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AT THE HEART OF THE MATTER, NZ DRUG FOUNDATION.
Te Tūāpapa Tarukino o Aotearoa

New Zealand Drug Foundation submission on the Therapeutic Products Bill

Submitted to the Health Select Committee on 4 March 2023.
We request an opportunity to make an oral submission.

Tēnā koutou

Thank you for the opportunity to contribute to the work of the Health Committee with our submission on the Therapeutic Products Bill.

We welcome the Bill and recognise the need to modernise the ways we approach access to novel therapeutic products in Aotearoa. This is once in a generation change and we encourage the Health Committee to continue to engage with communities that could benefit from improved access to medicines to make sure we get it right.

In our submission we make comments on the specific sections of the Bill that we believe are most relevant from the perspective of drug harm reduction in Aotearoa.

As we outline in our submission, we are broadly supportive of the provisions seeking to regulate therapeutic products in a risk-proportionate manner. We note that New Zealanders often suffer from suboptimal access to new therapeutic products due to our small population size (and patient numbers) that disadvantages us when competing for access with larger markets. In addiction treatment and drug harm reduction interventions, this is further compounded by the fact that the target population is often an even smaller group of people who may not generally have access to healthcare.

We encourage more recognition of the unique needs of the harm reduction sector. Harm reduction approaches are sometimes at odds with traditional attempts to only permit therapeutic products with no to very little risk. However, the consequence of this micro focus on individual product safety without looking at the big picture can result in much more harms. For example, in the case of naloxone, a life-saving opioid overdose reversal medicine, restricting access is likely meaning people with opioid use are dying from preventable overdoses. In our line of work, we must often act quickly and in limited-information environments. The cost of inaction can be serious, acute harm, including death, and that must be weighed against conservative approach to product assessment.

We strongly encourage the Health Committee to ensure that the Bill recognises the expertise offered by people with lived experience, community advocates, civil society, and patient groups. Very often, those directly affected bring in the missing insights required to appropriately prioritise interventions for maximum impact. Value added by the knowledge and networks of people with lived experience cannot be overstated, and we encourage the Health Committee to use this opportunity to embed it in our decision-making processes.

In our submission, we specifically support several provisions that enable the Regulator and the Ministry to arrange for access to medicines and medical devices without relying on global pharmaceutical industry's initiative in seeking authorisation. We specifically recommend that some of those proposed provisions are taken further to offer more flexibility when acting in the interest of public health. Importantly, we recommend more inclusion of the patient voice, civil society actors, and those with lived experience. This includes enabling access to therapeutic products that are also taonga, while recognising tino rangatiratanga principles under Te Tiriti o Waitangi.

This omnibus Bill undoubtedly presents a unique opportunity to address many issues at the intersection between the proposed therapeutic products regime and controlled substances framework regulated under the Misuse of Drugs Act 1975. We make specific recommendations throughout the document that include reviewing 'restriction notices'/'oversupplied persons' provisions, more sensible regulation of 'drug utensils' as medical devices used for harm reduction, prohibiting controlled substances advertising through therapeutic products regime instead of Misuse of Drugs Act, and others.

Finally, we recommend giving effect to Te Tiriti o Waitangi and engaging in a meaningful consultation with mana whenua, especially around rongoā practice and regulation (and commercialisation) of taonga species of indigenous plants and fungi. We strongly recommend implementing the recommendations made under Wai262 claim in the Waitangi Tribunal.

Thank you for considering our submission. We also request the opportunity to make an oral submission.

Sarah Helm

Executive Director

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.

We support the general objectives of the Bill

1. The Drug Foundation welcomes the Therapeutic Products Bill. We particularly welcome the aspiration to protect, promote and improve the health of all New Zealanders by providing a framework for risk-proportionate regulation of supply of safe and effective therapeutic products (TPs).
2. This legislation is needed to ensure New Zealanders have access to modern medicines, and the health agencies are empowered to offer efficacious treatments in a safe and timely manner.
3. We acknowledge the backstop date of 1 September 2026. We will be carefully monitoring the development of secondary legislation under the Act to ensure that principles of harm reduction are part of the tenets underpinning the regulatory regime of TPs in Aotearoa.
4. In this document, we make a number of specific comments to select clauses of the Bill, and we offer recommendations on maximising the positive impacts of the Bill on the health of New Zealanders, especially in the area of drug harm reduction.

