Briefing

Puberty blockers in gender affirming care: options for next steps

Date due to MO:	04 September 2024	**Action required by:**	N/A
Security level:	SENSITIVE - LEGAL	**Health Report number:**	H2024047656
To:	Hon Dr Shane Reti, Minister of Health Hon Matt Doocey, Associate Minister of Health		
Consulted:	Health New Zealand: ☐		

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Puberty blockers in gender affirming care: options for next steps

Security level:	SENSITIVE - LEGAL	**Date:**	05 September 2024
To:	Hon Dr Shane Reti, Minister of Health Hon Matt Doocey, Associate Minister of Health		

Purpose of report

1. This report responds to your request for options in appropriately safeguarding the use of puberty blockers in gender affirming care.

Summary

2. The use of medicines to delay puberty in young people with gender incongruence and dysphoria is a clinical practice that has grown internationally over the last 15 years. Use of puberty blocker medicines is one of a suite of health services that include mental health and other supports, selected and used in combination to meet individual health needs. This suite of services is known as gender affirming care.

3. As previously advised (see H2024040460 and H2024043566), the medicines used as puberty blockers in this way are not approved by Medsafe for this purpose. They are approved for a range of other indications, including to block puberty in children with precocious puberty.

4. The Ministry has limited visibility of how puberty blockers are currently prescribed in New Zealand, but dispensing data shows steady growth in the use of these medicines for children and young people between 2010 and 2022. Across all indications, the number of 10- to 19-year-olds who started treatment with puberty blockers each year (and by extension the number of prescribers) remained under 250 in this period.

5. A review of evidence for the effectiveness and safety of puberty blockers in young people with gender dysphoria has found a lack of good quality evidence. There is some evidence of a negative effect on bone density during use of puberty blockers in adolescence, but no evidence on longer term effects on bone density nor on other health outcomes including mental health outcomes.

6. While no particular instances of harm are known of in New Zealand, the Ministry is concerned that both prescribers and young patients and families are informed about this lack of evidence, and that any prescribing occurs in the context of broader health care for the young person and with informed consent. The Ministry has prepared a Position Statement to this effect, to release together with the Evidence Brief documents setting out the limited evidence on long-term impacts of these medicines in gender-dysphoric adolescents.

7. Along with issue of a Position Statement, additional safeguards are being developed. Health New Zealand – Te Whatu Ora (Health NZ) is updating clinical guidance. The Ministry is examining other actions in the clinical practice and dispensing environment and developing a monitoring framework to support adaptation to future evidence and trends.

8. It is important to ensure that access to quality gender affirming care continues and can be provided for children and young people close to where they live. At the same time, puberty blocking treatment as part of gender affirming care should not be inappropriately offered to children and young people at lower risk of poor health outcomes while the evidence for effectiveness and long-term safety remains poor.

9. Measures to limit the use of puberty blocking treatment in gender affirming care need to preserve access to these medicines (gonadotrophin releasing hormone agonists) for:

   a. children and young people (as well as adults) in need of treatment with these medicines for a range of indications outside of their use in gender dysphoria

   b. children and young people already receiving puberty blocker treatment as part of gender affirming care who consent to continue this treatment

   c. children and young people with gender dysphoria who are at high risk of significant poor health outcomes if they do not receive puberty blockers as part of gender affirming care

   d. use as part of a clinical trial that is conducted for the purpose of obtaining information about the safety and efficacy of puberty blocking treatment and is approved under section 30 of the Medicines Act.

10. A continuum of measures is available to manage treatment-related risks more broadly. Measures are generally selected based on factors that include the size, acuity and preventability of risks in comparison with benefits, to individuals and to the public. Treatment alternatives and overall costs are considered. In situations like this one, where knowledge of benefits and risks is poor, measures need to be adaptable and scalable as evidence is gained.

11. This briefing outlines the range of measures being developed, together with further measures that could be considered to build on them, and the associated advantages, disadvantages and risks.

