public scrutiny and the potential for ambiguity (how is a 'logical group' defined, for example?).

13. We have previously conveyed our concerns with the proliferation of independent prescribing rights for various non-medical health practitioner groups[6] as well as with shifting authorisation of who is entitled to prescribe to Responsible Authorities (RAs) regulating health practitioners under the HPCAA 2003.[7] We continue to believe that existing scopes of practice for most RAs are insufficiently specific to cover safe and appropriate prescribing restricted to a practitioner's competency. Furthermore, given that scopes of practice are self-defined by RAs, an RA wanting to assume prescribing rights for its profession could simply redefine its own scope of practice, undertake a consultation process and then report back to the Ministry which has limited competency to assess clinical considerations. If previous experience regarding changes to an RAs scope is anything to go by, what a profession's RA says tends to be what we end up with. This is of particular concern given that RAs are not set up, or funded appropriately, to be able to appropriately oversee safe prescribing of all allied health practitioner groups. It is likely that only the very worst cases of inappropriate prescribing are likely to be reported to them.

14. If prescribing rights are to be tied to scopes of practice, then we believe it is necessary to acknowledge that most of the current scopes for RAs are inadequate for that purpose (or for that matter many other purposes). If the current proposal is to be progressed, we also consider it essential to establish a system where scopes of practice are not independently determined by the profession's RA, but must instead be agreed by all of the professional groups where there is an overlap of scope. There is a risk that professional groups seeking greater professional independence will look to expand their scopes, including prescribing, on the grounds of improved access but with the potential for negative impacts on patient safety and integration of care. It will be essential for the Ministry or a separate entity to oversee the system of RAs. Furthermore, when seeking a new, or a change in, prescribing authority, relevant RAs must be required to consult widely including with professional groups such as the NZMA.

Pharmacy ownership, pharmacy activities, licensing and control

15. The GP sector has been advocating for changes to existing restrictions in these areas for some time to provide better health care to patients and improve the primary care system. Although there are a range of views, we are in favour of modifying the current restriction on prescribers from taking a financial interest in a pharmacy. While the current restriction reflects concerns about the potential negative influence of commercial incentives on prescribers if they could benefit financially from their prescribing decisions, we believe there are several legitimate arguments for change. For example, providing medications to patients at the time they require them, without the extra steps of having to visit a pharmacy, hand over their prescription and then wait or return to collect the medications, should increase adherence (and therefore improve outcomes). Many rural practices already dispense medicines that they prescribe—this is hugely appreciated by patients. Pharmacists already dispense prescribed products that are fully funded (eg, emergency contraceptive pill, trimethoprim for UTI). Even though a prescription is not

[6] Non-medical prescribing. NZMA position statement. July 2013. http://www.nzma.org.nz/__data/assets/pdf_file/0005/16979/Non-medical-prescribing-2013.pdf

[7] Draft options for the regulation of prescribing and dispensing in New Zealand. NZMA submission to the Ministry of Health. 20 January 2016. http://www.nzma.org.nz/__data/assets/pdf_file/0009/46692/sub-draft-options-for-the-regulation-of-prescribing-and-dispensing2.pdf

formally written, the commercial aspects underlying such dispensing are the same in all other respects.

16. Our view is that potential conflicts of interest that could arise from the above change are better viewed as professional and ethical issues. Rather than attempting to legislate for such matters, we believe that health practitioners should be accountable for managing potential conflicts of interest through meeting relevant ethical and professional standards. Health practitioners regularly manage such conflicts of interest. For example, no similar legislative restrictions apply when it comes to taking financial interests in general practice, private hospitals, or private specialist practice. Furthermore, with respect to prescribing activity, audits of prescribing that are currently conducted would be expected to identify aberrant prescribing.

17. The consultation makes a number of unsubstantiated claims regarding pharmacy activities. For example, paragraph 465 asserts that "the need for professional control of pharmacy activities by a pharmacist is clear". Paragraph 471 then goes on to state that the Government is considering two options "to ensure pharmacy activities remain under the control of a pharmacist". We believe that these assumptions about pharmacy activities warrant challenge and we seek evidence to support such statements.

18. With respect to pharmacy ownership, we do not believe that there is a need for pharmacies to be majority owned and effectively controlled by a pharmacist. Currently, a pharmacy license can only be granted to a company if a pharmacist has more than 50% of share capital and is not in effective control of the company. Individuals who are not pharmacists are restricted from holding a pharmacy license or holding a majority interest in a pharmacy. The consultation describes how this approach is not working as originally intended—ownership requirements are not well defined and have allowed a wide range of business arrangements to develop. Yet before proposing options to ensure pharmacy activities remain under the control of a pharmacist, we submit that it is necessary to clearly articulate why this control is necessary. Other health sector services such as General Practice do not have similar requirements.

19. It remains our view that opening up the ownership of pharmacy beyond pharmacists may better facilitate innovation and integration of services. Furthermore, the ability to ensure pharmacy services in rural communities may be improved if a pharmacist majority owner is not required. For example, under an opened-up ownership model, the pharmacy could be co-owned by general practice, a community interest / trust or a PHO (or other business interests).

Commissioning and funding of pharmacy services

20. We are not convinced that the Therapeutic Products Bill and accompanying regulatory scheme should attempt to address moves to support new commissioning and funding arrangements of pharmacy services. We note that the stated purpose of the Act is to protect personal and community health by: (a) ensuring acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle; and (b) regulating the manufacture, import, promotion, supply, and administration or use of therapeutic products. We cannot see how supporting commissioning and funding arrangements of pharmacy services has any relation to the officially stated purpose of the Act, and therefore question the appropriateness of addressing these areas in this legislation.

21. We do note however that a number of proposed regulatory measures relating to future regulation of pharmacy business activities are intended to support DHBs shift to more tailored commissioning of pharmacist services. The consultation reports that "DHBs are also shifting

from a one size fits all approach to a tiered commissioning model. This would provide national contracts for the supply of medicines and standardised services, while allowing DHBs greater flexibility to commission services locally, based on their specific needs." We have previously conveyed our concerns at proposals to create a new service agreement in parallel with the existing agreement for Community Pharmacy Services.[8] It is useful for DHBs to be able to look at flexible funding models for their pharmacy services that may lie outside the traditional frameworks centred around community pharmacy. If there were to be suggestions that DHBs enter into commissioning or contracting for pharmacy services outside the community pharmacy model, such changes to service design must be informed by a robust evidence-based approach. This work would need to be undertaken before changes are implemented and before new regulatory measures are introduced.

Categorisation (classification of medicines)

22. Currently, the medicines classification schedule is used as the tool for enabling wider access to specified medicines in particular categories, with entries such as 'prescription medicine except when supplied by pharmacists with appropriate training". This has been applied to various medicines such as erectile dysfunction drugs, trimethoprim and the combined oral contraceptive pill. The NZMA has had a number of concerns with such provisions.[9] We note that under the new scheme, regulations would instead be used to provide an authorisation, with the class of health practitioner who has the authorisation to perform specified activities listed along with named products or classes of products. We do not believe the proposal addresses our previous concerns but seek more details on this proposal. One particular issue that needs to be considered in any such proposal is the impact of widening access to antimicrobials on antimicrobial resistance. We note that the consultation states the regulator would be able to seek advice from an expert committee in relation to decisions about switching an active ingredient in a medicine from one category to another and therefore change the category of medicines with that ingredient. We submit that the regulator **must** be required to seek advice from an expert committee about such changes.

Modified approach to the use of unapproved medicines

23. We note that the draft Bill contains a modified process for accessing unapproved medicines (which include medicines prescribed for an off-label use), with an additional requirement for a special clinical needs supply authority (SCNSA). We note the intention of this modified process is to try to minimise the use of unapproved medicines in New Zealand by making sure prescribers are giving appropriate consideration as to whether unapproved medicines are the best option for the patient. While we agree, in principle, with this intention, we have some concerns relating to both of the main types of SCNSA are being proposed.

24. With respect to the off-label use of medicines that have been approved in New Zealand, we understand the aim is to authorise all health practitioner prescribers to issue a SCNSA for off-label use (as long as the medicine is covered by their scope of practice) with minimal requirements for what that SCNSA would need to involve (potentially a tick box). We believe that it is important to avoid the SCNSA assuming yet another onerous bureaucratic requirement for busy doctors, particularly when the prescription of medicines for off-label use is common

[8] Proposed Integrated Pharmacist Services in the Community Agreement. NZMA submission to TAS. 9 April 2018. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0013/82210/NZMA-Submission-on-Integrated-Pharmacist-Services-in-the-Community.pdf

[9] Agenda for the 51st meeting of the MCC. Submission to Medsafe. 25 March 2014. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0016/26530/sub-agenda-of-51st-meeting-of-the-MCC.pdf

practice. On the other hand, it is arguable whether a 'tick box' SCNSA would add any value. There is often a degree of comfort with off-label prescribing for non-approved indications as safety will have already been established (albeit for different indications). In some instances, however, prescribers may not be aware that a specific indication / population group they are prescribing for is off-label.

25. For medicines that do not have a product approval in New Zealand, we note that the intention is to continue to limit the ability to issue a SCNSA for these products to medical practitioners only, in line with the current approach to such medicines. We support this approach and would be opposed to widening access to unapproved medicines to other health prescriber groups. We note that this approach is also intended to increase awareness of the additional accountability that a medical practitioner takes on when prescribing this type of unapproved medicine. We are comfortable with the proposal that once a SCNSA has been issued, any health practitioner prescriber would be able to prescribe that medicine for the patient as long as it is within their scope of practice.

Personal importation rules

26. Under the new scheme, we note that while people will continue to be allowed to import non-prescription medicines from overseas, they will no longer be allowed to import prescription medicines. We recognise that this proposed change reflects a trade-off between balancing people's personal freedoms (by allowing non-prescription medicines to be personally imported) with the management of the risk presented by unknown products (which is more serious in the case of prescription medicines). However, we believe that it is vitally important to ensure that where appropriate, patients are still able to access prescription medicines from overseas that are approved but not funded in New Zealand. Currently, patients can import such medicines providing they obtain a prescription. A small number of patients depend on accessing unfunded medicines from overseas in this way, and such medicines have produced major benefits in terms of reduced relapse rates and improved survival in patients with certain types of cancers, for example. We note that under the new scheme, the ability for parallel importing of approved medicines that are not funded in New Zealand would be curtailed due to safety considerations. However, the consultation document appears to provide scope to authorise parallel importation of approved products "in exceptional circumstances". We seek an assurance that patients requiring access to such medicines will continue to be able to access these under the new scheme, and seek more details about how this would work.

27. With respect to the importation of unapproved prescription medicines, we note that persons wanting to import these would need to consult a medical practitioner to seek a SCNSA. If this is provided, the person would need to obtain the medicine either directly from their prescriber or a pharmacy. The pharmacy or issuer of the SCNSA could import the medicine themselves or obtain the medicine from a licensed wholesaler that was authorised to import and supply unapproved medicines. We note that the rationale for this approach is that those in the regulated supply chain have more knowledge of where they can safely source this product from. It will be important to ensure that importation requirements for prescribers / pharmacies / licensed wholesalers, and the SCNSA process, are as streamlined as possible so that patients who previously imported unapproved medicines that are not funded in New Zealand themselves can, when appropriate, continue to access these.

Permits

28. We wish to raise some concerns regarding the content and effect of permits under the proposed new regulatory system. In addition to licensing (the normal process for therapeutic products coming in to New Zealand), SCNSA (requiring application by a health practitioner for a named patient), and the exceptional circumstances being proposed to allow parallel importation of products that are approved in New Zealand, we understand that permits will provide a further way for therapeutic products to (legally) come into New Zealand. While the consultation document states that "permits are intended to be used for shorter-term and/or urgent situations" few details are provided of the purposes for the granting of permits.