We support the intention to regulate medicines supply and access in a robust fashion that enables community voice

5. We acknowledge and support the desire to provide for a robust regulatory system for medicines that would require demonstrating safety, quality, and efficacy of the products and an evaluation of risks versus benefits associated with them.
6. We note that strict regulation of medicines used in the health system is necessary to ensure public safety and trust. However, we also note the need to balance this need against the economic realities of the global pharmaceutical model that, at times, disadvantage smaller countries like Aotearoa, where financial incentives to manufacturers that supply the medicines may be insufficient.
7. While there is no universally accepted definition of harm reduction, it has been defined to refer “to policies, programmes and practices that aim to minimise the negative health, social and legal impacts associated with drug use, drug policies and drug laws. Harm reduction is grounded in justice and human rights. It focuses on positive change and on working with people without judgement, coercion, discrimination, or requiring that people stop using drugs as a precondition of support” (Harm Reduction International, 2023).
8. In harm reduction and addiction treatment sector, we operate within the context of global illicit drug markets which are highly volatile, leading to the need for public health systems to respond quickly. We strongly support

legislation that creates pathways that allow for medicine-based interventions responding to those challenges to be scaled up quickly and flexibly.

9. Managing risk of products must be managed against the risk of inaction, especially when offering support to people who use drugs who are vulnerable to the harms of illicit markets.

10. The current regulatory system has not always been enabling effective harm reduction. Recently, the NZ Drug Foundation encountered significant regulatory barriers in trying to access easy-to-administer naloxone formulations to deliver to people at risk of opioid overdose. Some of the products that are safely distributed to people at risk overseas are still not approved in New Zealand due to lack of manufacturer initiative. Only a small number of products are available locally, and many of those are carrying a high price tag because of a small patient pool.

11. Furthermore, the prohibitively conservative approach to distribution of naloxone by the current Regulator has been hindering the rollout that could prevent fatalities when adulterated supply incidents become more common in Aotearoa. A recent decision about whether to make naloxone more widely available has resulted in ampoules only being able to be given out by needle providers, meaning that if we have a 'crisis' event, such as the adulteration of a supply of another drug with a potent opioid like fentanyl, those best placed to get naloxone out may be prohibited from doing so. Our hands are tied, out of an overly cautious approach to the regulation of naloxone supply.

12. Under current legislation, no effective mechanism enables patient communities or civil society actors to effectively access and supply medicines, even in cases where robust evidence supports the intervention. We believe that a regulatory regime with embedded principles of consultation and giving effect to community aspirations would help getting that balance right.

13. Therefore, we strongly support provisions that strengthen community advocacy and people with lived experience in participation in the regulatory regime. This should be embedded both in the proposed Act and the secondary legislation.

We support clauses enabling robust and timely responses to health crises including effective harm reduction

14. We specifically support section 115 that allows for permitting special classes of persons to engage in controlled activities, when this is in the interest of public health. We acknowledge and agree with the rationale laid out in the exploratory notes, that such mechanism could enable effective roll out of interventions necessary to respond to emerging public health risks.

15. For example, we would envisage that section 115 may be utilised to enable peer workforce, community organisation workers, police officers and people

offering first aid to supply harm reduction interventions, including those requiring performing controlled activities. This could entail supplying or administering medicines, like naloxone to reverse overdoses.

16. We support the provisions that regulations made under this clause do not need to be limited to urgent or short-term challenges. Such understanding is crucial to enable responsive harm reduction interventions needed when the volatile illicit markets circumstances change quickly, yet the response systems require sustainable solutions.

We recommend including clauses that allow for therapeutic products to be classified in multiple categories depending on product characteristics

17. We recommend that the provisions allow for TPs to be included in more than one category depending on the product characteristics.

18. For example, CBD-only cannabis products are currently regulated as medicines. While there is a small number of products that have been sufficiently trialled to meet the medicine-level threshold for a narrow list of indications (e.g., *Epidiolex*), many patients could benefit from access to CBD-only products that are unlikely to ever receive trial-based approvals due to inability of manufacturers to receive patent protection. We note that such approach is common in similar jurisdictions, with New Zealand taking a uniquely conservative stance. We believe an appropriate classification would result in certain formulations, dosages, delivery modes or indications of cannabidiol products to be classified as medicines, while at the same time allowing patients to access quality-assured products as natural health products, meeting the same standards as many other plant-based products.