12. The measures being developed support prescribing of puberty blockers only for those gender-dysphoric children and young people for whom the benefits of accessing these medicines outweigh the potential risks. In my judgement, these measures:

   a. respond to the unknown risks of these medicines for gender-dysphoric children and young people

   b. substantially increase regulation of prescribing practice by firming up prescribing expectations, guidance and monitoring, together with the Medical Council of New Zealand's professional regulatory role

   c. retain flexibility for future adjustment as additional evidence accrues.

13. Given what we know now about this prescribing, the expected effects of the measures underway and planned are important for lowering potential health risk. Assessment of risk considers the:

a. unknown long-term impacts of this treatment on a young population

b. continuing emergence of evidence which is still being evaluated internationally

c. limited evidence that we have on our own population in New Zealand, including for Māori and Pacific peoples.

14. Taking a precautionary approach, it is prudent to consider whether further safeguarding measures should be put in place in the short-term, or reserved for the future should more risk information emerge. Further measures that could be adopted include more rigorous prescription monitoring and clinical supervision for prescribers or specific regulatory approaches.

15. Regulatory approaches that might specifically limit prescribing of puberty blocking medicines to treat gender dysphoria include:

a. making a regulation under section 105 of the Medicines Act 1981 to restrict prescribing, supply, administration and use, usually effective in six to eight months

b. a Bill designed for this purpose (or provisions inserted in a related Bill), subject to usual parliamentary debates, processes and timeframes.

16. The Ministry has also considered whether a less specific regulatory approach to restrict the supply, administration and use of these medicines may be possible via a notice under section 37 of the Medicines Act. 9(2)(h)
9(2)(h)

17.

Recommendations

We recommend you:

a) **Note** the Ministry's advice that additional safeguards should be put in place around the prescribing of puberty blockers for young people with gender dysphoria, because of the poor evidence available on any benefits or risks. **Yes / No**

b) **Note** that it is important to ensure that access to quality gender affirming care is provided for children and young people close to where they live. **Yes / No**

c) **Note** that measures to limit the use of puberty blockers in gender affirming care need to preserve access to these medicines for: **Yes / No**

   i children and young people (as well as adults) in need of treatment with these medicines for a range of indications outside of their use in gender dysphoria

   ii children and young people already receiving puberty blocker treatment as part of gender affirming care who consent to continue this treatment

   iii children and young people with gender dysphoria who are at high risk of significant poor health outcomes if they do not receive puberty blockers as part of gender affirming care

   iv use as part of a clinical trial that is conducted for the purpose of obtaining information about the safety and efficacy of puberty blocking treatment and is approved under section 30 of the Medicines Act.

d) **Note** the Ministry's position that clinicians who initiate puberty blocker treatment should be experienced in providing gender affirming care and be part of an interprofessional team offering a full range of supports to young people presenting with gender-related issues. **Yes / No**

e) **Note** that action is already underway to provide safeguards through: **Yes / No**

   i a Director-General Position Statement that will make clear to prescribers the expectations for use of the medicines

   ii Health New Zealand's updated clinical guidance, under development for completion in December 2024.

f) **Note** that the Ministry has limited visibility of how puberty blocker prescribing, though dispensing data indicates fewer than 250 children and young people 10-19 years started treatment per year to 2022. **Yes / No**

g) **Note** that the Ministry will progress work on the following: **Yes / No**

   i building a monitoring framework to inform when and how the safeguards in place are further modified

   ii improving clinical practice safeguards in the prescribing, dispensing and administration environment.