Our main concerns about permits extend to the following:
i) the criteria for granting a permit (Section 135 of the Bill) does not reflect use limited to short term and/or urgent situations—in fact, the Bill proposes granting permits for up to 2 years;
ii) The fact that permits can specify by class rather than individual could potentially mean supply to large groups of people;
iii) Anyone can apply for / be granted a permit—unlike for an SCNSA, there does not appear to be any requirement for a health practitioner or prescriber to be involved;
iv) We seek clarification of monitoring requirements for unapproved medicines in use via permits. While license holders (sponsors) are required to participate in pharmacovigilance and processes such as recalls, it is not clear what (if any) monitoring requirements will apply for permit holders;
v) We seek clarification on whether permit holders will be subject to the same sanctions as are proposed for sponsors for similar breaches.
While we accept that the above concerns may be addressed under yet-to-be developed regulations and rules, we are concerned that they represent possible gaps in patient safety arising from circumventing usual processes to ensure product safety and the safe and appropriate use of products.

29. We note that the consultation document states that “a permit may be a suitable approach for buying groups that have identified a suitable and safe supplier”. We seek clarification on whether the Ministry is supportive of this concept, as well as what it would mean for New Zealand's medicines system if an expansion in the use of permits for the purpose of group buying have the effect of diminishing PHARMAC’s role.

Clinical trials

30. We have major concerns regarding the proposal to make conducting clinical trials of therapeutic products a controlled activity requiring authorisation. We are not convinced by the rationale for this change, particularly given that the existing requirements for ethics approval already take into consideration matters relating to safety and methodology. We are very concerned that the proposal would represent an additional layer of bureaucracy that would further impede and delay clinical trials, with negative consequences for the researchers and the health of New Zealanders.

31. A number of the proposed criteria associated with the requirement to make clinical trials a controlled activity are unduly onerous or duplicate existing provisions. Currently, there is already a requirement by Ethics Committees for clinical trials to be registered as meeting Good Clinical Practice (GCP). We note the proposed requirement for the licensee to be a fit and proper person and seek clarification on expected time frames to meet this. We also note the proposal for the regulator to have the power to monitor trials and audit clinical trials. We believe that these

proposals are unnecessary as most trials already have Data Safety and Monitoring Boards (DSMBs). We seek further information about the criteria for the proposed monitoring or auditing requirements. In paragraph 424, we note the proposed additional requirements for trials continuing beyond 12 months. Our view is that the idea of a 12 month licence is completely impractical. Most clinical trials take 3 to 5 years, therefore having to reapply to continue every 12 months under the proposed new scheme is completely unnecessary.

Range of tools available to the regulator

32. We welcome the wider range of tools that would be available under the new scheme to encourage compliance and deal with serious offending. We agree these would enable more appropriate and timely responses when non-compliance occurs. We note the hierarchy of enforcement tools includes tiered criminal offences, enforceable undertakings and infringement notices. These tools would allow the regulator a wide range of enforcement options, meaning enforcement action could be commensurate with the severity of misconduct, and the regulator's approach could be flexible according to circumstances.

Pharmacovigilance

33. We welcome the proposed requirement for sponsors to have explicit legal obligations in relation to post-market monitoring, reporting and risk management for their products. We believe this is an advance on the current situation where such obligations are recommended but not underpinned by legislation. We note that it is proposed that these pharmacovigilance requirements would be set out in regulations, with the intention being that they would be aligned with international norms.

We hope our feedback is helpful and would like to be kept informed of this work as it progresses.

Yours sincerely

Dr Kate Baddock
NZMA Chair

Response ID ANON-DPZ8-G4R7-A

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-13 12:48:34**

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question 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 view?:
As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Ingo Schommer

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10 April 2019

Therapeutic Products Regulatory Scheme
Ministry of Health
PO Box 5013
Wellington 6140

By email therapeuticproducts@moh.govt.nz

CONSULTATION ON THE DRAFT THERAPEUTIC PRODUCTS BILL

Thank you for the opportunity to comment on the exposure draft of the proposed Therapeutic Products Bill (the Bill). PHARMAC's feedback on key issues is provided below. This feedback builds on the conversations and workshops that PHARMAC staff have had with Ministry of Health staff throughout the development of the draft Bill.

The Bill covers a large variety of issues and topics. We have focused our analysis and feedback on the areas of the draft Bill that we consider are most relevant to PHARMAC's activities. These areas include: medical devices regulation; the approval pathways for new medicines or medical devices; the provisions relating to unapproved products; and provisions that might have an impact on equitable access to medicines or medical devices. We also have some interest in the topic of direct to consumer advertising (DTCA).

PHARMAC is broadly comfortable with the high-level regulatory framework provided in the draft Bill. However, we have identified areas where we would like more information on the detailed implementation of this regulatory framework. We look forward to continued engagement with Ministry staff on the development of the regulations and other subordinate instruments that will contain these details.

Medical Devices

We note that the Bill represents significant change for medical devices, which have previously been unregulated (aside from some post-market controls). PHARMAC is increasing its involvement and activity with the medical devices sector, so we have a strong interest in ensuring that the regulatory scheme for medical devices is robust and fit for purpose.

We understand that the intent of the proposed scheme is that medical devices approvals would be relatively streamlined and would be based, as far as possible, on global models of regulation. We support this approach.

We are conscious that much of the operational detail will be contained in regulations or other regulatory instruments, and it will be important to get this detail right. We are keen to be consulted on the development of all relevant regulations and other subordinate regulatory instruments, to help ensure that these global models of regulation can be implemented effectively in the New Zealand context.

Approval pathways

We are supportive of the increased flexibility offered by more approval pathways for medicines and medical devices and greater recognition of overseas regulators [s 207]. This greater flexibility would potentially reduce administrative barriers to approval/registration, which could have a positive impact on the willingness of suppliers to bring their products to the New Zealand market.

Unapproved products

We acknowledge that the need for access to unapproved products would potentially reduce under the new scheme due to the greater flexibility offered in approval pathways. However, we consider that there would still be some situations where formal approval/registration is not feasible.

The relevant circumstances where PHARMAC may wish to facilitate access to unapproved products include:

- Individual patients seeking treatment in exceptional circumstances;
- Where a product listed for funding under the New Zealand Pharmaceutical Schedule (the Schedule) is out of stock and an alternative unapproved product needs to be funded temporarily (and potentially at short notice) to ensure continuity of supply;
- Where PHARMAC has funded (or wishes to fund) a product via a listing on the Schedule that is unlikely to ever be submitted for regulatory approval in New Zealand, perhaps due to the low value of the New Zealand market (e.g. less than $50,000 income per annum for the supplier);
- Where a hospital wishes to be prepared for a potential emergency situation. An example is the precautionary purchasing of snake anti-venom.

We understand that the first of these situations (individual patients) would be provided for through the proposed Special Clinical Needs Supply Authority (SCNSA) provisions [s 39]. From the information provided to date, we consider that these provisions would sufficiently meet the needs of individual patients in exceptional circumstances.

From our understanding and discussions with Ministry of Health staff, the remaining circumstances set out above seem to be adequately provided for via the proposed permit mechanism [ss 131-135]. These provisions appear to be a very useful and flexible tool.

We note that the permit mechanism is intended as an exceptional circumstances provision only and is not intended to be routinely used by suppliers to get access to the New Zealand market. Should this approach proceed, PHARMAC is committed to applying this principle in our dealings with pharmaceutical suppliers and the expectations we place on them.

Off label use

Another area of interest regarding unapproved products is the 'off-label' use of products outside of their formal approval, including compounded medicines. In these circumstances it appears that a SCNSA or other exemption/authority would potentially be required. We understand that Ministry of Health officials are working to minimise the barriers to off-label use where appropriate. We would be interested in engaging with you further on this issue as required.

Naming: Special Clinical Needs Supply Authority

As noted in our earlier discussions with Ministry of Health officials, there is a risk that the authority for import and supply may potentially be confused with approval for funding (via the Pharmaceutical Schedule or via PHARMAC's Exceptional Circumstances framework). This risk is heightened in relation to unapproved products because the proposed term "Special Clinical Needs Supply Authority" for product import and supply is very similar to the term "Special Authority" used in the Pharmaceutical Schedule for restricted funding. We ask that you consider using an alternative phrase/title to minimise this risk.

Access Equity

PHARMAC has a key organisational goal of eliminating inequities in access to medicines by 2025.

PHARMAC's main concern with respect to equity and the new regulatory scheme is to ensure that the scheme is sufficiently permissive and flexible that it does not inadvertently create any barriers to equitable access. We are also keen that the scheme allows for future models of care and service delivery that would facilitate more equitable access, particularly in community-based settings.

We have identified instances where regulatory 'workarounds' are currently being used under the Medicines Act to provide greater access and management of certain medicines for population groups facing inequities - such as the use of standing orders for patients accessing gout medications. We consider that this is potentially an instructive example of how existing regulatory tools can be used to provide better access to therapeutic products in inventive ways.

There are a number of initiatives contained in the Bill that are aimed at increased flexibility, and which we support, including:

- distribution and supply arrangements that would enable pharmacy services to be provided outside a traditional retail pharmacy business (e.g. rest homes, marae-based services, events such as Field Days, mobile pharmacies);

- the possibility to use licenses (or other tools) to allow certain controlled activities, such as permitting alternative professionals to prescribe or supply prescription medications in some circumstances [s 54]; and

- the proposal to allow Health Practitioners and Health Practitioner workers to supply 'pharmacy-only' medicines within the scope of their practice [ss 61(2) and 65].

Prescribing periods

Duration of supply (prescribing periods) is an issue we are particularly interested in from an access equity point of view. With longer periods of supply, patients would require fewer GP consultations and pharmacy visits (and would be able to avoid associated costs) in order to continue accessing needed medications. We consider that prescribing periods should be as permissive as possible, within the bounds of safety and other relevant considerations. Ideally, the duration of supply should be led by the circumstances of the individual patient, rather than an inflexible directive.

This is currently controlled via the Medicines Regulations 1984. We are very interested in being involved in the development of the new regulations that would govern prescribing periods under the new regulatory scheme.

Direct to Consumer Advertising (DTCA)

There is no evidence that PHARMAC's current activities are significantly affected by DTCA. However, there are some areas of our work where we see there are potential impacts. The primary area of concern relates to the potential unfavourable impacts on our implementation activity, particularly with regard to brand changes. PHARMAC sometimes chooses to change the brand of a medicine listed for funding on the Schedule. While many of these brand changes are implemented smoothly, in some cases in the past pharmaceutical suppliers have sought to use consumer advertising in a manner that undermined a proposed brand change.

We also note that, while the Pharmaceutical Schedule is specifically excluded from the definition of advertising in legislation, it is not clear whether some of PHARMAC's other activities would also fall outside the definition of advertising (e.g. advocating Hepatitis C testing in order to access newly funded medicines or development of patient focussed leaflets to provide information about a funded brand change). If DTCA were to be banned, this issue would need to be explored further.

Thank you again for the opportunity to comment on this draft of the Bill.

Yours sincerely

Sarah Fitt

Sarah Fitt

PHARMAC Chief Executive

THE HEARING HEROES

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Therapeutic Products Bill Consultation

April 2019

Submission of The Hearing Heroes Ltd

Overview

The Hearing Heroes submission is specifically focused on the provision of Hearing Aids and related devices and products and is supportive of aspects of the Bill as it relates to the manufacture, testing and approval to meet standards and wholesale distribution of the products. It is also supportive of the restriction of who is approved to fit Hearing Aids to specific groups (i.e. paediatric) where specialist training is required and where specific tailoring of the Hearing Aid shape and fit is necessary for the user of the device. It encourages careful drafting of the Bill to ensure cost effective, efficient and scalable access to hearing health care products and services is available via modern communication technology such as the internet, where it is appropriate to do so.

The Hearing Heroes

The Hearing Heroes Ltd is an organisation which has been established by people who have a significant combined experience in the hearing health care industry. The skill and knowledge base of the individuals involved cover manufacturing, wholesale distribution, clinic based fitting and academic areas of the hearing aid and hearing health care sector. The organisation is focused on utilising professional produced hearing assessments to enable the set up and programming of devices, which are directly delivered to the wearer, who is then supported through a blend of remote phone and internet-based support and clinic-based support. The Hearing Aid it self is purchased from our web site.