19. We therefore recommend that sections 20 and 21 clarify that a therapeutic product may be classified in more than one category depending on the intended indication, formulation, dosage and/or delivery mode.

We support clauses enabling robust and timely responses to health crises including effective harm reduction

20. We support section 116 enabling the Chief Executive of the Ministry to make emergency arrangement notices.

21. We recommend that these provisions are strengthened to extend to controlled activities governed by the Misuse of Drugs Act 1975. We note that under Misuse of Drugs Act regime, effective, and lifesaving, harm reduction interventions are prohibited even under emergency conditions, such as cyclone Gabrielle management. While proposed provisions under Therapeutic Products Bill would enable part of these to be permitted under section 116 (e.g., distributing naloxone), those involving supply of controlled

drugs would continue to be banned, even when they are lifesaving. This could include supplying and/or administration of controlled substances that could prevent acute withdrawal by any healthcare practitioner or by appropriately trained harm reduction workforce. We note that acute withdrawal from a number of substances may be life-threatening.

22. There is ample evidence that crisis situations, like pandemics or natural disasters, exacerbate drug harms (McCann-Pineo et al., 2021). We recommended that legislation allows flexible delivery of harm reduction, opioid agonist treatment, and other forms of support to people at risk of drug harm (Zolopa et al., 2021).

23. We recommend that this omnibus Bill empowers the Chief Executive of the Ministry, acting under emergency provisions contained in section 116, to permit to undertake controlled activities currently governed by Misuse of Drugs Act 1975 and associated Regulations. In particular, we recommend that supply and administration of controlled substances may be permitted more broadly when access through usual pathways is disturbed.

We support clauses that continue to enable provisional market authorisation of medicines

24. As we noted earlier, New Zealand's small market with a limited pool of patients, especially those suffering from low-prevalence conditions, may disadvantage New Zealanders trying to access modern medicines.

25. We believe that access to medicines should be improved in cases with limited commercial interest of the supplier. This is necessary when there is clear public health interest, and sufficient clinical advice on the appropriateness of the treatment. This may especially be the case with medicines with a history of use overseas, both as indicated or off-label, or with emerging diseases.

26. In such cases, a robust and transparent assessment process, which includes independent clinical and public health advice, can ensure safety and effectiveness of the product without relying on manufacturer or importer action.

27. Intermediary sponsors for such provisional approvals could be Crown agencies acting in consultation with civil society or patient voice. Robust process must continue to be implemented to ensure medicine safety and quality.

28. We support provisions enabling a provisional market authorisation (section 117(1)(b) and other detailed sections referring to provisional authorisation) and we recommend this be allowed for a period longer than two years, when appropriate. To ensure continued safety, mandatory two-yearly reviews may be required.

We support processes that allow for licences to be granted to import or supply products without market authorisation if there is public health benefit

29. We strongly support section 155. We recommend that the threshold to issue licenses described in this section offers a pragmatic balance between meeting an unmet health need and robustness of the usual licensing process.
30. In the area of drug harm minimisation, such measures may include rapid delivery of novel antidotes, medicines helping individuals undergoing withdrawal, or substitution therapies. Many of those interventions are not yet known, as harm reduction approaches often rely on rapid interventions that respond to illicit market volatility and new psychoactive substances with unclear mechanisms of action and associated harms.
31. We note that harm reduction often requires a higher risk tolerance threshold than many other areas of population health, due to required speed of action, as well as imminent risks associated with inaction, including risk of death.
32. We recommend that the threshold for granting section 155 licenses does not require 'emergency' situations, but rather a clearly demonstrated existing health need or an imminent prevention measure need. For the removal of doubt, section 158(1)(h) should be clarified to also cover situation where there are limited alternatives to adequately meet the health need of individuals or populations.

We recommend enabling access to effective therapies that do not have industry sponsors

33. We recognise that the Bill in its current shape does not address access challenges for therapies with long historic use and increasing formal evidence, but where there are no pharmaceutical products available. This is, for example, the case of psylocibin therapies.
34. We note that the Australian regulator (TGA) has recently created special access pathways for psychedelic treatments (Therapeutic Goods Administration, 2023) for treatment-resistant depression and post-traumatic stress disorder. Psychedelic therapies have also received breakthrough therapy status by the FDA (Business Wire, 2019). However, no approved products are currently available for this indication, despite broad availability of the compounds and it is likely that access will be restricted due to pharmaceutical industry not being incentivised to develop products without patent protection.
35. We also note local research assessing the use of taonga native *Psilocybe* species using kaupapa Māori frameworks (RNZ, 2023). If the results of initial trials are effective, we believe legislation must ensure the use of whole

plants/fungi or extracts of indigenous taonga species by whānau for therapeutic purposes is permitted under Te Tiriti o Waitangi principles of tino rangatiratanga (we further explore Te Tiriti considerations in points 72-77 of our submission).

