Burnett Foundation Aotearoa

Submission on the Therapeutic Products Bill

Burnett Foundation Aotearoa is a registered charity funded through a contract with Te Whatu Ora - Health New Zealand and independent fundraising to provide a range of HIV and Sexually Transmitted Infections (STIs) related services, including prevention and health promotion, community-based and home testing, counselling and support, research, policy, and information services. Burnett Foundation Aotearoa advocates for healthy public policy and environments that support our communities.

Burnett Foundation Aotearoa welcomes the opportunity to comment on the Therapeutics Products Bill (the **Bill**). Burnett Foundation Aotearoa wishes to be heard at the Select Committee.

Q1: We wish to make the following comments:

Introduction

Burnett Foundation Aotearoa is generally supportive of the proposed Therapeutic Products Bill (and as a result, the repeal of most of the provisions of the Medicines Act 1981 (the **Medicines Act**) and the regulations made pursuant to the Medicines Act). Burnett Foundation Aotearoa believes the Medicines Act is out of date and unable to respond efficiently and effectively to public health needs.

We strongly support the Bill's purpose of protecting, promoting, and improving the health of all New Zealanders through regulation of the therapeutic products in Aotearoa. We also strongly support the principles guiding exercise of powers under the Act which ensure risk-proportionate regulation, timely availability of therapeutic products, and co-operation with overseas regulators, including potential alignment with international standards and practice where appropriate. We are also in support of ensuring opportunities, choice of, and equity of access to therapeutic products for Māori.

Our comments are provided by theme.

Advertising

1. In our view, an example of failing of the Medicines Act is the current mpox outbreak. On the 23rd of July 2022, mpox was declared a Public Health Emergency of International Concern by the World Health Organisation – an emergency that was predominantly affecting gay, bisexual, and other men who have sex with men (**GBM**) (World Health Organization, 2022). GBM are a marginalised population group in Aotearoa that continues to face persistent health inequities.
2. As a community organisation that primarily serves the GBM population due to our work in HIV and STIs, Burnett Foundation Aotearoa wrote a joint letter in August 2022 (with the New Zealand Sexual Health Society and Gay Men's Sexual Health Research Group) to the Prime Minister. That letter called for urgent action to protect our communities against this new pandemic. In the letter, we argued that clear, consistent, and stigma-free public health messaging to GBM

regarding mpox, including the necessity for sound health promotion and communication strategies regarding vaccination to ensure optimal acceptability and uptake.

3. We note this because the Medicines Act limits the ability to advertise the availability of mpox vaccines in Aotearoa (and other medicines, including the mpox antiretroviral medication, Tecovirimat). Section 20 of the Medicines Act operated to prohibit the advertisement as to the availability of the mpox vaccine in New Zealand, despite it having arrived, because it had not yet secured consent under section 20 (or provisional approval). That restricted our organisation's ability (and the ability of others) to engage in appropriate health promotion related to the mpox vaccine (and the antiviral medicine).
4. As a result, GBM communities have faced a mpox health promotion campaign that has been confusing, lacked clarity, and ultimately undermines their right to good health by restricting access to appropriate information required to make informed decisions about health. This recent example has shown that even during public health emergencies that primarily affect marginalised populations, the current law in respect of advertising medicine is does not protect the health of New Zealanders. Without changes to the law, Aotearoa will continue to face unnecessary obstacles relating to the introduction of new therapeutic products to the country.
5. In respect of advertising, we note the following:

    - As currently drafted, the Bill carries through the Medicine Act's prohibition on advertisement of medicines that have not yet attained authorisation. For the reasons we have explained above, Burnett Foundation Aotearoa is not supportive of this because it can, in certain circumstances, put its communities at risk. A very real example of this is the experience with mpox.
    - We support the inclusion of clause 193(3)(a) that clarifies that "public safety announcements" made under section 236 will not constitute advertisements. Relatedly, we support the inclusion of clause 236 that allows the Regulator to make statements relating to therapeutic products for the purpose of protecting, promoting, and improving personal health or public health. We hope that this will be utilised by the Regulator to fill the gap left by the prohibition against advertising medicines that do not yet have approval.
    - We note the language in clause 194(1) that describes restrictions on distributing advertisements for therapeutic products. This is different to the language used in section 20 of the current Medicines Act, which restricts advertising the "availability of" medications. "Advertisement" is defined in clause 193 as a communication made for the purpose of promoting the product, and communication is also defined. Notwithstanding our view on the prohibition on advertisement, we are supportive of the clarity that these definitions provide, as the current language in the Medicines Act – and Medsafe's approach to the legislation – has caused uncertainty.