The Regulatory Scheme

The Hearing Heroes is supportive of a regulatory scheme that ensures the safety, quality, and performance of Hearing Aids. Standards should be set out that ensure manufacturers and wholesale distributors meet quality management, packaging, labelling and safety standards and can prove they can conduct swift and effective product recalls in the event of a product issue arising. However, we propose caution in the creation any aspect of the Bill that too tightly restricts the retail sale and distribution of Hearing Aids and any legislation or rules that allow any one industry group or body to gain control over all the retail distribution methodology and systems.

Hearing Aids

Hearing Aids are currently categorised as class 4 medical devices. While they are a medical device, certain versions of Hearing Aids provide low to minimal negative risk to the health of the person using the device.

Hearing Aids are produced in various forms and broadly fit into three categories

a) The Hearing Aid electronic componentry is contained in a separate housing that sits behind the persons ear. A small tube containing a wire transmits the sound to a receiver (loud speaker) that sits in the entrance of the persons ear canal. This category is commonly referred to as 'Receiver in Canal' (RIC) and is the most commonly worn device. It presents practically no physical risk to the person using the device.
b) The Hearing Aid electronic componentry is contained in a separate housing that sits behind the persons ear. A tube carries the sound from the device into the persons ear canal. Often a silicon-based mould is custom made for the client that sits in their ear canal and retains the sound tube in place. The Hearing Aids are referred to as 'Behind the Ear' (BTE) devices and typically used for people with a more severe hearing loss. The silicon mould is custom made and the process of taking an impression of the client's ear canal requires specific training and care. While the Hearing Aid itself poses nil to minimal negative risk to the person, the process of creating the impression for the mould does.
c) A plastic shell is custom made to fit inside the persons ear canal. The electronic components and power source (battery) are housed inside the shell. These devices are individually made for each person and tend to be the most problematic to fit, work effectively and provide long term reliability. They require a trained clinician to take an impression of the persons ear canal and fit the assembled device to the person. They are referred to as 'In the Ear' (ITE) devices. They represent around 20% of all Hearing Aids sold and while the hearing aid itself presents little negative risk to the person, the process of impression taking, fitting and the ongoing nature of having an electronic device in your ear canal presents a higher level of risk.

Hearing Aids are complex and highly developed electronic devices controlled and managed by advanced technology and software. They all contain safe guards to ensure any negative risk to the person is minimised. For instance, all Hearing Aids have maximum sound output limitations to ensure there is no chance of the person being exposed to sudden loud noise that could damage their hearing.

It is the position of The Hearing Heroes that a blanket restriction across the supply and fitting of all Hearing Aids is unnecessary in relation to the risk elements to the person wearing the device. Receiver in the Canal (RIC) devices represent nil to low negative risk. From a physical nature perspective, they are managed in a similar way to commonly available earbuds and headphones except they are individually tuned to each person's particular hearing loss.

However, Hearing Aids that require some level of customised intervention and manufacture do expose the person to some level of risk, especially during the assessment and fitting process. It is important that these processes are restricted to and carried out by trained professionals.

Assessment of A Persons Hearing

Each persons hearing loss is different. Hearing loss can be caused by a number of things and affect people in different ways. Assisting someone with a hearing loss is not just a matter of providing amplification of sound. The hearing loss needs to be assessed so that the Hearing Aids can be specifically tuned to that individuals needs. Today, the client and hearing assessment is best carried out in a face to face consultation with a trained professional.

However, technology advances are rapid in this area and like many health care disciplines, the use of technology to make assessments of clients is proving to be valuable and increasingly accurate. On line hearing tests and electronic 3D scanning technology is available today and is continually improving. There are several on line tests that have been independently verified as being 98% accurate when compared to traditional face to face in clinic tests. 3D ear canal scanners can provide on line visual images of an ear canal for assessment and the electronic image of the shape of the ear canal is proving to be more accurate than physically taken impressions by clinicians in a clinic environment.

The Hearing Heroes is supportive of legislation that protects the safety of people where they are exposed to negative risk, however it recommends that the introduction of legislation is carefully crafted to ensure it does not restrict or block the use of technology-based advances that can provide efficiencies and improved standards

Cost Effectiveness

The Hearing Heroes recognise the importance and value of professionally trained clinicians working in hearing health care. The assessment and care of people, especially those at the higher risk parts of the hearing loss spectrum (paediatric, vulnerable elderly, specific acute cases) needs to be conducted by appropriately trained professionals. The cost of providing these services is high because

a) The training is extensive
b) Audiologists and Audiometrists are in short supply globally. Not enough are being trained to meet the needs of this rapidly growing sector, and so the cost of individual clinicians is high.
c) The cost of operating physical clinics is high and so the number of clinics and their locations are restricted.
d) The use of technology in this industry is high. Manufacturers research and development spend is high and consequently hearing aids are of high cost.

There is however a large segment of the hearing-impaired community that are very competent, capable and have a mild to moderate hearing loss. They are confident with technology and alternative retail purchasing channels and are willing to buy goods and services over the internet. They present very little risk due to their age group and awareness and are comfortable receiving technology by courier as long as adequate pre and post-sale support is available. This is particularly relevant for people buying their second or subsequent hearing Aids or those replacing devices via insurance claims. The removal of the face to face fitting element of the Hearing Aid purchase process removes a large portion of the cost element, enabling internet-based retailers to offer the same products as clinic-based retailers at significantly lower retail prices.

The Hearing Heroes position is that while there are segments of the hearing-impaired community who need professional face to face care, any legislated rules should reflect that there is a significant proportion of the community who can be safely and professionally supplied hearing Aids at significantly lower prices. Therefore, legislation should not restrict the options available to the appropriate segment of the community to safely purchase hearing Aids via alternative retail channels such as the internet, as long as the devices being supplied meet regulatory safety standards.

Access to Service and Hearing Health Care

In our section above, Cost Effectiveness item b) we referred to the widely known shortage of Audiologists and Audiometrists. There is also a significant reluctance by owners of hearing aid clinics, especially the globally owned corporate chains that dominate the New Zealand industry, to locate clinics in areas that are remote, with low population, as it is unlikely that a clinic would be profitable or sustainable. Combining the shortage of qualified

clinicians with the relatively small clinic network footprint, access to services by the hearing-impaired community, particularly outside of the main centres, is severely restricted.

Without providing subsidies to encourage organisations to operate clinics in these areas, the alternative is to utilise the technology available and provide access to hearing aid services via the internet and courier delivery of products.

Supply of hearing Aids via the internet is considerably more efficient than by way of face to face clinic-based service. More clients can be treated by less clinicians, the cost base of service provision is much lower and the ability for people in distant communities to access services is much greater.

It is the position of The Hearing Heroes that any legislative changes, while they should protect the person, shouldn't restrict access to services or lower prices where its appropriate to deliver services in that fashion. We encourage therefore that the Bill is carefully drafted to not restrict the sale and supply of hearing Aids to a tight group following the traditional style distribution model, but to ensure that modern sales and supply channels that present efficiency and cost effectiveness are retained.

Services Offered by Alternative Sales Channels

It is often promulgated by traditional health care service providers that if a person purchases medical devices through channels different to the standard face to face clinic retail model that service, support and benefits are restricted. This is not the case, as detailed below

a) Warranties offered on Hearing Aids are provided by the manufacturer and delivered by the retailer. Provided an internet retailer sources the products from the local manufacturer who meets the required quality and compliance standards, the warranty offered is identical.
b) Trial and return periods offered by clinics are intended to ensure the Hearing Aid supplied meets the needs of the person. Trial and return periods are provided by the manufacturer and delivered by the retailer. Provided an internet retailer sources the products from the local manufacturer who meets the required quality and compliance standards, the trial and return period offered is identical.
c) Pre and post-sale support can be delivered in a number of ways. Face to face support can be appropriate at times and provided an internet-based retailer has can offer these support facilities when they are required, support levels are not diminished to the person. The rapid advance in technology is quickly providing an environment where remote support using the internet and services like Skype is providing care standards proving to be as effective as face to face support. Remote fine tuning of hearing aids where a clinician can access a person's hearing aids over the internet and perform fine tuning adjustments without the need for the person to physically visit a clinic is now common place in most leading Hearing Aid manufacturers products.

It is the position of The Hearing Heroes that the Bill should be carefully crafted to ensure the effective, efficient and cost-effective provision of products and services via the internet, where it is appropriate to do so, should not be restricted as it will be to the detriment of the hearing-impaired community and the ability to provide scalable and cost-effective services.

Summary

The Hearing Heroes is very supportive of the need to protect the health and safety of people using Hearing Aid technology. This should be provided by

1. Ensuring that Hearing Aids provided to people in New Zealand are sourced from appropriate wholesale and manufacturing organisations that meet the necessary quality standards. These quality standards should be appropriate, be regulated and administered by a suitable body, independent of the industry sectors. (refer to Australia with the need for manufacturers to meet international ISO standards that are independently audited annually)
2. Ensuring that appropriate levels of assessment and care are available for those people with a hearing loss where conditions dictate a high level of face to face care is administered. (i.e. paediatric, acute cases, people requiring specific custom-made devices and accessories)
3. Access to modern technology that enables provision of services efficiently and cost effectively, via alternative service delivery methods, where it is appropriate to do so, is not restricted.
4. Access to alternative sales and distribution channels that provide safe and effective service and product supply in a cost-efficient fashion is available to all New Zealanders requiring those hearing health care services.
5. Improved access to services to people in remote communities who can utilise internet-based supply and care is not restricted.

The Hearing Heroes is supportive and encourages this Bill in relation to the areas that provide protection for New Zealanders from inappropriate care or sale of low-quality sub effective hearing care technology. We encourage careful drafting of the Bill to ensure that it does not restrict access to and availability of cost effective, efficient services that can be provisioned in a quality way utilising modern communication technologies such as the internet.

For many years now I have been concerned about allegedly beneficial health products being promoted by well-known N Z "celebrities", e.g. Kieran Read Bernadine Oliver-Kirby, Richie Mc Caw (and wife), Hosking, etc. These celebrities lack integrity in as much as they are in it for the almighty dollar! Have they done any homework?

When examined closely, there exists no empirical research to confirm any actual benefits of these drugs/supplements. What is worse, they are advertised in high-profile viewing time, e.g. T V One News, something the elderly never miss viewing.

Some, e.g. "Arthrem", were later proven to have totally minimal or little benefit, if any, at all.

What is worse, the high profile advertising is supported by pharmacists who I must say display minimal rectitude with these promotions by having massive displays in the access to their shop aisles.

Any drug or health supplement allowed to be promoted in any media, should Have a highly visible reference to the research and scientifically-proven benefits of the said product.

"Celebrities" promoting the products should understand their role and also display personal sincerity with full and abundant knowledge of what they are doing.

K F Williamson

College of Intensive Care Medicine
of Australia and New Zealand

New Zealand National Committee

Sheila Swan
Chief Advisor
Ministry of Health
PO Box 5013
Wellington 6140

April 11 2019

Dear Ms Swan

Re: Therapeutic Products Bill Consultation

Our comment relates to changes to section 29 drugs.

The College of Intensive Care Medicine (CICM) is supportive of reform of the rules concerning drugs covered under Section 29

CICM would like to draw attention to the fact that there are several Section 29 drugs in routine use in intensive care units across New Zealand that are potentially immediately life-saving, and essential to current practice of intensive care medicine.

Recommendation: Any changes to Section 29 must bear in mind the need in intensive care medicine for immediate availability of some drugs currently covered under the Section.

Yours sincerely

Dr Andrew Stapleton
Chair, NZ National Committee CICM

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Therapeutic Products Bill Consultation
Ministry of Health
PO Box 5013
Wellington 6140

12 April 2019

Tēnā koutou

Thank you for the opportunity to make a submission on the draft *Therapeutic Products Bill*. Overall Family Planning supports the development of new legislation to replace the outdated Medicines Act 1981. Given that medicines and health care provision is changing rapidly, it seems appropriate that the approach to the new legislation is high level, with much of the detail to be set out in regulation.

Family Planning provides comment on aspects of the draft Bill which may impact our operations, professional practice and the provision of services. In some areas, it is unclear to us how the draft Bill would impact our organisation and the provision of services. We have provided a number of examples of how we currently obtain and provide medicines and devices, with the aim of providing the drafters of the Bill with information to consider so the new legislation does not inadvertantly create barriers to accessing sexual and reproductive health services.