36. As outlined earlier, it is our expectation that powers granted to the Chief Executive of the Ministry under section 155 of the proposed Bill may be used in such cases.

37. We recommend that future regulations under the Act set out the criteria for licenses with a threshold that is not prohibitive for community groups and tangata whenua to undertake controlled activities in the interest of health of their communities.

We recommend increased acknowledgment of equivalent agencies overseas that use similarly robust product authorisation processes

38. As we noted earlier, New Zealanders have limited access to certain modern medicines due to a small market and robust approval process comparable to that required by countries with larger populations and patient pools. Larger consumer base provides more incentives for suppliers to seek approval to enter the market, effectively leaving countries like New Zealand at the back of the queue.

39. We support provisions from section 346 that enable consideration of overseas regulatory decisions in comparable states with robust pre-authorisation evaluation by equivalent agencies. We understand these agencies may include Australian Therapeutic Goods Administration, European Medicines Agency, US Food and Drugs Administration, and similar.

40. However, we strongly recommend that lived experience voices and patient groups are consulted when decisions to harmonise (or not to harmonise) with overseas regulators are made.

41. Many community groups have robust international networks and rich experiences that can inform the real-world impacts of the decisions made by the regulator. However, currently, the opportunities to input into decision-making are limited.

42. Recently, we were disappointed by the decision of Medsafe to classify alkyl nitrites as medicines in harmonising with Australian TGA. Alkyl nitrites ('poppers') have a long history of very limited harm when used by gay men to facilitate intercourse, and this decision has resulted in reduction of access to safer varieties of the products. No community groups were consulted in the processes, and no approved product is currently available for this purpose or is likely to be approved in a foreseeable future.

43. On the other hand, decisions not to harmonise may also be detrimental to access. Medsafe recently decided not to harmonise with Australian TGA on

down-scheduling CBD-only cannabis products. Consultation with the community affected was not prioritised in the process of making the decision, resulting in poor access.

44. We believe that meaningful consultation with people with lived experiences and other community voices has the potential to improve the Regulator's decision-making and we strongly recommend that his is embedded in the Act and in secondary legislation.

We recommend risk-proportional approach to medical devices regulation that enables community to deliver health interventions

45. We support the requirement to seek market authorisation for medical devices as outlined in section 118.

46. We expect that the process for approval will be accessible to suppliers of medical products for small groups of patients and will be risk-proportionate.

47. We recommend that low-risk medical devices may be authorised following a notification and self-assessment of the criteria by supplier. The process should reserve the right of the Regulator to withdraw the product from the market if safety concerns arise.

48. We support the provisions in section 119(2)(a),(b),(c), and (d). We expect that future regulations set out rules that allow community groups to have streamlined access to medical devices product authorisation, especially when delivered as part of not-for-profit activity. An example may include sexual health self-tests delivered by community organisations.

49. We recommend that the Act specifies that international agreements can be made for mutual recognition of certification for medical devices. This could include participation in programmes such as Medical Devices Single Audit Programme (MDSAP). Members include TGA, Health Canada, FDA and other state agencies with robust regulatory frameworks.

50. We expect that this can improve consumer choice of medical products, including vaporisers for medical cannabis currently restricted by rules from the Misuse of Drugs (Prohibition of Utensils) Notice 2020 (Ministry of Health, 2020).

We recommend appropriate classification of devices used in harm reduction

51. We note that a number of products that can be used in harm reduction are currently banned as 'drug utensils' under Misuse of Drugs Act 1975.

52. These provisions exacerbate drug harm and hinder efforts to deliver effective harm reduction to clients in need. For example, the supply (and possession)

of clean straws that can help avert infectious diseases (including hepatitis C) is currently prohibited even when delivered as part of harm reduction programmes.

53. We recommend that this Bill revokes the clauses of Misuse of Drugs Act 1975 that prohibit possession and non-commercial or social supply of drug utensils when these are used as harm reduction measures.