h) **Note** that the Ministry considers the above safeguards will provide a response to the lack of good quality evidence for the effectiveness and safety of puberty blockers in young people with gender dysphoria that supports prescribing only for those children and young people for whom benefits outweigh risks, and allows for future adjustment as additional evidence accrues. **Yes / No**

i) **Note** that taking a precautionary approach, it is prudent to consider whether further safeguarding measures should be put in place in the short-term, or reserved for the future should more risk information emerge

j) **Indicate** whether you wish to receive further advice on more rigorous prescription monitoring and clinical supervision. **Yes / No / Defer**

k) **Indicate** which of the following regulatory approaches, if either, you wish to proceed with:

i making a regulation under section 105 of the Medicines Act 1981 to restrict prescribing, supply, administration and use **Yes / No / Defer**

ii a Bill designed to restrict prescribing, supply, administration and use (or provisions inserted in a related Bill), subject to usual parliamentary debates, processes and timeframes. **Yes / No / Defer**

9(2)(h)

l) **Yes / No**

m) **Yes / No**

Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date: 5 September 2024

Hon Dr Shane Reti
Minister of Health
Date:

Hon Matt Doocey
Minister for Mental Health
Date:

Puberty blockers in gender affirming care: options for next steps

Background / context

18. 'Puberty blockers' describes one use of a class of medicines – gonadotrophin releasing hormone agonists. Given by injection, they delay the onset of puberty in treatment for:

    a. children with precocious puberty (premature pubertal changes in girls under 8, boys under 9)

    b. young people with gender incongruence or gender dysphoria (when the experienced gender is persistently different from the sex that was assigned at birth and this has adverse health and wellbeing impacts).

19. These medicines have a range of other uses in adults (and sometimes young people) that include treating breast and prostate cancers and endometriosis, along with a number of other, less common indications. They are available only on prescription and are funded by Pharmac.

20. Medsafe, like other regulators, has approved these medicines for other uses but not to delay puberty in gender affirming care; no application for such approval has been made. Their use for this purpose has grown internationally over the last 15 to 20 years, with practitioner guidance being issued based on consolidated clinical experience.

Review of evidence on treatment outcomes

21. As previously advised (see H2024040460 and H2024043566), the Ministry of Health reviewed the evidence on impacts of puberty blockers on clinical and mental health and wellbeing outcomes in 13-18 year olds with gender dysphoria.

22. The quality of the evidence was found to be poor as studies had significant limitations. Knowledge is insufficient on how effective the treatments are and on whether there are long-term adverse effects that differ from those seen during use in precocious puberty.

23. There is some evidence that bone density may increase at lower than the expected rate for the person's age or stage of development. However, any long-term effects have not been adequately studied. Evidence on improved mental health and wellbeing outcomes was of poor quality; there is insufficient information on impacts of puberty blocker treatment on outcomes related to depression, anxiety or suicidal ideation.

New Zealand prescribing context

24. In New Zealand, medicine dispensing data shows steady growth in use of these medicines for children and young people aged 10 to 19 years between 2010 and 2022. Less than 25 young people typically started treatment each year before that time, growing to some 200-odd each year by the end of the period. Treatment is initiated by a range of vocationally registered practitioners, most frequently paediatricians, endocrinologists and general practitioners.

25. The dispensing data cover all indications for these medicines, and the Ministry has limited visibility of prescribing for children and young people with gender dysphoria. We assume that much but not all of the increase has been for this indication. A very rough estimate is that between 2 and 3 young people per thousand receive this treatment at some point during their adolescence, making the treatment uncommon but not rare.

26. Experience of gender incongruence is common during adolescence. Over the same 15-year period, there has been an increase in recognition of and services for children and young people with gender incongruence and dysphoria. Services include youth health services and other health services that provide multi-disciplinary care across a range of mental and physical health needs including gender affirming care for gender incongruence and dysphoria.

International responses

27. Also as previously advised, at the same time as the Ministry's review of evidence, similar reviews were occurring in other jurisdictions. The United Kingdom has moved to prohibit new initiation of puberty blocking treatment for gender-dysphoric adolescents outside of clinical trials; these trials are in planning stages and are yet to be initiated.

28. Scandinavian countries have restricted puberty blocking treatments to clinical trials except in very exceptional circumstances (Sweden) or after non-medical options have been explored and deemed insufficient (Norway and Finland).