Pathways to authorisation

6. Burnett Foundation Aotearoa is concerned that at times, manufacturers may be disincentivised to apply for approval (now authorisation) in the New Zealand market due to the resource-intensive nature of the process (time, cost, administration) and the fact that Aotearoa consists of a relatively small market for their product.

7. This issue has resulted in delays in getting the mpox vaccine approved. It is also a key barrier to ensuring availability of Alkyl Nitrate ('poppers' – commonly used during sexual activity in GBM communities, with a long history of very limited harm) and new medicines like oral lead in tablets for long-acting injectable antiretroviral therapy for people living with HIV in Aotearoa.
8. Burnett Foundation Aotearoa is concerned that the maintenance of the current approval / authorisation process significantly limits access to therapeutic products in Aotearoa by requiring manufacturers to apply for approval (which can be a slow process). To that end, we support the inclusion of clause 346, which allows the Regulator to rely on reports or decisions of "recognised entities" (as we understand it is already able to do). However, we would like to see alternate pathways to approval for products that are already approved in other countries to allow Aotearoa to gain timely access to therapeutic products.
9. Burnett Foundation Aotearoa also strongly recommends that people with relevant lived experiences, patient groups, and community organisations are meaningfully consulted in decisions to harmonise with overseas regulators. We note our disappointment in MedSafe's decision to classify alkyl nitrites as medicines, harmonising with the Australian Therapeutic Goods Administration. No community groups were consulted in this process and no approved product is available for this purpose, despite the relatively low risk of harm.
10. Burnett Foundation Aotearoa also supports the appropriate resourcing of the new Regulator to ensure it has the resources to process applications in a timely way.

Emergency arrangements

11. Burnett Foundation Aotearoa supports the inclusion of clause 116(1) that allows a person to do something that would otherwise contravene a provision of subpart 1 or 2 of Part 3 if an 'emergency arrangements notice' allowed them to.
12. However, we are concerned that (3) of this clause restricts this provision to medicines or medical devices that have market authorisation for at least 1 authorised indication. In the case of an emergency (i.e., a pandemic), even provisional approval will take time to process, ultimately impacting Aotearoa's ability to respond in a timely manner to that emergency.

Regulatory interpretation of the Bill

13. More generally, Burnett Foundation Aotearoa would like to note our concern as to how the Regulator will interpret the language of the Bill once it is passed as law.
14. Our view is that MedSafe has historically drawn on conservative interpretations of the current Medicines Act in ways that impact engagement in health promotion.
15. For example, MedSafe interprets s 20 of the Medicines Act as prohibiting advertisement in respect of an off-label use of an otherwise approved medicine[1]. It is not clear that this is what the statutory language says. MedSafe also interprets advertisement very broadly[2].

[1] MedSafe. (2020, December 4). *Use of Unapproved Medicines and Unapproved Use of Medicines.* https://www.medsafe.govt.nz/profs/riss/unapp.asp

[2] For example, MedSafe considers "word of mouth" and "private communications" regarding the availability of an unapproved medicine to be advertising (MedSafe. (2019, November 26). *Marketing Products Which Are Not Approved Medicines.* https://www.medsafe.govt.nz/compliance/Marketing.asp)