About Family Planning

Family Planning is New Zealand's largest provider of sexual and reproductive health services and information. We are a non-governmental organisation operating 30 clinics as well as

school and community-based services. We offer accredited clinical courses and workshops for doctors, nurses, midwives and other clinicians working in sexual and reproductive health. Our health promotion teams run professional training and education programmes in schools and the community for children and young people, parents, teachers and other professionals. We employ doctors, nurses and nurse practitioners. Many of our nurses have become registered nurse prescribers in community health under expanded designated nurse prescribing rights, announced by the Ministry of Health in 2017.

Family Planning New Zealand is committed to increasing health equity as a strategic priority, with a focus on improving Māori health and wellbeing. To achieve health equity, we have made a commitment to:

- prioritise and embed health equity into all areas of our work
- promote equitable access to services and deliver sexual and reproductive health and rights in the areas of highest need
- prioritise services to rangatahi Māori
- advocate for changes that will increase health equity, such as policies and practices to tackle social and economic determinants of ill-health including stigma, racism, disparities in educational achievement, violence and poverty.

The overall approach to regulating medicines and devices

As stated, overall Family Planning supports the design of the new regulatory scheme. As much of the detail will be set out in regulation, it will be important that there are transparent and inclusive processes surrounding the development and review of regulation. Additionally, decision-making by the regulator should also be transparent and based on meaningful consultation and clearly set out processes, so the views of all relevant stakeholders are considered. The current regulator, Medsafe, has not always been transparent in its decision-making and processes. Additionally, the processes surrounding medicines approval and classification seem to have been skewed toward drug manufacturers and big pharmacy companies that have the resources to engage and present evidence. The voices and perspectives of health professionals and health care providers have sometimes been less visible.

Purpose and principles

The draft Bill sets out the purpose and principles of the legislation.

In New Zealand, and globally, one of the greatest challenges for health care is reducing health inequity. It would be useful for the Ministry of Health to consider incorporating the issue of health equity into the purpose or principles section of the new legislation, bearing in mind that safety must be paramount. While medicines regulation should be focused on

safety, safely increasing access to medicines, in order to improve health equity, should also underpin the approach. Could section 4 (b) (ii) be modified to read:

> *support the timely **and equitable** availability of therapeutic products:*

Many of the innovative ways Family Planning works with regard to accessing medicines and devices is for the purpose of removing barriers for clients. By ensuring staff are well-trained and processes are robust, patient safety can be maintained while using innovative practices. For example, obtaining medicines via a practitioners supply order (PSO) means that clients will not have to make an extra trip to a pharmacy and pay a pharmacy fee to access a particular medicine or device. We would advocate for the new legislation to enable safe innovation.

Proposals around authority to prescribe

The Ministry states "The legal basis for a Health Profession's authority to prescribe would be linked to its scope of practice, rather than set out in the Bill or Regulations."

Family Planning supports this approach. Family Planning has been at the forefront of expanding prescribing authority to registered nurses and worked with the Nursing Council on a trial of community nurse prescribers. Family Planning nurses prescribe within their scope of practice – sexual and reproductive health. We support prescribing being linked to scope of practice, rather than limiting prescribing to a strict list of professionals included in the law. Eliminating the existing categories of prescribers (eg authorised, delegated) is also useful, as they seemed to cause confusion and were, in some cases, underutilised. We support the oversight provided by the Ministry of Health which requires approval from the Minister where an amendment is made to a scope of practice to include prescribing.

It has been proposed that lists of medicines which can be prescribed could be attached to a scope of practice for a particular practitioner group – such as sexual and reproductive health nurses. These lists would be held and maintained by the appropriate regulatory authority. It is worth considering whether this is the best approach. Lists would be difficult to maintain and update, given how quickly front line medicines change. Is it not practical to restrict health practitioners to a regulatory authority managed list. It may be better to simply ensure that medicines prescribed by a health practitioner must be limited to those used within their described area of practice. The Health Practitioners Competence Assurance Act (HPCAA) already states that registered health practitioners will not be permitted to practise outside their scopes of practice.[1] This legislation should align with the approach taken by the HPCAA

[1] Ministry of Health (2014) About the Health Practitioners Competence Assurance Act. https://www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/about-health-practitioners-competence-assurance-act

as prescribing will be expressly set out as part of how a health care practitioner practices under their scope of practice.

It is also important to consider who defines scope of practice and the medications that would logically sit within that scope. For example, misoprostol is a medicine licensed for use for gastric protection from anti-inflammatories, so that would probably sit with gastroenterology. However it is routinely used by gynaecologists pre op, and for doctors providing early medical abortion, and occasionally by Family Planning health practitioners for difficult IUD insertions, but all off-label. It would be important that the use of this medicine be recognised as used under a number of scopes of practice. The law and regulations must be able to accommodate the range of indications and health practitions prescribing different medications.

Practitioner Supply Order (PSO)

Family Planning health practitioners rely heavily on PSOs. We obtain numerous contraceptive devices and medicines through PSOs including some oral contraceptives, IUDs, medicines to treat sexually transmitted infections, medicines to treat urinary tract infections, emergency contraception and condoms. The Ministry of Health defines PSOs as follows:

"A practitioner supply order is a written order made by a practitioner on a form supplied by the Ministry of Health, or approved by the Ministry of Health, for the supply of community pharmaceuticals to the practitioner. The pharmaceuticals are for emergency use, for teaching and demonstration purposes, and for provision to certain patient groups where individual prescription is not practicable."[2]

Family Planning uses PSOs to improve access to medicines and to our services for our patient groups. Having medicines and devices available for immediate supply at our clinics reduces barriers for clients who have an immediate need and may not be able to make an extra trip to a pharmacy or pay a $5 or more dispensing fee to a pharmacists. Reducing barriers to access is important for improving health equity. Additionally, with the scope of practice of nurses changing, and the use of standing orders a training ground for nurse prescribing, medicines must be available for these practitioners outside the regular prescription process to support ongoing training. Ensuring our nurses work to the top of their scope also promotes more equitable access to medicines and devices.

The consultation document indicates that the new Bill would enable regulations to be made which could "allow pharmacists to wholesale to other health practitioners in a similar manner to current practice under practitioner supply orders."

[2] Ministry of Health https://www.health.govt.nz/system/files/documents/publications/using-practitioner-supply-orders-and-standing-orders-rheumatic-fever-prevention-programme-feb15-v5.pdf

Family Planning would like to stress the importance of access to medicines on PSOs, particularly for groups experiencing significant barriers to health care, such as young people, people on a low-income and Māori.

It is important to note that PSOs are handled differently depending on how medicines and devices are packaged, and how they are needed for clients. For example, some PSOs involve a pharmacist "repackaging" items for Family Planning (e.g. counting out pills) while others simply involved a pharmacist providing pre-packaged medicines in bulk. We want to ensure the language in the new Bill does not exclude either of these activities. It appears that under section 59 (2) pharmacists can take a step in the manufacture of a medicine, which appears to indicate that a pharmacist could repackage or prepare a medicine as needed under a PSO. In the past, PSOs were only available to doctors. However, at Family Planning nurse practitioners and registered nurse prescribers can also obtain medication and devices through a PSO. It appears that under the draft legislation, a pharmacist would have the authority to provide medicines under a PSO to any health practitioner prescriber who can prescribe that medication. It will be important to ensure this remains the case.

The Bill indicates that, as is currently the case, a limited number of medicines will be available through a PSO. It is assumed this issue would be addressed in regulation. It will be important to ensure processes are not overly burdensome so the list can be easily updated and will maintain currency and align with any new first line medications, otherwise it will quickly become out of date. For example, nitrofurantoin is the new first line medication for urinary tract infections (UTI), however it is not currently listed as a medicine which can be provided on a PSO. This is problematic for women who are in great discomfort with a UTI and cannot access this medication as easily as possible.

Obtaining medicines direct from an importer or manufacturer

Family Planning obtains mifepristone for our abortion service directly from the importer, which is a registered non-profit pharmaceutical company. We also purchase Mirena for women who do not meet funding criteria directly from the pharmaceutical company, Bayer. Clients then pay Family Planning for the cost of the Mirena. These medicines are regularly used and needed, but unfortunately they are not funded by PHARMAC and, therefore, not available through the usual processes.

Family Planning understands that there is nothing in the draft Bill which would prohibit a health practitioner from purchasing a prescription medicine directly from a pharmaceutical company, or charging our clients for a prescription medication which was obtained directly from a pharmaceutical company. Family Planning is a specialist sexual and reproductive health provider. It is important that there is enough flexibility in the legislation to ensure that specialist providers like Family Planning can continue to access needed medicines and

devices for our clients, including those that are not funded, without undue barriers like significant administrative costs.

Pharmacy activities, dispensing and supplying medicine

It would be useful to further clarify issues related to pharmacy activity, dispensing and supplying medication. It is unclear under what circumstances it may be acceptable for a health practitioner to dispense medicine after obtaining it either wholesale from a pharmacy or direct from an importer. For example, how is providing prescription medicines to a patient under a PSO different to a pharmacist dispensing the same medicine to a patient based on a prescription? It is useful to have two different processes to oversee the use of the same medication? Would it be useful to further enable community-based health practitioners to stock and supply certain medications without pharmacy involvement, as is the case in a hospital setting? This would reduce barriers, improve adherance, but what systems would need to be in place to ensure safe practice?

Standing Orders

It is our understanding that the draft legislation maintains consistency with current legislation with regard to standing orders. The consultation document acknowledges there are concerns about standing orders currently.

> *We are aware of a range of concerns about the current use of, and requirements for, standing orders. Under the new scheme, we consider the need to use standing orders is likely to decrease because more options would be available for authorising this type of supply, where appropriate (eg, via regulations or permits). However, it is likely that the need for standing orders will continue in some situations and, if used appropriately, they can help improve access to medicines when a prescriber is not immediately available.*

While Family Planning has relied heavily on standing orders in the past so nurses could provide medication and devices under the authority of a prescriber, as more registered nurses become prescribers, there is less of a need for standing orders. However, they are still important to our provision of services and the proper use of standing orders is a valuable training ground for nurse prescribing. Family Planning has clear and robust processes around the selection and monitoring of health practitioners working under standing orders (e.g. standing orders at Family Planning are currently reviewed twice a year).

There is a gap where current legislation does not include the use of standing orders for ongoing supply of medication. We would like to see the new legislation enable the use of standing orders for ongoing supply of long term medication in certain situations, such as for

contraceptives. It appears that the draft legislation would be flexible enough to enable this to be achieved through regulation?

While we agree that the need for standing orders will likely diminish, it is important that they are maintained, especially as a training ground for new prescribers.

Off-label prescribing

Family Planning understands that there are proposals in the draft Bill around off-label prescribing. The Bill indicates that anytime a medicine is prescribed for off-label use, it is considered an unapproved medicine and would require a special clinical needs supply authority (SCNSA). Family Planning would be most impacted by the requirements around off-label use of medicines that have been approved in New Zealand. It is unlikely that we would seek a SCNSA for unapproved medicines.

We understand that off-label use of medicine is considered use which is outside the use described in the product approval or product prescribing information. For example, when a medicine is used for a different clinical indication, used with a different age group than is covered under the approval or at doses outside of those included in the approval.

We believe the primary ways Family Planning staff prescribe off-label is for oral contraceptive pill taking, when prescribing emergency contraception (ECP) for women with a high BMI (double dose), and when using misoprostol for abortions - and occassionally for inserting IUDs – when this medicine is not currently approved for this indication. These medicines are frequently or exclusively used off-label by Family Planning health practitioners.

The consultation document indicates that a SCNSA may be issued by simply ticking a box on a prescription which shows that the medicine has been prescribed off-label. Family Planning already notes off-label prescribing in client notes.

It is important to note that off-label prescribing is very common. There are many, many medicines that are routinely used off-label. These are usually well-used medicines that have been around for decades but the licensing is not updated. It is common for on-label use to have been superceded by research and expert opinion. It will be important that off-label prescribing requirements do not impose any new adminstrative burdens on health practitioners.