29. Other countries have emphasised consent processes and have continued to support professional guidance that promotes the range of supportive and mental health services that should be provided by a multidisciplinary team first and foremost, with puberty blocking treatment remaining an option. These countries include Australia, Canada and most European countries.

The Ministry's work in response to the evidence

30. No particular instances of harm are known of in New Zealand, and numbers of young people receiving puberty blocking treatment for gender dysphoria have grown (although absolute numbers remain low). The Ministry is concerned, however, that both prescribers and young patients and families are informed about the lack of evidence, and that any prescribing occurs in the context of broader health care for the young person and with informed consent.

The Ministry's position

31. We wish to emphasise the importance of providing access to quality gender affirming care for children and young people close to where they live. This is a group of young people at risk of poor health, including mental health, outcomes for a range of reasons not least being higher rates of social exclusion, discrimination, victimisation, trauma and abuse.

32. The Ministry's view is that, given the poor evidence on puberty blocking treatment outcomes, supportive care including a range of social and mental health supports should be the starting point. Puberty blocking treatment as part of gender affirming care should be reserved for children and young people at high risk of poor health outcomes while the evidence for effectiveness and long-term safety remains poor.

33. Treatment should be initiated only by prescribers who are experienced, working within their scope of practice, meeting professional practice and ethical standards, and working as part of an interprofessional team offering a range of supports and services. This includes informed consent, knowing the medicine is for an unapproved use with only poor evidence on long-term effects and having had discussion of the potential risks and benefits.

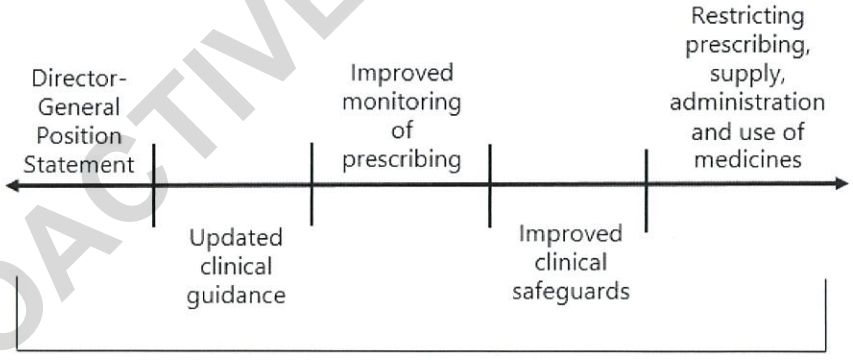
34. Children and young people who have already started puberty blocking treatment should not have this treatment discontinued without their consent, however. The poor evidence of outcomes from puberty blocking treatment does not justify cessation but should be discussed and consent to treatment reaffirmed.

Considering the health risks

35. The Ministry has considered, in the light of all available evidence, the size, acuity and preventability of potential risks from treatment of gender incongruent and dysphoric young people 12 to 16 years with gonadotrophin releasing hormone agonists. We have considered how these potential risks compare with potential benefits to individual young patients and to the public, along with the alternative treatments and supports available, their accessibility and their benefits and risks.

36. We have assessed that immediate safeguards should be put in place so that the potential risks of this treatment are carefully considered and any initiation of its use is reserved only for young people for whom its benefits are judged to substantially outweigh these risks. In addition, further measures should be considered, as discussed below.

37. A continuum of interventions can be selected from, as indicated in the diagram below.



Level of intervention determined by level of health risk relative to benefits for individuals and the public

Safeguarding measures already underway

38. The current approaches and possible further measures are summarised in Appendix 1.

Director-General Position Statement

39. The Ministry has prepared a Director-General Position Statement to communicate expectations of prescribers and other practitioners involved in providing care for young people with gender incongruence and dysphoria. We intend that this statement be

released together with Evidence Brief documents that set out the limited evidence on long-term impacts of these medicines in gender-dysphoric adolescents.

