New Zealand Drug Foundation Submission on the Therapeutic Products Act Repeal Bill

Submitted to the Health Select Committee on 29 July 2024.

We request the opportunity to make an oral submission to this Bill.

The Drug Foundation is a charitable trust. We have been at the forefront of major alcohol and other drug debates for over 30 years, promoting healthy approaches to alcohol and other drugs for all New Zealanders.

Tēnā koutou,

Thank you for the opportunity to provide feedback on the Therapeutic Products Act (TPA) Repeal Bill.

New Zealanders deserve access to modern medicines through a rational and modern framework of regulation. Medicines Act 1981 does not deliver on this, and as issues like medicines supply chain disruptions and emerging infectious diseases appear to grow, we need to make sure our framework is responsive.

While we welcomed the introduction of TPA into the Parliament as a step to modernise our approach and improve on many issues, we were disheartened that many of our key recommendations were not implemented. We felt the Act missed some opportunities to prevent drug harm among New Zealanders and allow for greater flexibility of the system.

In the area of drug harm reduction, with the pressures from the global illicit drug market, the assessment of risks and benefits of a health intervention often does not stack up quite the same as it does for other health issues. We need flexibility, responsiveness, and constant innovation to respond to the challenges posed by illicit supply changes.

We were disappointed with the lack of provisions enabling for harm reduction devices (such as sterile snorting straws to prevent blood-borne virus transmission) to be distributed to people at risk of serious harm under the TPA. We were also concerned that some of the emergency provisions in the Act were simply too limited to respond to the emerging risks in the illicit drugs supply.

Importantly, we continue to have concerns about some of the existing provisions that are included in the Medicines Act and were that carried over into the TPA. Namely, we are concerned about the lack of transparency and review mechanisms of the 'restriction notices' ('oversupplied persons' in TPA), whose impacts on people affected or on the diverted drugs supply is unknown.

Other issues that should be addressed include insufficient streamlining of product approvals for lower-risk products already approved by robustly resourced international regulators, insufficient avenues for community voice, and the failure to restrict the direct-to-consumer advertising.

Lastly, we continue to call for meaningful engagement with Māori to ensure that any regulation of natural health products gives effect to the rights of Māori to fully govern the use, and any potential benefit from commercialisation, of native species and rongoā knowledge.

While we maintain a largely neutral view on the repeal of the TPA itself, we must stress to the Parliament and the Minister of Health that a modernisation of our existing system is necessary and should be prioritised. This could be achieved by enacting alternative legislation, as well as by amending the TPA, which would have the benefit of retaining some of the positive aspects of the Act.

Nāku noa, nā

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NZ Drug Foundation Te Puna Whakaiti Pāmamae Kai Whakapiri

Introduction

1. In 2023, the NZ Drug Foundation provided feedback on the Therapeutic Products Bill. We supported the general objectives of the Bill and the aspiration to protect, promote and improve the health of all New Zealanders by providing a framework for the risk-proportionate regulation of supply of safe and effective therapeutic products (TPs).
2. The Therapeutic Products Act 2023 (TPA) contains much needed, modern solutions to some of the challenges of regulating medicines, and other therapeutic products. The provisions in the Act are needed to ensure New Zealanders have access to modern medicines, and that our health system is empowered to offer efficacious treatments in a safe and timely manner.
3. In our submission on the Therapeutic Products Bill, we outlined a number of points that we supported, and a number of issues that we were concerned about. We remain concerned that the TPA did not go far enough in addressing some of the critical issues for modernising New Zealand's outdated medicines and medical devices regulatory system.
4. Despite our concerns, the Drug Foundation is worried to see that TPA is being repealed with no clear pathway to alternative legislation proposed. We note that the option to amend parts of the TPA has not been presented. We urge the Government to promptly publish its' plans for a modernised, efficient and flexible regulatory system, as has been suggested.
5. Our submission on the Therapeutic Products Bill last year raised a number of issues regarding the new regulatory system, modernising our medicines regime, products classification, emergency provisions, classification of harm reduction tools, reviewing restriction notices, and rongoā Māori considerations. Now that the Government has proposed repealing the TPA, we have an opportunity to ensure that new provisions in replacement legislation are fit for purpose.
6. Our chief recommendations remain around making emergency approvals for harm reduction products easier, as well as modernising the regulation of harm reduction products which have proven public health benefits.
7. We remain seriously concerned that the TPA did not address the outdated approach of classifying patients as 'oversupplied persons' by placing restriction notices on them, without a mechanism to track whether this intervention achieves its aims.
8. There are several beneficial provisions that can be introduced into new legislation. We will closely monitor the development of new legislation, and continue to advocate for a more modern, streamlined approach to our regulatory system.
9. Within this process, we strongly urge collaboration with Māori to create a system which is truly based on partnership between the Crown and Māori, according to

the principles of te Tiriti o Waitangi. We also urge meaningful collaboration with lived experience voices and patient groups, to understand the real-world impacts of their current and potential future access to medicines, devices, and natural health products.