It is unclear how the SNCSA system would apply to medicines obtained through a PSO and then are prescribed off-label? Currently, Family Planning records information about who is receiving medication via a PSO in client notes, but there is no requirement to report back to

the pharmacy/regulator. Additionally, it is unclear how an SCNSA would be addressed where prescription medicines are obtained without a prescription (e.g. oral contraceptives).

It may be worth considering how the issue of off-label prescribing could be addressed at a systems level, when off-label prescribing of a particular medication becomes common and accepted practice. What would trigger a regulator review of how medicines are being prescribed off-label, so effort is made to include new doses, age ranges or indications in the approval of the medicine? Pharmaceutical companies likely have little interest or motivation to seek approval changes as the medicines are still being used regularly. It is unclear generally how SCNSA's would be monitored by regulators and for what purpose.

Medical devices - contraceptives

It is our understandign that all medical devices will be regulated under the new Bill – including supply-restrictions and use-restrictions (e.g. only adequately trained health practitioners can use some devices such as IUDs). Family Planning raises questions about how the new law would interact with requirements for contraceptive devices under the Contraception, Sterilisation and Abortion Act 1977.
The Medsafe website states:

All contraceptives devices supplied in New Zealand must comply with the Medicines Act 1981 and the Contraception, Sterilisation and Abortion Act 1977. The Medicines Act 1981 provides the definitions that indicate whether contraceptives are medicines or medical devices. The Contraception, Sterilisation, and Abortion Act 1977 established the requirement for contraceptive devices to comply with Standards approved by the Minister of Health.

The Contraception, Sterilisation and Abortion Act states:

Standards for manufacture of condoms

> *(1) No person shall manufacture for sale or sell any condom or other contraceptive device that does not comply with a standard for the time being approved for the purposes of this section by the Minister of Health by notice in the Gazette.*
> *(2) Every person who manufactures for sale or sells any condom or other contraceptive device in contravention of subsection (1) commits an offence and is liable on conviction to a fine not exceeding $5,000.*
> *(3) For the purposes of this section the term condom includes a prophylactic sheath.*

It is our view that it would be beneficial for contraceptive devices to be treated like any other medical devices under new legislation. It appears that there is an extra layer of regulation around contraceptive devices currently, which does not exist for other devices. The unique requirements around contraceptive devices may simply reflect out-of-date legislation rather

than any actual need for extra regulation. The draft Bill lists the Contraception, Sterilisation and Abortion Act as one that will be amended, but it is not clear whether it is the section on condoms and devices which will be changed.

Supply of prescription medicines without a prescription (eg oral contraceptives, ECP)

It is our understanding that the Bill will allow regulations to be used to provide authorisation to enable wider access to specified medicines, rather than this change being made through the classification of a medicine. For example, allowing pharmacists to supply oral contraceptives to women, in certain situations, without a prescription would have been achieved through regulation rather than through reclassification of the medicines, as was the case.

It is unclear which regulatory body would oversee these regulations. Would it be the regulator or a regulatory authority? As a change around accessing medicines without a prescription does not relate to a prescribing authority, it could be assumed that the changes would still be made by the regulator, not a regulatory authority? However, if the change relates to a specific health professional group and professional training, would the regulation be advanced by the professional regulatory body (eg the Pharmacy Council) and included as part of scope of practice? It is unclear how these changes would be achieved.

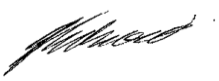
Regardless of the approach, there is a need for a transparent process surrounding a change in access to medicines without a prescription, which includes all relevant stakeholders, including experts in prescribing the particular medicines.

Regulators utilising work done by overseas regulators to assist with efficiency

Family Planning supports allowing the regulator to utilise research, data and decisions from overseas in determining the safety of medicines and devices, as long as the information is considered within the context of New Zealand's health care and regulatory environments and systems, and our population.

Thank you for the opportunity to provide comment. Family Planning is happy to provide further information if needed.

Ngā mihi nui



Jackie Edmond
Chief Executive

HCL TPB submission (9/04/2019)

Contents

Chapter A

A1

Consultation Question	Response
A1 Do you support the general design of the new regulatory scheme for therapeutic products?	**1 Support (Healthcare Logistics supports the general design of the regulatory scheme.)** 2 Partially support 3 **Neutral** 4 Partially don't support 5 Don't support.

Chapter B

B1 - Part 1: Preliminary provisions

Consultation Question	Response
B1 Please provide any comments on the purpose of principles of the Bill (ss3 and 4)	Healthcare Logistics agrees with the purpose and principles as outlined in ss3 and ss4. We support risk-proportionate regulation and timely availability of therapeutic products. We believe that administration of this Act should be open and transparent, and that there should be co-operation with overseas regulators, compliance with international obligations and alignment with international standards and practice. We make further comment on these principles below. ss4(b)(i) **Risk-proportionate regulation** We support the proposal to have a wide and flexible range of product approval pathways, dependent on risk and to replace the current provisional consent with the ability to have approvals with conditions (ss105-107). Ss4(b)(ii) **Timely availability of therapeutic products** We support the principle of timely availability of therapeutic products (ss4(b)(ii)) as this is an essential principle to ensure that people that need access to these products, get access in the timeliest manner possible while ensuring the appropriate checks have been done. However, assurance is needed that this principle will be sufficient to keep the regulator accountable to making decisions in a timely manner We believe the scheme will need to establish transparent and meaningful timeframe target setting and reporting of the regulator's performance.

	Ss4(c) **Open and transparent regulator** We support the principle that the regulatory scheme is administered openly and transparently (ss4) but seek further information on how this principle will be achieved. It is not clear with any of the options for the form of the regulator, how will the regulator ensure that processes, decisions, and policies are administered with openness and transparency to industry. Furthermore, we would also encourage inclusion of "fairness" in principle ss4(c). We believe it is essential that administration is open and transparent, and carried on in a fair manner. Ss4(d) **Regulator's reliance on overseas regulators work** We support both the principle to have a regulator that engages internationally and recognises the work of trusted overseas regulators (ss4(b)) and the provision (ss207) that the regulator may rely on reports, assessments, decisions, or information of recognised authorities (such as overseas regulators), to make decisions. Furthermore, we consider this approach should not be limited to new and extended indications, line extensions, new strengths etc but rather applied to all product applications, and major changes to increase the efficiency and timeliness of decisions.

B2 Part 2: Interpretation

Consultation Question	Response
B2 Please provide any comments on the definitions or meanings set out in the draft Bill (ss14-50)	We believe that a definition that a "person" is either a body corporate or a person, should be added to the definitions, as it is not always an individual person who imports, supplies or advertises a product. This is particularly relevant to (ss30; ss42; 44; ss47,ss48, 52 and 83(2)(a)(i)).

	Ss30 meaning of import The scope of persons who are importers under ss30 is very wide. Ss30(2)(a) indicates that this includes "a person who does the physical activity of importing the product". We are concerned that this definition is broader than the definition of an importer under the Customs and Excise Act 2018. This may unreasonably pass liability to a broad range of persons such as freight operators and we question the rationale for this broad definition. **Ss31 meaning of manufacture, manufacturer, and responsible manufacturer** We seek confirmation that our of the definition of a 'responsible manufacturer' (ss31(3)) is correct. In particular the considerations 31(4)(b) and (c): "*who is responsible for the overall quality assurance and quality control in relation to the manufacture of the product*" and "*if the product is, or is intended to be, released into the supply chain, whose name or trademark the product is, or is to be, supplied under*.". Does this mean that the parent company (international headquarters) of the local New Zealand sponsor could be nominated as the responsible manufacturer? We believe this would be the best decision because in many cases, the parent company will hold agreements with the many parties involved in manufacture of a medicine. Additionally, pharmacovigilance and other reporting is reported back to them. Therefore, the parent company (international headquarters) is often in the best position to assist with supply of required information back to the local New Zealand sponsor as and when required. For companies like HCL that are "outsourced" sponsors because there is no NZ affiliate of the parent company, the NZ sponsor is usually procured by the parent company via an Australian or regional affiliate and there are no contracts direct with manufacturers. We believe the requirements of this contractual relationship should be more clearly defined for local affiliates and outsourced companies who are sponsors of medicines.

	Ss36 meaning of pharmacy business and pharmacy activity Ss36(3)(c) defines that a pharmacy business can supply medicines and medical devices by wholesale supply in circumstances permitted by regulations, and that this is a pharmacy activity. If a pharmacy is permitted to supply by wholesale we strongly recommend that the pharmacy must meet the requirements of a wholesaler as per Part 4 of the New Zealand Code of GMP, Wholesaling of Medicines and Medical Devices (facility suitability, stock control, temperature control and monitoring, invoicing, traceability of sales for purposes of recall) and attain a wholesale licence for such an activity. Additionally, allowing such an activity within a pharmacy licence rather than a separate wholesale licence would cause difficulties for suppliers like ourselves to distinguish between customer types for the purposes of monitoring excessive or aberrant ordering patterns. **Ss47 fit and proper person and Ss48 meaning of senior manager** Ss 47 defines the decision of whether a person is a "fit and proper" person. As it is currently written, it appears to be unreasonably wide-reaching for the 'fit and proper' person test. For example, if Person A is a Company ("Company A"), then any individual that is currently or has ever been a director, CE, CFO or similar of Company A, as well as any company that is able to exert significant influence over the management or administration of Company A is included. For clarity, we suggest there be two definitions, in order to differentiate between individual and company sponsors/licensees. We also suggest there be a time limit or timeframe given in the senior manager definition.

B3 – B12 Part 3: Dealing with therapeutic products

B3 Please provide any comments on the product approval controls (ss 51 and 52).	**Ss51 product approval required to import or supply medicine, medical device, or type-4 products** We support the requirement to have a product approval, approval exemption or an authorisation to import or supply a medicine, medical device or type-4 product. **Ss52 sponsor's consent required to import approved product** We support the provision to prohibit parallel importation.
B4 Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).	**Ss53 Authorisation required for controlled activity** We question the rationale for including compounding and dispensing in the definition of manufacturing a medicine. For clarity, we would suggest these activities are separated from the definition of "manufacture" and listed separately as a controlled activity in ss53. **Ss55 Persons in supply chain must comply with regulations** The description of activities persons in the supply chain must comply with is broad, and encompasses activities related to manufacturing of therapeutic products (packaging and labelling), supply (storage, transport, disposal and tracing/recall) and clinical practice (monitoring of conduct in relation to a supply order or special clinical needs supply authority). The regulations must be specific about application of requirements across the range of persons in the supply chain, in light of the range of supply chain activities defined in s44(1).

B11 Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.	**Ss71-75** We agree with the authorisations created in ss71-75. **ss78 Authorisation for unapproved product stock in supply chain** We support the proposal to allow the Regulator to issue a 'use of current stock' notice. This would be an improvement on the current system; where Sponsors typically need to wait until date of last product expiry in the market before de-registering the product. We suggest that a 'use of current stock' notice could also be used for cases where a major change has been made (and approved) to a product and an amount of the original/unchanged product is still present in the market. **ss79 regulations may grant authorisation** Section 79 appears to allow for more tailored authorisations for specific circumstances (paragraph 91 of consultation document). We support this change.
B12 Please provide any comments on the offences created in sections 81–94.	**ss82 meaning of advertisement and related terms** We believe that a definition of "promotion" should be added to the Bill in order to clarify the differentiation between education and promotion

B13- B17 Part 4: Product Approval

Consultation Question	Response
B13 Please provide any comments on the sections covering product approval requirements (ss 94–104).	**Ss97 Criteria for sponsor of approved product** **ss97(c)** While the rationale for a requirement for a contractual relationship with the responsible manufacturer is reasonable, we believe there are issues that need to be resolved: Some local sponsors who are part of large multinational pharmaceutical companies would not ordinarily hold individual agreements with each of the many manufacturing sites. These agreements are held by the parent company and an agreement between the local affiliate and parent company is standard practice. Furthermore, for companies like ours that are “outsourced” sponsors because there is no NZ affiliate of the parent company, the NZ sponsor is usually procured by the parent company via an Australian or regional affiliate and there are no contracts direct with manufacturers. We believe the requirements of this contractual relationship should be more clearly defined for local affiliates and outsourced companies who are sponsors of medicines. We seek confirmation that the parent company (international headquarters) of the local New Zealand sponsor could be nominated as the responsible manufacturer under ss31(3) If this interpretation is correct, we support the proposal as the parent company will hold agreements with the many parties involved in manufacture of a medicine and pharmacovigilance etc is reported back to them.