54. We believe that Therapeutic Products Bill offers an appropriate legislative instrument to include provisions that enable low-risk market authorisation of harm reduction products delivered to people who use substances as part of risk minimisation programmes. We recommend that the Bill specifies that medical devices may include products used as harm reduction and that future regulations prescribed under Therapeutic Products Act are a more appropriate avenue to govern this process than current regulation under Misuse of Drugs Act.

55. As a minimum and intermediate measure under current regulations, we 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 appropriate notice, similar to the notice regulating medical cannabis vaporisers access (Ministry of Health, 2020).

We have a number of serious concerns about the provisions included in sections 226-229 regarding 'oversupplied persons'

56. We understand that provisions in sections 226-229 are a continuation of section 49 of the current Medicines Act and equivalent provisions in section 25 of Misuse of Drugs Act.

57. In our view, there is insufficient evidence of the benefit to the public to continue the current practice of 'restriction notices' without an adequate review. This Bill presents an opportunity to appraise this process and its impacts on those with substance addiction and their whānau.

58. We strongly recommend undertaking an urgent review and consultation with people affected (including patients currently and/or previously on the restrictions lists) before carrying these provisions over to new legislation.

59. We are concerned the current and planned provisions do not achieve the intended purpose of meaningful reduction in medicine diversion. In our experience, the majority of diversions occur from 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 diversion to illicit market.

60. We are seriously concerned that including people on the 'oversupplied persons' list results in stigmatisation. Anecdotal evidence we hear from the community shows us consistently that inclusion on the list may limit the ability of people to use healthcare. It labels the patient as 'drug-seeking' and

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

61. We also have concerns that the 'restriction notices' are ineffective in preventing escalating prescription or controlled medicine use and turn people into illicit markets creating more harm. We note that majority of those who misuse prescription medicines are not on the list.

62. At the same time, restrictions list may create an impression among clinicians that checking the list relieves them of their duty to assess each patient's dependency risk when prescribing potentially addictive medication.

63. The patient-monitoring systems changed drastically since the provisions were originally included in the Medicines Act. Currently, most clinicians and pharmacies rely on electronic systems that allow for tracking of recent prescriptions and dispensations of medicines. This allows the clinicians to assess oversupply risk for each patient much more effectively, and it is likely that workforce development around addiction risk screening will further facilitate this process.

64. We have a number of further specific concerns about the current wording and details of the provisions.

65. For example, specific wording about drug 'addiction' and 'habituation' may limit access to appropriate medication (a large number of 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.

66. We also note that the proposed provisions give the patient no right to dispute the inclusion on the 'oversupplied list', and do not offer any time limits for the notices to be in place, as well as they do not require regular review of the list.

67. We are not aware of any recent reviews of the 'restriction notices'/'oversupplied persons' mechanism despite it carrying a risk of harm to patients. Due to a number of concerns we cannot support these provisions in their current form and strongly recommend that urgent consultation and review is undertaken before these are carried over.

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

68. We recommend including provisions prohibiting direct-to-consumer-advertising of prescription medicines.

69. Current evidence shows that 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 population, including those with poorer self-reported health status, older, less educated, with lower incomes, and ethnic minorities (Khalil Zadeh et al., 2017).
70. We note that while regulation 50 of the Misuse of Drugs Regulations 1977prohibits advertising of controlled substances, a number of substances that may be addiction-forming are not currently on the controlled substances list (e.g., tramadol).
71. 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.

We recommend appropriate inclusion of Te Tiriti o Waitangi principles and recognition of tino rangatiratanga over taonga species

72. We urge the Health Committee to engage in appropriate consultation with mana whenua about the impacts of the Bill on rongoā practice (and especially on rongoā rākau).
73. We recommend inclusion of clauses recognising Māori sovereign ownership of rongoā and tino rangatiratanga over taonga species.
74. We expect the future Regulations to give effect to the above principles by creating an appropriate Māori-led process for authorisation, harvesting, and marketisation of taonga species.
75. We recommend that this process is developed in true partnership with Māori and giving 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).
76. In particular, we expect that the provisions allow Māori sovereign regulation of all taonga species. Provisions must allow for TPs that are also indigenous species to be regulated in true partnership with tangata whenua.
77. We note that there are also taonga species that are currently regulated under Misuse of Drugs Act 1975, which include certain *Psilocybe* gena with potential therapeutic applications and recommend that appropriate provisions are included that give back control of indigenous species to mana whenua.