We support streamlining the approvals process for medicines and devices

10. We recommend a risk-proportional approach to medicines and medical devices regulation that enables community-based delivery of health interventions.
11. We strongly recommend that legislation specifies that international agreements should be made for the mutual recognition of therapeutic products registrations, with adequate safety checks and real opportunities for community input.
12. We strongly support exploring New Zealand's participation in programmes such as the Medical Devices Single Audit Programme (MDSAP). Members include the Australian Therapeutic Goods Administration (TGA), Health Canada, the US Food and Drug Administration (FDA), and other state agencies with robust regulatory frameworks. Section 354 of the TPA allows the Regulator to rely on the decisions of overseas regulators, but participating in the MDSAP is not specifically outlined. We understand these 'overseas regulators' may include bodies like MDSAP and others. Legislation should not only allow for the Regulator to consider overseas regulations, but should explicitly allow for New Zealand to have the ability to apply to join bodies such as the MDSAP.
13. We also recommend that future legislation allows for consultation with lived experience voices and patient groups when decisions to harmonise (or not to harmonise) with overseas regulations are made. Many community groups have robust international networks and rich experiences that can inform the real-world impacts of the Regulator's decision-making process. However, currently, the opportunities to input into decision-making are limited. Meaningful consultation would allow potentially affected community members to raise any matters which need further investigation before automatic approval is granted, and should be embedded in any future legislation.
14. We expect that streamlining the approvals process will improve consumer choice of medical products. For example, prescription cannabis patients who use vaporisers to take their medicine will have access to a wider range of high quality, safe devices. However, some of the high-quality devices that are available overseas are currently restricted by the Misuse of Drugs (Prohibition of Utensils) Notice 2020 (Ministry of Health, 2020) and this should be addressed as well.

Harm reduction products should be more appropriately classified under medicines and medical devices legislation than the Misuse of Drugs Act 1975

15. The TPA missed some opportunities to enable access to harm reduction products and devices, as well as access to novel treatments for substance use. For example, a number of products that can be used in harm reduction interventions are currently banned as 'drug utensils' under section 13 of the Misuse of Drugs Act 1975 (MODA).
16. The current ban on drug utensils exacerbates drug harm and hinders efforts to deliver effective services to at-risk clients. For example, distributing clean snorting straws, which can prevent transmission of the blood-borne hepatitis B or C viruses, is illegal.
17. We recommend that any new legislation includes a revocation of the MODA clauses that prohibit possession and not-for-profit or social supply of drug utensils, when these are used as harm reduction interventions.
18. Enabling streamlined market authorisation of harm reduction products, delivered to people who use substances as part of risk minimisation programmes, needs to be written into law. We need legislation that specifies that medical devices may include products used as harm reduction tools. Therapeutic products legislation is a more appropriate avenue to govern this process, compared with the status quo under the MODA.
19. As a minimum and immediate measure under current regulations, we urgently recommend that the Minister of Health specifies that straws, safer-to-use pipes, vaporisers, and similar products, when used as part of harm reduction programmes, are not considered drug utensils. This can be achieved with an issue of a gazetted notice, similar to the notice regulating medical cannabis vaporisers access (New Zealand Gazette, 2020).

Emergency approvals for harm reduction products need to be expanded

20. Any legislation that regulates products used for harm reduction interventions must allow for broad and flexible emergency approval powers with a reasonable threshold.
21. We support allowing special classes of persons to engage in controlled activities, when there is a public health interest. This could enable the effective roll-out of life-saving interventions, for example, supplying or administering naloxone to reverse opioid overdose. Responsive harm reduction interventions are usually needed to be rolled out rapidly due to the volatile nature of the illicit drug market, and the regulatory framework needs to allow for this.

22. There is ample evidence that drug harms are exacerbated in crisis situations like pandemics or natural disasters (McCann-Pineo et al., 2021). We therefore support the Chief Executive of the Ministry of Health being able to make emergency arrangement notices under medicines legislation. However, the provisions should be strengthened to extend to controlled activities governed by the MODA. The MODA prohibits effective and lifesaving harm reduction interventions, even under emergency conditions, as was the case during the 2023 Cyclone Gabrielle response.

23. We recommended that legislation allows for the flexible delivery of harm reduction interventions, opioid agonist treatment, and other forms of support to people at risk of drug harm (Zolopa et al., 2021). This would also include allowing the wider supply and administration of controlled substances when access through usual pathways is disturbed. This could help people with the safe supply of products in an emergency, like an increase in the toxic adulteration of illicit supplies.