	As a further point, we question why the determinations of a 'responsible manufacturer' for a medicine differs substantially to that for a medical device or type-4 product (ss31(4) vs ss31(5). For medical device or type-4 product it is noted in ss31(5)(a) that a person may be a 'responsible manufacturer' "whether or not they personally undertake the manufacturer of the product", whereas as for a medicine or AMI such as clause is not included. We suggest that the same approach of "a person may be a 'responsible manufacturer' "whether or not they personally undertake the manufacturer of the product", should apply to a medicine or AMI as well. **ss97– Criteria for sponsor of approved product** There would seem to be disagreement between the definition of a responsible person (called the Sponsor) in the consultation document, and the draft Bill, where the responsible person is named on the licence, but is not necessarily the sponsor. We believe the Sponsor should, be responsible for activities associated with product registration, manufacture up until product supply to third parties, such as wholesalers and pharmacies. But the Sponsor cannot be held accountable for all activities after the product has left their control. This responsibility resides with the wholesalers and pharmacists in the supply chain. **Ss98 Content of approval** Please refer to comments on the responsible manufacturer ss31. It is not clear whether only the address of the place of the responsible manufacturer would be required to be included in the approval or the approval will be required to list an extensive array of sites directly and indirectly involved in product manufacture, given the broad definition of manufacturer in s31.

	Ss99 Scope of approval Please refer to comments on ss100 below **ss100 – Major changes results in new product** We do not agree with the proposed requirement that "major changes result in a new product" (ss100), or the proposal that "once the application [for the major change] is approved, a new approval document would be issued. We agree with what we understand to have been stated by Ministry of Health representatives at the Medicines sector forum on 18 March 2019, that the changed product would be given a separate entry on the regulator's public register to the original product, and a separate identifying number (TT50 entry). **ss101 – Sponsor must notify regulator of certain minor changes** HCL supports the management of changes to an approved product based on a framework of risk-based assessment of minor variations. This is particularly important in allowing certain types of minor changes that are low risk and do not impact the quality, safety or efficacy of medicines to be notified to the regulator rather than requiring formal assessment prior to approval. A post-approval lifecycle framework for quality changes/applications aligned with that in the EU and Australia that reduces the submission burden for industry and establishes activity-based timelines for evaluation of those that require evaluation is supported. **Ss102 Change of sponsor** We support the requirements set out in ss102 for changing a sponsor (transferring an approval).

	ss103 – Duration of approval HCL agrees with the proposal for product licence approvals generally not to have expiry dates, thus licences are perpetual until such time that the Sponsor or regulator considers cancelling the licence. This is aligned with current Australian practice (ie TGA). Under the current New Zealand regulatory system where product approvals lapse after 5 years if there has been no regulatory activity or no commercial supply of the product, there is often confusion on the status of the product approval. There does not seem to be any compelling reasons to assign an expiry date on the licence. HCL anticipates that the conditions applicable to a "maximum duration for the approval", where applicable, will be specified in the regulations (ss103 (2) (b)) **Ss104 Approval lapses on death, bankruptcy, or insolvency of sponsor** Please refer to the response to B22 ss151.
B14 Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).	<u>ss105 – 107 – Conditions on approval</u> HCL agrees that the regulator should have the right to impose conditions on approval. HCL agrees that the sponsor also has opportunity to comment. <u>ss108 – 112 – Cancellation of approval</u> HCL agrees that the regulator should have the right to cancel an approval based on the grounds cited in s108. HCL agrees that the sponsor also has opportunity to comment

	ss113 – Therapeutic products register HCL agrees with the proposal to develop a Therapeutic Products Register (s113) which contains a copy of the latest prescribing information and consumer medicine information for approved products. It is unclear whether the practice of assigning a registration number to the product (ie TT-50 number) will continue under the new regulatory scheme. It is also not clear whether only the address of the place of the responsible manufacturer would be required to be included in the approval or the approval will be required to list an extensive array of sites directly and indirectly involved in product manufacture or, given the broad definition of manufacturer in s31. HCL agrees that, all applications submitted to the regulator and all approved products, should be made publicly available, on a product However, for declined or withdrawn applications, we believe these should only be made public with the consent of the sponsor. Following receipt of a negative decision on the application, the Sponsor should have the opportunity to voluntarily withdraw the application, without having this included or made public on the Therapeutic Products Register (consistent with other jurisdictions like Australia and EU where only negative recommendations made after specific evaluation milestones can be made public without sponsor consent).
B15 Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).	ss114 – 115 – Subpart 2 – Approval-exempt products It appears Medsafe would like a sponsor (even though approval is not required) so that they can contact someone in the event of any issue with the product. However, for a class of approval exempt products, who would be liable for product quality/safety? If no one opts to sponsor a potential approval-exempt product, will the Crown or other entity be the sponsor? What is the process for the Crown to become a sponsor of a product? Would approval-exempt products be included on the proposed Therapeutic Products Register? =

B16 Please provide any comments on the sections covering sponsor obligations (ss 116–119)	<u>ss116-119 – Subpart 3 – Obligations of sponsors</u> The scope of responsibility of sponsors appears to have widened in the draft TPB proposes. The Sponsor should, rightly, be responsible for activities associated with product registration, manufacture up until product supply to third parties, such as wholesalers and pharmacies. Whilst the sponsor will be responsible for post marketing safety activities and investigation of Quality Issues, the Sponsor cannot be held accountable for all activities after the product has left their control. In general, HCL supports the introduction of a new tiered offence structure for offences. However, the penalty (up to $300,000) appears high for a Band A (strict liability) offence where a sponsor or individual may commit these offences without knowledge of the circumstances and the potential harm. We also question whether the defences are reasonably open to provide protection for inappropriate prosecution. ss119 – HCL is in agreement that the sponsor is not responsible for approved products imported without consent. However, details are lacking on what sponsor obligations in relation to Pharmacovigilance are tied to the penalties outlined in subsection (1) and subsection (2). While we agree that sponsors should be accountable for complying with applicable obligations, we think it would be unreasonable if the entirety of Part 8: Pharmacovigilance / applicable device regulations form part of the legislation. We would seek to be consulted further in relation to the specific requirements and believe these should be fairly aligned to other comparable agency requirements.

B17 Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).	<u>ss120 -122 – Subpart 3 – Obligations of sponsors</u> We note that many HCL's principals would not support the continuation of 5 years of regulatory data protection (ss 102-104) for innovative medicines from the Medicines Act 1981. They would argue this is inconsistent with the increase to regulatory data protection for innovative veterinary medicines from 5 to 10 years made through the Agricultural Compounds and Veterinary Medicines Amendment Act 2016, and the EU which provides a 8-year period of data exclusivity, plus two years of marketing exclusivity (with a potential 1 year extension) and for orphan exclusivity, there is 10 years of market exclusivity with a potential 2 year extension if extended to juveniles, a territory New Zealand is negotiating a future trade agreement with. Also, it does not account for the lengthy period between product approval and reimbursement by PHARMAC and also does not preclude entry by a generic company using their own clinical data. With use of the term active moiety the draft TPB appears to allow for the protected period to apply in the event of significant modifications of an active ingredient that serve to alter characteristics of the active ingredient (such as formulation of a complex salt that results in significantly altered pharmacokinetic properties).

B18 – 23 Part 5: Licences and Permits

B18 Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss123-127)	**Ss123 What licence may authorise** Healthcare Logistics agrees in principle with ss123. **Ss124 Content of Licence** ss124(1)(e) – We question the proposed requirement that the licence will list the therapeutic products covered by the licence. Product registrations are constantly changed, and it is indicated in ss137 that licences remain in force for 3 years. Therefore ,consideration needs to be given to the time and cost of varying licences due to changes in products during each 3 year period. **SS126 Effect of pharmacy licence: additional provisions** **N/A** **Ss127 Grant of Licence** We agree with the requirements ofSs127(3) provided that if the Regulator is not satisfied, the applicant should be provided with an opportunity to comment/opportunity to provide further information in order to meet criteria before the license is declined.

B19 Please provide any comments on the sections on the criteria for: granting a licence; licensees; and responsible person (ss128-130).	**Ss128 Criteria for granting licence** No comment. **Ss129 Criteria for licensee** We agree with the criteria in ss129. **Ss130 Criteria for responsible persons** We suggest that the drafting of the TPB must accommodate (as the current legislation does) an overseas person being listed on a licence provided there is a minimum of one New Zealand resident on the licence. We note that the overseas person is usually a senior staff member (e.g a Regulatory or Quality manager) of the affiliate where there is no resource for that company in New Zealand. The number of employees in New Zealand of pharmaceutical companies is small, with many functions such as regulatory often based out of Australia or another country overseas.
B20 Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss131-135	**Ss131 What permit may authorise** ss131(1) (a) – The criteria for importing an approved product without the sponsor's consent needs to be outlined and specified in the Regulations with very tight restrictions and controls on it. **Ss132 Content of permit** We agree with the specifications listed in ss132.

	Ss133 Effect of permit We agree with the requirements listed in ss133. **Ss134 Grant of permit** We agree with the requirements list in ss134 provided that under Ss134(3) the applicant should be provided with an opportunity to comment/ provide further information in order to meet criteria where the Regulator is not satisfied that criteria are met. **SS135 Criteria for granting permit** Please refer to our comments under ss131. We support the explicit statement in ss135(b) but seek further information on intended situations where a permit would be authorised. Under ss4(a) "the likely benefits of therapeutics products should outweigh the likely risks associated with them".
B21 Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations (ss136-149)	**Ss136 Regulator may split application** We have some concern regarding ss136. Specifically,ss136(2) gives the Regulator discretion to assess the application together, or as discrete applications. We are concerned that this may slow down application processing times. We believe there should be clear guidance as to what types of applications would be likely to be split and where the regulator should and should not split applications, and so that applicants may be able to prepare ahead of time an appropriate application so that it is processed as efficiently as possible. **Ss137 Duration** ss137 indicates that a licence remains in force for 3 years. However, if changes are required eg if individual therapeutic products are named on the licence, has consideration been given to the timeframe and cost involved with making multiple updates during this time period?

	SS138 Conditions We agree with ss138. **Ss139 Regulator may impose conditions and ss140 Variation** We seek further information on what changes will require a variation of a licence.
B22 Please provide any comments on the sections covering the transfer of licences and permits (ss150 and 151)	We suggest that ss151 regarding license details that if the licensee or permit holder dies need further refinement. An executor/administrator of an estate would often not be appointed within 5 working days of a death, let alone in a position where they fully understand the assets within the estate and the action required to notify the Regulator. We suggest 15 working days (21 calendar days) would be more appropriate. It is also unclear what the consequence will be if the executor of the estate fails to notify the regulator within 5 working days. It would seem there may be business continuity issues if the Regulator has the discretion to cancel the license without giving the licensee opportunity to comment.
B23 Please provide any comments on the obligations of licensees and responsible persons (ss153-159)	ss158 requires the responsible person to comply with the requirements, in relation to the competency of workers in the licensee's business. At this stage it is unclear what the competencies are or how the responsible person is realistically able to comply with this requirement. Further clarification on this is sought.

B24 – B28 Part 6: Regulator (Subpart 4 – Review of Regulator's decisions ss 200-204)

Consultation Question	Response
B24 Please provide any comments on the regulators powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss160-182)	s160 allows the regulator to 'perform monitoring', with respect to safety monitoring. This would introduce the ability for Medsafe to conduct regulatory inspections. While we do not object to the inclusion of this provision, we would welcome further consultation prior to implementation. The TGA can do this in the situation of a 'for cause inspection', however this power seems a little excessive for 'routine monitoring', unless of course this means that access cannot be prevented, in which case the powers we believe are similar. ss168 – 171: Clarification is sought whether "person" in these clauses relating to Directions orders and Product Prohibition orders, extend to the sponsor or an individual only? ss178 (2) (c) (i): mentions the "person who distributed the advertisement". Clarification is sought whether "person" in this case also means the sponsor of the product being advertised as the definition of person in the TPB is currently unclear.