40. Issue of this statement will set out clear expectations for health practitioners and put additional safeguards in place to protect children and young people from any potential harm. It will provide a firm basis for regulatory oversight of prescribers by the Medical Council of New Zealand. It will uphold the rights of children and young people not to be subjected to medical or scientific experimentation without consent and not to be subject to discrimination (including on the basis of sexual orientation or preferences or gender), as well as other rights set out in such statutes and statements as the Human Rights Act, Bill of Rights Act, Care of Children Act, Code of Health and Disability Consumer Rights and United Nations Convention on the Rights of Children.

Updated clinical guidance

41. Health New Zealand – Te Whatu Ora (Health NZ) is updating clinical guidance. Current clinical guidance (issued in 2018) is consistent with the Ministry's position statement but brief. The updated guidance will include clinical pathways and is planned for completion in December 2024.

Monitoring framework

42. The Ministry is developing a monitoring framework to support adaptation to future evidence and trends. This will collect information, both actively (such as through commissioned research and regular dispensing information reports) and passively (such as through monitoring international trial results and clinical reports), that will allow us to monitor prescribing and use as well as broad population outcomes for cohorts of young people. It could include diverse elements from population studies to complaints investigation outcomes.

Prescribing and dispensing environment measures

43. We have also started examining other actions in the clinical practice and dispensing environment that could further shore up safe prescribing. This includes assessing international practices and tools as they become available, given some are currently under development. It may be that tools for better assessment of health needs or risks, and/or information resources to support informed consent are adaptable for New Zealand use.

44. Any measures to limit the use of puberty blocking treatment in gender affirming care need to preserve access to these medicines (gonadotrophin releasing hormone agonists) for:

    a. children and young people (as well as adults) in need of treatment with these medicines for a range of indications outside of their use in gender dysphoria

    b. children and young people already receiving puberty blocker treatment as part of gender affirming care who consent to continue this treatment

    c. children and young people with gender dysphoria who are at high risk of significant poor health outcomes if they do not receive puberty blockers as part of gender affirming care

d. use as part of a clinical trial that is conducted for the purpose of obtaining information about the safety and efficacy of puberty blocking treatment and is approved under section 30 of the Medicines Act.

Comparing with other prescribing safety situations

45. We have considered the effective means of modulating prescribing practices that have been employed in other prescribing safety situations.

46. It is fairly common for medicines to be prescribed for an indication or patient in a population group for which they are not approved. This occurs frequently for medicines that have been on the market for some years and/or the new indication is an uncommon or rare one, when there is little incentive for suppliers to apply for an additional approval. It also occurs where alternative treatment options are unavailable or unsatisfactory and a patient's health needs or suffering justify second or third line treatment or less orthodox approaches.

47. In general, prescribers working within their scope of practice are able to obtain specialist or collegial advice, weigh up the known or unknown benefits and risks, and discuss the options with the patient and their supporters. Added structure, beyond generally available prescribing guidelines, is not usually required. An example is the use of the antidepressant fluoxetine for children, approved for adults 18 years and over but able to be prescribed for children with guidance in the NZ Formulary for Children.

48. In some instances, structured prescribing guidance, consent processes, specialist-only prescribing, second opinion or ethical review processes and safety monitoring regimes have been used. They have been used where there is:

    a. heightened risk of severe adverse outcomes

    b. availability of prevention or mitigation actions to reduce severe adverse outcomes

    c. need for protection against rights infringement

    d. support required to provide valid consent.

49. Examples of these more structured approaches include:

    a. the antipsychotic clozapine, where there are high potential benefits along with life-threatening adverse reactions and a patient group not always able to consent to treatment or to reliably report emerging health problems that may become severe (clozapine is approved by Medsafe for patients 16 years and older, and guidance is available in the NZ Formulary for Children for use in younger children)

    b. methylphenindate, used to treat attention deficit hyperactivity disorder (ADHD) which is also misused as a recreational drug and has for that reason been restricted; it does however have substantial benefits for children with ADHD, along with potentially significant rare adverse effects

    c. special processes under enactments such as for welfare guardianship, care of children, abortion or end-of-life choice.