Personal importation

16. Burnett Foundation Aotearoa would like to express significant concern over the proposed clause 105(6) that effectively bans personal importation of prescription medicine via delivery. The inclusion of this subsection will adversely affect people living with HIV whose antiretroviral therapy (ART) medication is not locally available, as well as people importing tenofovir alafenamide (TAF) - based PrEP (generic Descovy equivalents). This subsection also has implications for access to cheaper, generic medicines via the Internet where those medicines have ongoing funding restrictions in Aotearoa or are new medications that have yet to be approved or made available in Aotearoa.
17. The current regulatory framework allows an individual to import medicines, including unapproved medicines, for personal use (although they will generally require "reasonable excuse" which Medsafe interprets to require a locally acquired prescription). There are numerous migrants, including temporary migrants, in Aotearoa who rely on this existing importing legislation to ensure they have ongoing, stable access to their life-saving ART medication or HIV prevention medication. The current range of PHARMAC funded HIV treatment options is particularly limited as compared to other high-income countries, leading migrants to have to import their medicine from their country of origin or previous residence. We note that there are reputable pharmacies that sell ART and TAF-based PrEP overseas and many people in Aotearoa are ordering their medication from trusted pharmacies in their home country.
18. While access barriers to treatment are an issue for many people living with chronic illnesses, there is a severe risk of resistance associated with even short HIV treatment interruptions, which can be life threatening for people living with HIV. This means that increasing barriers to accessing medication pose a serious threat to the health of people living with HIV.
19. Furthermore, HIV treatment and PrEP are distinctly important to protecting public health, given they are crucial to combination prevention of HIV transmission in Aotearoa. ART is vital to ensuring patients maintain an undetectable viral load, which both ensures their own health, while also protecting others from further HIV transmission. We now know that people living with HIV who have suppressed, undetectable viral loads do not transmit HIV to their sexual partners (UNAIDS, 2018). "U=U" (Undetectable=Untransmittable) is one of the most important components of combination prevention of HIV. Ensuring people living with HIV have prompt and sustained access to antiretroviral treatment and thus maintain an undetectable viral load helps eliminate the risk of forward transmission. Similarly, PrEP is highly effective at preventing HIV acquisition and is a crucial biomedical tool in our HIV response.
20. UNAIDS set out a target of virtual elimination of HIV by 2030, which involves a 95% reduction in the number of new HIV infections compared to the 2010 baseline (General Assembly United Nations, 2021). If Aotearoa is to meet UNAIDS HIV targets we have committed to, it is imperative that we support people living with HIV to continue to maintain suppressed viral loads and ensure optimal uptake of PrEP, instead of introducing new barriers.
21. Burnett Foundation Aotearoa also is concerned that the proposed clause will enable those with the resources to travel internationally to gain differential access to medications, in turn producing inequities in access to medication and health outcomes.

Controlled activities

22. We support the inclusion of clause 65, which enables health practitioners to carry on a controlled activity with a medicine or medical device that does not yet have NZ authorisation provided the special case requirement is met.
23. We support the inclusion of clause 115, which provides for the possibility that controlled activities could be carried by persons other than those permitted by virtue of section 67. We agree that it should be possible to expand the group of persons able to prescribe and administer vaccines, expanding the possible scale of vaccine delivery (including, for example, where a large portion of the population is getting vaccinated in a short period of time).

Rongoā

24. Burnett Foundation Aotearoa expresses concern of over the implications of the Therapeutic Products Bill for rongoā and rongoā practitioners.
25. We are concerned that the bill in its current form may exert restrictions on rongoā and rongoā practitioners that are inconsistent with Māori rights to self-determination under Te Tiriti o Waitangi and the UN Declaration on the Rights of Indigenous Peoples (Article 24). We are also concerned that rongoā practitioners and Māori were not appropriately or meaningfully partnered with in the drafting of this proposed bill so far. We advocate strongly for further work to ensure this bill upholds Tino Rangatiratanga for Māori.