'Oversupplied persons' provisions and restriction notices need to be thoroughly reviewed, as they may be disenfranchising or harming patients

24. We are seriously concerned about the provisions in the TPA regarding 'oversupplied persons'. These are simply a continuation of section 49 of the Medicines Act and equivalent provisions in the MODA. There has been no critical appraisal of the intention, wording, and purpose of the restriction notices and their impact on people seeking healthcare who may also use, or have used drugs.

25. In our view, there is insufficient evidence of public benefit to continue the current practice of 'restriction notices' without an adequate review. In the event the TPA is repealed, we strongly recommend a thorough review of the current restriction notices mechanisms, and their impacts on those with substance addiction and their whānau. This review should be conducted in consultation with people affected (including patients currently and/or previously on restriction lists).

26. We are concerned the current provisions do not achieve their intended purpose of meaningfully reducing medicine diversion. In our experience, most diversion occurs among those who have never been, and are unlikely to become, listed as 'oversupplied persons'. We would like to see an appraisal of the impacts of this process on the extent of diversion into the illicit market.

27. We are seriously concerned that including people on the 'oversupplied persons' list results in stigmatisation. People with lived experience of substance use have consistently told us that inclusion on the list can limit access to healthcare. Patients are labelled as 'drug-seeking' and restricted in their ability to access

other medication they may need. This is inconsistent with effective harm reduction approaches that require people who use drugs to continue to have access to healthcare, regardless of their current drug using practices.

28. We also have concerns that 'restriction notices' are ineffective in preventing the escalation of prescription or controlled medicine use. Instead, people may turn to illicit markets, creating substantially more harm. We believe that the majority of those who misuse prescription medicines are not on the list.

29. A restrictions list may also create the false impression among clinicians that checking the list relieves them of their duty to assess each patient's dependency risk when prescribing potentially addictive medication.

30. We have several further specific concerns about the current wording and details of the provisions. For example, specific wording about drug 'addiction' and 'habituation' may limit access to appropriate medication (several substances create physiological habituation very rapidly) and is considered obsolete. The DSM-V lists criteria to diagnose substance use disorder where there is current clinically and functionally significant impairment. Before a person's access to health care is restricted, appropriate diagnosis should occur rather than the usage of broad terms that are not consistently applied. This should also be time-limited, matching how the diagnostic criteria are meant to be applied.

31. We also note that the proposed provisions give the patient no right to dispute the inclusion on the 'oversupplied list'. Likewise, there are no time limits for the notices to be in place. There is also no formal requirement for a regular review of the list.

32. We are not aware of any recent reviews of the 'restriction notices' or 'oversupplied persons' mechanism, despite them carrying a significant risk of harm to patients. We therefore strongly call for an urgent review of these mechanisms with a view to either amending the TPA or the Medicines Act, and the relevant provisions under the MODA.

Therapeutic products should be able to be classified in multiple categories, depending on their characteristics

33. We recommend that there be provisions that allow for TPs to be included in more than one category, depending on the product characteristics. Legislation should allow for flexibility for the Regulator to decide whether certain plant-derived products can be classified as natural health products.

34. For example, CBD-only cannabis products are currently regulated as medicines. There are a small number of products that have been sufficiently trialled to meet the medicine-level threshold for a narrow list of indications (for example, *Epidyolex* for certain types of seizures). However, many patients could benefit

from access to CBD-only products that are unlikely to ever receive trial-based approvals, due to the inability of manufacturers to receive patent protection.

35. A flexible approach is common in similar jurisdictions, and New Zealand takes a uniquely conservative stance. We believe that appropriate classification would result in certain formulations, dosages, delivery modes or indications of some non-intoxicating medicinal cannabis products to be classified as medicines, and others as natural health products or supplements. With adequate regulation, a flexible approach would allow patients to access quality-assured products as natural health products.
36. We therefore recommend that legislation should clarify that a therapeutic product may be classified in more than one category depending on the intended indication, formulation, dosage and/or route of administration.

We support the appropriate inclusion of te Tiriti o Waitangi principles, and recognition of tino rangatiratanga over taonga species

37. We welcomed the Health Committee's consultation with mana whenua about the impacts of the Therapeutic Products Bill on rongoā practice. In particular, we welcomed sections 112, 355, and 365 to 369 of the TPA regarding the Crown's obligations to give effect to te Tiriti principles. In future discussions about how legislation affects the use of rongoā, we strongly encourage further dialogue between tangata Tiriti and the Crown.
38. We strongly support recognising Māori sovereign ownership of rongoā and tino rangatiratanga over taonga species. In developing any future regulations or legislation, we recommend that an appropriate Māori-led process for authorisation, harvesting, and marketisation of taonga species is developed in true partnership with Māori. This should give effect to the principles of kotahitanga, kaitiakitanga, tino rangatiratanga, whanaungatanga and kia tūpato as outlined by the recent Wai262 best practice guide (Potter & Rauika Māngai, 2022).
39. In particular, we expect that the provisions allow sovereign regulation of all taonga species by Māori. The law must allow for TPs that are also indigenous species to be regulated in true partnership with tangata whenua. Rongoā practitioners must be empowered to practice in accordance with rongoā principles, and if appropriate, we recommend that a Māori-led body is resourced to appropriately and safely regulate rongoā practice.
40. We note that there are also taonga species that are currently regulated under the MODA, which include certain *Psilocybe* gena with potential therapeutic applications. We recommend that appropriate provisions are included in legislation that give back control of indigenous species to mana whenua.