Are further safeguarding measures needed?

50. We consider that the measures under development, above, support the prescribing of puberty blockers only for those gender-dysphoric children and young people for whom the benefits of accessing these medicines outweigh the potential risks. They:

    a. respond to the unknown risks of these medicines for gender-dysphoric children and young people

    b. substantially increase regulation of prescribing practice by firming up prescribing expectations, guidance and monitoring, together with the Medical Council of New Zealand's professional regulatory role

    c. retain flexibility for future adjustment as additional evidence accrues.

51. Given what we know now about this prescribing, the expected effects of the measures underway and planned that are described above are important for lowering potential health risk. Assessment of risk considers the:

    a. unknown long-term impacts of this treatment on a young population

    b. continuing emergence of evidence which is still being evaluated internationally

    c. limited evidence that we have on our own population in New Zealand, including for Māori and Pacific peoples.

52. Taking a precautionary approach, it is prudent to consider whether further safeguarding measures should be put in place in the short-term. It is also prudent to consider how any residual risk can be managed, including whether any safeguarding measures should be held in reserve for the future should more risk information emerge. Note that further options are likely to have resourcing and other implications.

Further safeguarding options

53. Additional options that can be employed, should a higher level of risk become evident, include measures that can be employed within current settings, and other measures that would require a regulatory lever.

Prescribing supervisory actions

54. More rigorous prescription monitoring, supervisory and practice audit options could be explored and would also require resourcing. These would build from more robust dispensing information than is currently collected and potentially help build good practice as well as provide early alerts and intervention for outliers in prescribing patterns.

55. These further safeguarding options ensure that medical practitioners follow best practice and that children and young people experiencing gender incongruence and dysphoria receive appropriate treatment. They should be added if required to address health risks. 9(2)(h)

Making a regulation under section 105 of the Medicines Act 1981

56. Section 105 of the Medicines Act 1981 allows the Governor-General to make regulations that cover a wide range of purposes related to prescribing and other medicines-related activities. These regulations are made by Order in Council on the advice of the Minister

of Health after consultation with organisations representative of those likely to be substantially affected. A six- to ten-month period is the usual minimum required to develop, consult and implement through to such regulations coming into effect.

57. Using this option would have the intent of pausing new prescribing of puberty blocking medicines for use in gender-affirming care, except in very high-risk circumstances and for use in clinical trials. Access to the same medicines would continue for young people who have already started this treatment and for people who are prescribed the medicines for other reasons such as treating precocious puberty, endometriosis and breast, prostate and other cancers. This option would not be time limited and could be designed to specifically restrict the prescribing of puberty blockers for the treatment of gender dysphoria.

58. A s.105 regulation would require the development of clear criteria by which health practitioners could prescribe what products for which people, and exclusions defined. The broad range of activities covered by s.105 mean that it is suited to regulate prescribing of a class of medicines in relation to a specific purpose.

59. 9(2)(h)

60.

De novo legislation

61. A Bill (which could be an amendment Bill or provisions inserted in a related Bill) could be drafted specific to the purpose of safeguarding the use of puberty blockers in gender affirming care. This option would require House time and would need to be progressed in the context of the Government's wider legislative programme and priorities. We expect such a Bill would generate considerable debate, given the strong views held on issues related to gender identity.

Issuing a notice under section 37 of the Medicines Act 1981

62. Section 37 of the Medicines Act 1981 provides that the Minister may from time to time, by notice, prohibit the import, manufacture, packing, sale, possession, supply, administration, or other use of medicines of any specified description or medical devices of any specified kind, either absolutely or subject to such conditions as he thinks fit, for any specified period not exceeding 1 year; but he shall not exercise this power more than once in respect of medicines or medical devices so specified.