B25 Please provide any comments on the regulator's investigative powers	ss183, 185, 188, 191, 192 – we have no specific objection to the amendment to bring the Bill under the remit of the *Search and Surveillance Act 2012* as it brings it into line with what is generally the standard set of investigative powers in New Zealand. However, it would be important to clarify the potential tension between: (i) a prohibition on shipping overseas any products that are subject a prohibition order (ss170(2)(f)); and (ii) an ability for therapeutic products that are seized by the regulator / border security to be returned to the country of origin if the regulator requires it (ss194). In order to relieve this tension, we presume that this right to return products to a country of origin would be exercised by the regulator only where the product does not pose significant risk of death or harm. If this is not the intent, we are concerned that therapeutic goods that would otherwise be subject to a prohibited product order and therefore not able to be returned to their country of origin would be treated differently if seized at the border rather than if they were released to the sponsor (either erroneously or as they were subsequently found to have concerns).
B26 Please provide any comments on the offences relating to the regulator (ss 197-199)	We consider that the provision of (ss243) where defence for any prosecution of an offence under the Bill is permitted if the defendant took "all reasonable steps to ensure contravention was not committed" provides adequate grounds to protect against unfair prosecution under ss197-199.

B27 Please provide any comments on the review of regulator's decisions (ss 200–204).	<u>ss200 – 204 – Subpart 4 – Review of Regulator's decision</u> HCL agrees with the proposal to have regulator's decisions in relation to product approvals, licences and permits reviewed through a merits review process instead of the current process of utilising an independent standing committee with set membership. The proposal to appoint 3 people (including a lawyer) who have not previously been involved in the decision will allow for an independent and unbiased review which will be welcomed by Sponsors. Additionally, appointing subject-matter experts, people with appropriate knowledge, skills and experience, for the reviewable decision, is critical in ensuring there is a fair and equitable review of decisions. However, we consider that a timeframe of 60 working days (ie approximately 3 calendar months) rather than the proposed 30 working days, for the Sponsor/Applicant to submit their application with any supporting data/justifications for review of a Regulator's decision would be more appropriate. This timeframe is aligned with other regulators, such as the Australian Therapeutic Goods Administration (TGA). Likewise, the draft TPB (ss203) does not specify the timeframes given for convening the review panel or the review timeframe for the review panel to provide a decision. HCL suggests a timeframe of 30 or 60 working days would be appropriate and would ensure both the regulator and Sponsor/Applicant could be held to account for meeting their obligations.

B28 Please provide any comments on the administrative matters relating to the regulator (ss 205-222)	The draft TPB (ss207) states that the regulator may rely on reports or assessments made by recognised authorities to enable efficiencies. This approach seems sensible to HCL.. The Bill states that confidential information that is shared with an overseas regulator or organisation should have its confidentiality maintained. HCL suggests further: (i) that "confidential information" needs to be defined, particularly given the reports that might be required to be made available to the regulator under the Bill and the regulations; (ii) if a decision is being reviewed, that decision should only be shared with the overseas regulator / organisation if it is accompanied by a note that the decision is subject to review to ensure that a precedent is not set when it is subsequently not followed in New Zealand; and (iii) that this right to disclose information to third parties should be subject to the protection period for protected active ingredient information that is addressed in ss120-122.

B29 – B31 Part 7: Enforcement

Consultation Question	Response
B29 Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).	No comment
B30 Please provide any comments on the sections covering penalties, court orders, liability, defences and evidentiary matters for criminal offences (ss 233–248).	**Subpart 3 – Offences** **Ss233 – Penalties for Offences** We request that the Ministry of Health provide their rationale for the proposed penalty amounts, and the information used to decide on these amounts. While we agree that the penalties for most offences under the Medicines Act 1981 are inappropriately low, we are concerned by the significant proposed increase to the penalties. Compared to similar modern legislation (Food Act 2016, Agricultural Compounds and Veterinary Medicines Act 1997, Hazardous Substances and New Organisms Act 1996, Biosecurity Act 1993), the penalties proposed by the TPB are very high. The prison sentences are at the higher end of the spectrum, and it seems that the TPB imposes the highest fines out of the comparable modern legislation for both individuals and for companies. Therefore, we seek rationale for these proposed penalty amounts, and that the Ministry of Health provide the information that was taken into consideration when calculating these.

	Ss237 – Order to pay Regulator's expenses of mitigating risk harm We submit that for the definition of "caused harm or a risk of harm" in ss237(3), the definition that conduct that indirectly "causes harm" (ss237(3)(i)) is a low threshold for paying the Regulator's expenses. It is requested that this be qualified – as like ss237(3)(ii), (iii) and (iv) which are given the word(s) "significant(ly)". We suggest wording such as "causes material harm" or "causes harm that is not insignificant" which would be on the basis of reasonableness. **Subpart 4 – Attribution of liability and defences** Conduct of senior managers, workers and agents within the scope of that person's actual or apparent authority is attributed upwards to the relevant entity (ss239). As a reciprocal measure, if a body corporate contravenes the Bill then this will be attributed down to its senior managers (ss242). The Bill defines "senior managers" to include people such as directors, chief financial officers and chief executives (ss48). This is not an approach that appears to be taken consistently across New Zealand legislation and appears to be a rather stringent standard.
B31 Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).	HCL support the proposed sections (ss 249-255) covering infringement offences and the related penalties and processes. This is considered to not be out-of-line with recent New Zealand legislation which is following this two-tier infringement process, including the Food Act 2014 and the Financial Markets Conducts Act 2013.

B32 – B34 Part 8: Administrative Matters

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).	ss256 indicates that the intention is for cost recovery by way of fees or charges specified in the regulations. HCL is not opposed to a cost recovery model. However, we believe that in addition to stipulated costs, there should be clear and transparent timelines. These are lacking under the current regulatory system.. Appropriate accountability measures both within the regulator and external to the regulator are needed to ensure appropriate timeliness is a lasting feature of the new scheme. We suggest that maximum evaluation timeframes are stipulated in regulations. With the tightening of unapproved supply, plus a high likelihood of increased fees, the regulator should look at having an orphan designation/application pathway with associated reduction in fees for rare diseases. With NZ's very small population there may be a handful of patients treated each year and for many products in this space it will not be commercially viable to register these in NZ. If there is some kind of fee waiver in place this would give the regulator more control over what is being supplied in NZ in these kinds of circumstances. **Ss267 Consultation** We support the approach of making the Therapeutic Products Bill (TPB) principles-based and having operational details of the scheme in subordinate legislative instruments. practice. However, this approach to the drafting of and consultation on the TPB creates a high level of uncertainty for stakeholders.. We believe, the Ministry of Health should commit to forming working groups of sector groups affected by the TPB to facilitate drafting of regulations that are workable and fit-for-purpose. Healthcare Logistics has noted interest from individuals in the prescription medicines industry who would be qualified and prepared to participate in a medicines sector working group. We also strongly recommend a consultation that provides sufficient time and opportunity for stakeholders to comment..

B33 Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).	No comment
B34 Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).	No comment

Schedule 1: Transitional, savings and related provisions

Consultation Question	Response
See under individual sector subheadings in Chapter C for sector-specific questions.	No comment

B35 Schedule 2: Reviewable Decisions

Consultation Question	Response
B35 Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).	Schedule 2 – Reviewable decisions HCL agrees with the list of decisions reviewable by the Applicant or Sponsor which are listed in Schedule 2 (Items 1 to 6) of the draft TPB.

B36 Schedule 3: Regulations, rules and regulator's notices

Consultation Question	Response
B36 Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).	No comment

B37 Schedule 4: Amendments to other enactments

Consultation Question	Response
B37 Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?	No comment

Chapter C

C1 (Changes to Approved Products)

C1 Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).	Please refer to response to Question B13

C2 (Medicines Classification/Categorisation)

C2 Please provide any comments on the approach for medicines categorisation (classification).	We agree in principle with the categorisation system for medicines and in particular with having numbered categories (1,2,3,4). However, we note that the numbers for categorisation have been proposed are the inverse to the numbering system used by the TGA. This may create a point of confusion for those working across both territories, or those transferring to the New Zealand market from Australia.

C3 (Transition for existing products and applications)

C3 Please provide any comments on the transition arrangements for existing medicine product approvals.	The transition provides 3-12-month period for applications for approvals and licences. However, we note that the widened scope of the scheme for example to cover additional products (e.g medical devices) and activities (e.g clinical trials for registered medicines), will result in a large volume of applications received. We note there is industry wide concern about the potential backlog created by this influx of applications, the length of time until normal operations resume and the impact of this on routine applications such as CMNs and new medicine applications. We note the Regulator will be adequately resourced during this transition period. **Transitional Arrangements** It is proposed that the arrangements that will provide temporary approvals, licences and permits to applicants. However, feedback from the industry indicates that there will be a very large volume of applications made within 3-12 months from the commencement date, and that this will create a large backlog of work for the regulator.

	We understand that there are approximately 400-500 products currently supplied via section 29. We understand the intention for these medicines is they will either be available to patients via the Special Clinical Needs Authority scheme, or they will first need to receive a product approval under the new scheme. Our concern is that receiving these approvals will take a long time considering the number of medicines and device approvals that will be submitted, and the number of licence applications that will be received during the transition period. What if any specific transitional arrangements are proposed for the section 29 medicines?. We expect there will be a number of medicines (e.g anaesthetics) which will need to be stockpiled and have continuous import until they receive a product approval, or they are requested via the SCNSA scheme. We note on page 93 of the consultation document that "As a wholesaler, you would **only be able to import an unapproved product if your licence specifically authorised** this (s 51(1)(b)). Our question is, will the transitional arrangements allow a wholesaler to apply for a temporary licence to continue the import of medicines currently supplied by the section 29 of the medicines act? This may be necessary to enable a wholesaler to maintain a small stockpile of the product, so it is available for immediate release once a SCNSA has been issued.

C4 (PV)

C4 Please provide any comments on the approach to post-market controls	As a general comment, we agree in principle. However, we would like to see more detail in terms of what requirements would be enforced in relation to risk management. We seek clarification on whether the TPB requires the sponsor contact for dealing with pharmacovigilance matters and reporting to Medsafe to be a NZ resident. Currently this person can be based overseas as long as they are contactable during NZ business hours.

C5 (Manufacturing)

C5 Please provide any comments on the manufacturing-related definitions.	Please refer to the response to B2.

C6 (Hawkers Licence as part of wholesale licence)

C6 Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.	HCL notes and supports the intent of the new hawker scheme which would enable licensees to have secure online access to its database as it would improve efficiencies for both the regulator and companies.

C7 - C10 (Cell and Tissue)

C7 Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered? **C8 Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.**	No comments

C9 Please provide any comments on the transition arrangements for product approval controls for cell and tissue products. **C10 Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.**	

C11 - C15 (Medical Devices)

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?	HCL thinks products that have similar features and risks to medical devices but are not for a therapeutic purpose should be regulated by other legislation but are outside the scope of the Therapeutic Products Bill
C12 Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?	HCL supports the use of the global model to regulate medical devices. However as with medicines sponsorship the contracts for local affiliates and local outsourced sponsors are usually not directly with the manufacturer. Such contracts are between the parent company and the local affiliate. Outsourced sponsors are usually procured by the parent company via a regional affiliate and no direct contract with the parent company/manufacturer is in place.

C13 Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.	HCL generally supports the proposal to enable some medical devices to have restrictions applied to their use or supply as this is currently the practice of most medical device companies.
C14 Please provide any comments on the transition arrangements for product approval controls for medical devices.	HCL supports the proposal to allow grouping of devices under one registration in a manner similar to current WAND listings to reduce the cost and time. HCL considers the 6 month period for companies to submit the applications for approval of devices (groups) to be too short. A period of 2 years would be more realistic for companies with hundreds of potential registrations to complete. HCL agrees that interim approval is granted for companies to continue to supply their devices under the current regime until consent is granted under the new regime.