We recommend prohibiting direct-to-consumer advertising of prescription medicines, due to evidence of social harm

41. The TPA does not prohibit direct-to-consumer-advertising of prescription medicines. Current evidence shows that the risks of direct-to-consumer advertising outweigh any potential benefits (Lexchin & Menkes, 2019). Local research suggests that these harms are more likely to manifest in more vulnerable populations, including those with poorer self-reported health status, who are older, less educated or with lower incomes, and ethnic minorities (Khalil Zadeh et al., 2017).
42. Regulation 50 of the Misuse of Drugs Regulations 1977 prohibits advertising of controlled substances. However, some substances that may be addiction-forming are not currently on the controlled substances list, and the evidence is fast-evolving around some other substances.
43. We strongly believe an effective solution to the risk of advertising addictive substances is to prohibit direct-to-consumer advertising of all prescription medicines, especially considering the risk of other harms caused by this commercial practice.

Summary of our recommendations

Recommendation 1: streamlining the approvals process for medicines and devices

i. We support exploring New Zealand's participation in programmes such as the Medical Devices Single Audit Programme (MDSAP).

ii. Future legislation should allow for consultation with lived experience voices and patient groups when decisions to harmonise (or not to harmonise) with overseas regulators are made.

Recommendation 2: harm reduction devices should be more appropriately classified under either the TPA or alternative medicines and devices legislation

iii. We recommend that any new legislation includes a revocation of the Misuse of Drugs Act clauses that prohibit possession and non-commercial or social supply of drug utensils, when these are used as harm reduction interventions.

iv. In the short term, we recommend that straws, safer-to-use pipes, vaporisers, and similar products, are not considered drug utensils when used as part of harm reduction programmes, through the Minister of Health issuing an appropriate gazette notice.

Recommendation 3: emergency approvals for harm reduction products need to be expanded

v. We support allowing specified classes of persons to engage in controlled activities, when there is a public health interest in regard to medicines or medical devices.

vi. We support the Chief Executive of the Ministry of Health being able to make emergency arrangement notices, but these must be strengthened to extend to controlled activities governed by the Misuse of Drugs Act.

vii. We recommended that legislation allows for flexible delivery of harm reduction interventions, such opioid agonist treatment, and other forms of support to people at risk of drug harm.

Recommendation 4: thoroughly review provisions regarding 'oversupplied persons' provisions and 'restriction notices'

viii. We strongly recommend a thorough review of current restriction notices mechanisms, and their impacts on those with substance addiction and their whānau. This review should be conducted in consultation with people affected (including patients currently and/or previously on the restriction list).

ix. In particular, we recommend an assessment of the impact of restriction notices on the diversion of substances to the illicit market.

x. We also recommend a careful review of the language used to describe reasons why a person may be designated an 'oversupplied person', in accordance with modern diagnostic criteria.

xi. We recommend that patients have the right to dispute the inclusion on the 'oversupplied list', and that there are provisions for regular review of the list.

Recommendation 5: therapeutic products should be able to be classified in multiple categories

xii. We recommend that legislation clarifies that a therapeutic product may be classified by the Regulator in more than one category depending on the intended indication, formulation, dosage and/or route of administration. For example, plant-derived products, such as CBD-only medicinal cannabis products, could be included in more than one category.

Recommendation 6: continued inclusion of te Tiriti o Waitangi principles and recognition of tino rangatiratanga over taonga species

xiii. We strongly encourage meaningful dialogue between tangata Tiriti and the Crown regarding the impacts of any new legislation on rongoā practice.

xiv. We recommend that an appropriate Māori-led process for authorisation, harvesting, and marketisation of taonga species is developed in true partnership with Māori.

xv. We recommend that appropriate provisions are included that give back control of indigenous species to mana whenua, such as certain *Psilocybe* gena with potential therapeutic applications that are currently regulated under the Misuse of Drugs Act.

Recommendation 7: prohibiting direct-to-consumer advertising of prescription medicines due to evidence of social harm

xvi. We recommend prohibiting direct-to-consumer advertising of all prescription medicines, especially considering that the risks of such advertising outweigh any potential benefits.

References

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