Summary of recommendations

The Drug Foundation **welcomes** the Therapeutic Products Bill. We particularly welcome the aspiration to protect, promote and improve the health of all New Zealanders by providing a framework for risk-proportionate regulation of supply of safe and effective TPs.

Therefore, we strongly support provisions that enable effective harm reduction and strengthen community participation among civil society and people with lived experience in in the regulatory regime. This should be embedded both in the proposed Act and the secondary legislation. Below are our key recommendations:

I. We **recommend** that sections 20 and 21 clarify that a therapeutic product may be classified in more than one category depending on the intended indication, formulation, dosage and/or delivery mode.

II. We support section 116 enabling the Chief Executive of the Ministry to make emergency arrangement notices. We **recommend** that this omnibus Bill empowers the Chief Executive of the Ministry, acting under emergency provisions contained in section 116, to permit to undertake controlled activities currently governed by Misuse of Drugs Act 1975 and associated Regulations. In particular, we recommend that supply and administration of controlled substances may be permitted more broadly when access through usual pathways is disturbed.

III. We support provisions enabling a provisional market authorisation (section 117(1)(b) and other detailed sections referring to provisional authorisation) and we **recommend** this be allowed for a period longer than two years, when appropriate. To ensure continued safety, mandatory two-yearly reviews may be required.

IV. We strongly support section 155. We **recommend** that the threshold does not require emergency situations, but rather a clearly demonstrated existing health need or an imminent prevention measure need. For the removal of doubt, section 158(1)(h) should be clarified to also cover situation where there are limited alternatives to adequately meet the health need of individuals or given populations.

V. We **recommend** that future regulations under the Act set out the criteria for licenses outlined in section 155 with a threshold that is not prohibitive for community groups and tangata whenua to undertake controlled activities in the interest of health of their communities.

VI. We support provision from section 346 that enable consideration of overseas regulatory decisions in comparable states with robust pre-authorisation evaluation undertaken by equivalent agencies. However, we strongly **recommend** that lived experience voices and patient groups are consulted when decisions to harmonise with overseas regulators are made. Meaningful consultation with people with lived experiences and other community voices has the potential to improve Regulator decision-

making and we strongly recommend that his is embedded in the Act and in secondary legislation.

VII. We support the requirement to seek market authorisation for medical devices as outlined in section 118. We expect that the process for approval will be accessible to suppliers of medical products for small groups of patients and will be risk proportionate. We **recommend** that low-risk medical devices may authorised following a notification and self-assessment of the criteria by supplier.

VIII. We support the provisions in section 119(2)(a),(b),(c), and (d). We **expect** that future regulations set out the rules that allow community groups to have access to medical devices product authorisation, especially when delivered as part of not-for-profit activity.

IX. We **recommend** that the Act specifies that international agreements can be made for mutual recognition of certification for medical devices.

X. We believe that Therapeutic Products Bill offers an appropriate legislative instrument to include provisions that enable low-risk market authorisation of harm reduction products delivered to people who use substances as part of risk minimisation programmes. We **recommend** that the Bill specifies that medical devices may include products used as harm reduction and that future regulations prescribed under Therapeutic Products Act are a more appropriate avenue to govern this process than current regulation under Misuse of Drugs Act.

XI. As a minimum and intermediate measure under current regulations, we **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 appropriate notice, similar to the notice regulating medical cannabis vaporisers access (Ministry of Health, 2020).

XII. In our view, there is insufficient evidence of the benefit to the public to continue current practice of 'restriction notices' under proposed sections 226-229 without an adequate review. We **strongly recommend** undertaking an urgent review and consultation with people affected (including patients currently and/or previously on the restrictions lists) before carrying these provisions over to new legislation.

XIII. We **recommend** including provisions prohibiting direct-to-consumer-advertising of prescription medicines.

XIV. We **urge** the Health Committee to engage in appropriate consultation with mana whenua about the impacts of the Bill on rongoā practice (and especially on rongoā rākau).

XV. We **recommend** inclusion of clauses recognising Māori sovereign ownership of rongoā and tino rangatiratanga over taonga species.

XVI. We **recommend** that this process is developed in true partnership with Māori and giving 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).

XVII. We note that there are also taonga species that are currently regulated under Misuse of Drugs Act 1975, which include certain Psilocybe gena with potential therapeutic applications and **recommend** that appropriate provisions are included that give back control of indigenous species to mana whenua.

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