C15 Please provide any comments on the transition arrangements for regulating activities involving medical devices.	HCL considers the 6 month timeframe for applying for a licence to supply devices by wholesale to be sufficient and granting a temporary licence is a sensible approach. It is not clear whether the assessment of applicants will be based on the New Zealand Code of GMP Part 4: Wholesaling of Medicines and Medical Devices.

C16 and C17 (Clinical Trials)

C16 Please provide any comments on the change in approach to regulating clinical trials **C17 Please provide any comments on the transitional arrangements for clinical trials**	**License to run CTs:** No comment **Importation of Investigational Medicinal Products (IMP)** We could not find any reference to the importing of IMP. It is assumed that this comes as part of the regulators' approval of the trial . **Exporting biological samples (blood/serum) and tissues** We were unable to find reference to provisions for the export of samples or tissues derived from CT participants. . **The Regulator also has the power to monitor trials and audit CT sites… p90 of the consultation document** No comment

	Schedule 1 – Transitional Arrangements No comment.

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 imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?	ss64 Healthcare Logistics supports the provision in the Bill for supply of an unapproved product via a Special Clinical Needs Supply Authority (SCNSA). It is important that requirements for supply via this mechanism are clear in the regulations, including: - Responsibilities for Adverse Event reporting - Requirements for notifying local sponsor of supply - Provisions for a cross-over period should an unapproved medicine supplied under a SCNSA become approved - Under what circumstances wholesalers are able to have on hand a small stockpile of unapproved medicines ("urgently needed" needs to be defined, as does "small") - Measures of control of products imported by "buyers' clubs" and/or healthcare professionals bulk importing unapproved medicines

C52 and C53 (Advertising)

C52 Please provide any comments on the advertising requirements and enforcement tools. **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 view?**	HCL welcomes the fact that the status quo regarding DTCA is proposed to be maintained at this stage (with an enhanced range of enforcement options and higher penalties for breaches). HCL believes the benefits for consumers of DTCA far outweigh the purported negatives. DTCA in New Zealand is currently highly regulated and is required to be compliant with a number of regulations and codes. DTCA allows New Zealand consumers to access factual, high quality New Zealand specific information about therapeutic products. The current review process when developing an advertisement ensures that promotional claims are accurate and substantiated by quality references and all information is consistent with the Medsafe Data Sheet and Consumer Medicine Information. In addition, under the new Bill, the regulator can issue Advertising Remediation Orders, which provides a further level of control if necessary. Empirical New Zealand evidence overwhelmingly concludes that DTCA of prescription medicines promotes health awareness and encourages patients to take a proactive role in the management of their own health. DTCA of prescription medicines comprises only a small percentage of advertising and considering the abundance of unregulated information on the internet readily available to patients, banning the regulated and controlled DTCA of prescription medicines is pointless and will not result in any time saved for doctors during consultations – saving time appears to be one of the main reasons for vocal doctors' call to ban DTCA. Continuing DTCA reinforces patients' rights to find out about treatment options. DTCA of prescription medicines has been allowed in New Zealand since 1981.

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising of prescription medicines in New Zealand.

There is an inherent conflict when advertising medicines between health care and boosting sales. As with all advertising, emotional images and information are employed and these are not a good basis for making informed decisions on one's own or family's healthcare.

Basically I concur with the points made in the consumer magazine's template for submissions as listed below

- *Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.*
- *Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.*
- *Unnecessary prescription of medicines leads to increased costs for consumers and the health system.*
- *DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.*
- *There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.*

Also the drug companies' financial interests leads to marketing more drugs to more people with the bounds for what is considered "disease" being broadened in the process.

Please ban this advertising as it does nothing to help the health of the population and just makes it increasing difficult for patients and doctors to come to sound decisions when it comes to medicines.

Yours sincerely

Joe and Cathie Khan

Would value a policy similar to many European countries were advertising by pharmaceutical companies direst to public is banned ..we are one of the few countries which allow this practice ..
Regards
Michael

Therapeutic Products Regulatory Scheme Consultation
Ministry of Health
Submission on: Therapeutic Products consultation
As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Robyn Gandell

Hi,
As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.
I believe advertising a particular drug gives a ‘manufacturers viewpoint’ which may not have full information on potential risks or side effects of a particular drug.
Pharmac is already cash strapped to supply some drugs that may help certain patients but those treatments are unavailable due to cost, people making uninformed requests to their GPs will only drive up Pharmac’s costs with a real risk of ineffective treatment.
Most all other countries ban this practice of direct advertising of drugs & I believe we should follow their lead, also most NZ doctors & medical practitioners support banning direct to consumer drug advertising.

Thanks & best regards,

Thomas Waite

As a New Zealander, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

As a pharmacist I constantly see consumers demanding advertised prescription medicines especially those made OTC. The worst are Voltaren 25mg and codeine containing tablets. Seeing the advertisements gives the consumers a feeling of entitlement and they have taken in the buzz words, seen the endorsements and totally disregarded any small print concerning precautions. The health professional are only standing in the way and are treated as such. How could diclofenac be bad? The All Blacks use it!

Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.

Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.

Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
 Why go to the doctor to be diagnosed when you can get the answer on television?

DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
There’s also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.
Yours sincerely
Virginia Vlug

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Errol Keown

Submission on: Therapeutic Products consultation

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely

Christoph Ridder

To whom it may concern
As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand. I deeply resent the way drug companies with deep pockets can directly target vulnerable ill people to make more profit.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
anne Patel

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand. My reasons are:

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and for the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Regards

Joe Carson,

Submission on: Therapeutic Products consultation

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

[Points you may want to make in your submission]

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Robin Booth.

As a taxpayer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

Advertisements for prescription medicines do not give me the information I need to make an informed decision about healthcare treatments. Furthermore I believe:-

- That research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- That unnecessary prescription of medicines leads to increased costs for taxpayers, consumers and the health system.
- That DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- That there's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Cliff Gibson

Dear Sir / Madam,

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand, for the following reasons:

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There’s also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Sincerely
Dr David Hirst

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments. Invariably, the relevant information I need in order to make an informed decision, is in very small print and extremely difficult to read.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Doug Leggett

Therapeutic Products Regulatory Scheme Consultation

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

As a parent I was strongly disapproving of pimple products containing antibiotics being marketed at teens. I complained to Pharmac and the Health dept with nil result. Today my now adult daughter has MRSA Staph throat she cannot cure as she is immune to all antibiotics now.

- Advertisements for prescription medicines do not provide all the information need for an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers as shown above.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Vi Cooper

Therapeutic Products Regulatory Scheme Consultation
Ministry of Health
PO Box 5013
Wellington 6140

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- DCTA creates unnecessary pressure on Pharmac as uninformed consumers, swayed by advertising, push the agency towards funding particular medications to the benefit of the manufacturers.
- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely

Paul Bushnell

13 April 2019

Therapeutic Products Regulatory Scheme Consultation
Ministry of Health
PO Box 5013
Wellington 6140

By email: therapeuticproducts@moh.govt.nz

Submission on: Therapeutic Products consultation

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers. Research shows that medical professionals are influenced to prescribe by pressure from patients. This is part of the reason why pharmaceutical companies spend money on marketing to consumers. Advertisements for prescription medicines do not give consumers all the information they need to make an informed decision about healthcare treatments. DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.

In addition, unnecessary prescription of medicines leads to increased costs for consumers and the health system. PHARMAC's budget is under too much pressure, and reducing unnecessary prescribing can only improve allocation of budget to priority areas.

Yours sincerely
Anne Russell

To : Therapeutic Products Regulatory Scheme Consultation. Ministry of Health, Wellington

As a private citizen, I strongly support amending NZ law to ban TV and other direct-to-consumer advertising (DTCA) of prescription medicines.
I believe that in many countries, DTCA is not permitted.
There is no doubt in my mind that NZers, particularly those who are easily influenced, are asking for products they have seen advertised, even though they lack the knowledge to review alternatives or even to assess the likely value of the product for their own situation. We need to protect our more vulnerable citizens.
No doubt the pharmaceutical companies involved will lobby to resist a ban but I see no reason why NZ should continue to tolerate DTCA.
Yours sincerely
David Irvine

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Judy McDonald,

Submission on: Therapeutic Products consultation

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.
- Asking your doctor as suggested in the TV advertisement would be unwanted lobbying.
-

Yours sincerely
Hugh Webb

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.

They promote only a single option to treat my health issues which does not give me the full picture.

Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.

Unnecessary prescription of medicines leads to increased costs for consumers and the health system.

DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.

There’s also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Let's do the right thing here!

Elwyn Benson

Submission on: Therapeutic Products consultation

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand. DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection. The USA is not a good model to follow - our health system is far superior and we should keep it that way.

Research shows DTCA increases the risk of inappropriate prescribing, leading to possible addiction, and generally poor health outcomes. We do not want companies like Purdue Pharma pushing their product to gullible consumers! There's also strong support from doctors and other medical professionals for a ban on DTCA.

Jon Dumble

Submission on: Therapeutic Products consultation
As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.
Specific Points:

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Jean Tompkins

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- **Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.**
- **Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.**
- **Unnecessary prescription of medicines leads to increased costs for consumers and the health system.**
- **DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.**
- **There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.**

Yours sincerely
Heather & Richard Armishaw

As a registered health professional and consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

This legislation was controversial when it was introduced, and it has not contributed to improved health of our population. On the contrary, it has likely increased the reliance on medication rather than healthy lifestyle changes.

Medical staff are often pressured to prescribe advertised medications, and their competence questioned if not agreeing to do so.

Many of the conditions drug advertising is targeting would potentially respond well to healthy lifestyle changes as a first line of treatment. This is the type of public health information that should be advertised in the media.

Unnecessary prescribing of subsidised medications is a gross waste of tax payers money. The only group that benefits from the advertising is the manufacturer of the drug.

Yours sincerely
Ingrid Perols

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

The following reasons further support the ban...

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely

Nigel Woolf

As a consumer I strongly support changing the law to ban direct to consumer advertising of prescription medicines in NZ for the following reasons:
* advertisements for prescription medicines prey on the vulnerable and ill informed and generate pressure on doctors to prescribe medicines that may not be the best choice
* they are simplistic and do not provide sufficient information to make appropriate decisions
*they may lead to over prescribing of medicines that are more expensive than other equally effective but cheaper ones, or advice about lifestyle changes which may also be effective
* with exception of the US, no other country permits this unethical practice. We are better than that country, and deserve the same protection as other first world countries from pressure from big pharma on our public health system
Yours sincerely
Simon Collin

Submission on: Therapeutic Products consultation

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely

Gesina Todd

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.

Yours sincerely
Karin Martin

As a consumer and retired medical professional, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

The pharmaceutical industry only spends millions of dollars on DTCA because it drives sales and their revenues. Benefits of the drug are maximised while adverse events or contraindications are given far less exposure.

Most TV adverts end with “Ask your doctor if this drug is right for you.” This generates unnecessary doctor visits at the patient’s expense. If a switch in treatment occurs to the advertised drug, it will likely be more expensive (for the patient and the healthcare system) as the advertised drug will still be on patent. Conversely if no switch in treatment occurs, this can affect the doctor patient relationship.

Inappropriate prescribing can result and lead to specific harms and even death. The history of rofecoxib and celecoxib (non-steroidal arthritis treatments) in the US exemplify this point. They were among the most heavily advertised products and thus widely prescribed. Unfortunately, these drugs were later found to have potentially fatal side-effects leading to large-scale population mortality and morbidity. Celecoxib was restricted and rofecoxib withdrawn, but not before the occurrence of thousands of avoidable deaths.

The medical professions in New Zealand strongly support a ban on DTCA as it is seen as creating more harm than good. The Council of Medical Colleges in New Zealand said it could lead to increased costs, inappropriate prescribing, over treatment and iatrogenic harm and may put the doctor-patient relationship at risk.

Finally, in countries where the pharmaceutical industry has lobbied to have DTCA introduced, this has been denied by regulators as being inappropriate for many of the reasons outlined above. On DTCA, New Zealand should side with the rest of the world and not the USA.

Yours sincerely

Alexander (Sandy) Simpson

Hi there
As a consumer I strongly protest about drugs being advertised on TV.
And I feel sorry for the GP's as they are pestered and manipulated by clients to prescribe these drugs.
It's not right.
Yours sincerely
Jude Grace