Medical devices

26. Burnett Foundation Aotearoa expresses strong concern over the increased regulation of medical devices in the Therapeutic Products Bill.
27. The requirement that medical devices gain market authorisation is a major change to the legal environment and may create a significant barrier for our organisation to import HIV and syphilis testing devices.
28. We support the principles of ensuring acceptable safety, quality, and performance of medical devices. As such, we support market authorisation of medical devices in general. However, we strongly advocate for the threshold to be low, especially for community groups seeking authorisation.
29. In the course of providing our services, we rely on the regulatory systems of other major countries and careful review of public health evidence to select our devices. Our approach is fit-for-purpose and has enabled a safe and effective health programme to be carried out that is foundational to Aotearoa's HIV response.
30. To illustrate, between 2019-2022, 8064 individuals used Burnett Foundation Aotearoa HIV self-testing service, the vast majority GBM. These users reported the HIV self-testing device was easy, convenient, discrete, flexible and non-restrictive. 34 individuals have been diagnosed with HIV using this service, many of whom reported other testing methods were not convenient or acceptable. Latest data from the Sex and Prevention of Transmission Study (SPOTS) also showed that approximately a quarter of respondents who last tested HIV negative, likely received this result using Burnett Foundation Aotearoa's devices (Saxton, 2023). 9.3% received their negative result via point of care testing at Burnett Foundation Aotearoa Clinics and 16.1% via a self-test kit, most likely obtained through Burnett Foundation's website (Saxton, 2023).
31. As discussed previously, UNAIDS set out a target of virtual elimination of HIV by 2030 (General Assembly United Nations, 2021). Supporting regular testing is foundational to meeting this target, as it enables prompt access to treatment, ensuring optimal health for the individual and reducing risk of unwitting onward

transmission, thus protecting population health as well. In this context, it would be irresponsible to introduce legislation that could jeopardise community-based testing programmes.

32. Burnett Foundation Aotearoa hopes that clause 346 and principles guiding exercise of powers under the Act – which ensure risk-proportionate regulation, timely availability of therapeutic products, and co-operation with overseas regulators, including potential alignment with international standards and practice where appropriate – are used to ensure ease of access to these testing devices. However, we believe the current proposed Bill does not adequately guarantee that programmes like ours will not be jeopardised. We advocate strongly for a low-risk pathway to approval of medical devices that will not compromise our HIV and STI testing programme. Any new system or regulation process should be permissive enough to ensure ongoing access to these high-quality HIV and STI testing devices in Aotearoa. Manufacturers opting not to seek authorisation due to the resource-intensive process and relatively small market in Aotearoa should not create a barrier to importing HIV and STI testing devices.

Other

33. We support the inclusion of clause 379 that allows the Regulator to exempt therapeutic products, other things, classes of products, and classes of persons from provisions in the Act (if satisfied of certain things on reasonable grounds).
34. We support the inclusion of clause 155, that allows products without NZ authorisation into the local supply chain.

Q2: We wish to make the following recommendations:

Based on our views set out above, we make the following recommendations:

1. It should be permissible, in certain circumstances (i.e., where it would be in the interests of public health), to communicate the availability or existence of therapeutic products that have not been authorised.
2. We advocate for the Therapeutic Products Bill to address the issue of manufacturers being unwilling to submit applications for authorisation of medications due to the resource intensive process and Aotearoa being a relatively small market for their product. A solution may include creating clear alternate pathways to approval for products already approved in other major countries, like Australia. Although we also recommend robust consultation with those with relevant lived experiences in the decision-making process to harmonise with overseas regulators.
3. We advocate strongly for the inclusion of a low-risk pathway to authorisation of medical devices that will not compromise Burnett Foundation Aotearoa's existing HIV and STI testing programme, as well as similar health protection programmes in the country.
4. We advocate strongly for clause 105(6)(a) to be removed, so that prescription medication can be imported via post. Relatedly, we advocate for clause 105(6)(b)to be amended to increase the 3-month limit of medication supply that can be imported.
5. We advocate strongly for meaningful involvement of and partnership with Māori (iwi, hāpū, Māori health providers, and rongoā practitioners) to ensure the Therapeutic Products Bill protects rongoā and rongoā practitioners and upholds Tino Rangatiratanga under Te Tiriti o Waitangi and the UN Declaration on the Rights of Indigenous Peoples.

Ngā mihi nui

Joe Rich
Chief Executive

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