63. The Ministry has considered whether such a notice could be used to restrict the supply, administration and/or use of puberty blockers for the purpose of delaying puberty in gender affirming care. This would have the intent of pausing new prescribing of puberty blocking medicines for use in gender-affirming care, while maintaining access to the same medicines for other uses such as treating precocious puberty, endometriosis, and breast and prostate cancer.

64. As well as practical challenges akin to those outlined in paragraph 59, there are important technical issues related to using a s.37 notice to restrict prescribing of puberty blockers:

    a. it cannot regulate prescribing of medicines. This section was designed primarily to regulate supply of medicines, especially supply into New Zealand of non-approved medicines. As such, it could penalise pharmacists, nurses and patients, but not prescribers, and would require a range of clinical practice and patient safeguards alongside

    b. this section can only be used for a single period, at maximum 12 months, for any medicine.

65. Issue of notices under this section has occurred only twice to date, both times to control importation and use of non-approved COVID-19 products during the earlier stages of the pandemic. Importation, use, etc of unapproved RAT tests and vaccines were prevented temporarily. In these instances, issuing this notice was a relatively quick action that ensured only safe, effective and high-quality products were being used in New Zealand. Notices could be enforced by Medsafe.

66. 9(2)(h)

67.

Timeframes for regulatory actions

68. Should you wish to consider regulatory action, using section 105 of the Medicines Act is likely to be the most suitable approach. In usual circumstances, this would take six to ten months, but it may be possible for this timeframe to be reduced by up to three months should the Government consider this an urgent matter to address. It may be possible, for example, for the following to be approved or employed:

    9(2)(h)

9(2)(h)

69. Indicative timeframes for a section 105 regulation are outlined in Appendix 2, according to three possible scenarios.

70. The Medicines Act 1981 requires consultation with such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations. 9(2)(h)

71. During the time taken to make such as regulation, an announcement that it was being made would likely act to reinforce for prescribers and the public the seriousness of the expectations presented in the Position Statement and highlighted in updated clinical guidance.

72. 9(2)(h)

73. Timeframes for de novo legislation can be highly variable. Should you wish to pursue this approach, having a regulation in place already would likely make the legislative process more predictable, if not less controversial.

s 9(2)(h)

s 9(2)(h)

Equity

80. Adolescents in general, and adolescents with gender-related concerns in particular, experience a high rate of mental health difficulties along with discrimination, victimisation, trauma and abuse. Any perceived reduction in supports or services available to this group may add to concerns about inter-generational inequities and inequities for LGBTQI+ communities and for provincial and rural communities where specialist services may be less accessible.

81. To avoid adding to inequitable outcomes, any restrictions on prescribing of puberty blockers should be carefully aligned with clinical needs and accompanied by additional service options, especially in community settings close to where young people live and gather.

Next steps

82. I intend to publicly release the Ministry's position statement and evidence brief as soon as practicable.

83. The Ministry recommends adding further measures in the prescribing, dispensing and administration environment, and a monitoring framework that will assure Ministers and the public that further measures will be put in place.

84. Once we have received your indication of the safeguard options you would like progressed, we will develop more detailed advice on implementation, together with a draft Cabinet paper to ensure that Cabinet Ministers are consulted on and well informed about action being taken.

85. 9(2)(h)

ENDS.

Appendix 1. Summary of current and potential measures for puberty blocker prescribing in gender affirming care

	Approach	Description	Effect	Enforceability	Timeframes
ALREADY UNDERWAY	1 Director-General of Health Position Statement	DG directive immediately issued publicly and communicated to all medical practitioners. Stipulates experience of prescribers and their practice environment Stipulates requirements for services to be offered	Sets clear expectations of all prescribers covering experience and service setting	Enforceable on complaint to Medical Council or investigation by Health & Disability Commissioner Potential loss of or restrictions on practice	Immediate on issue
	2 Updated clinical guidance	Includes requirements for services, team and prescriber, with range, quality, training, experience, etc Can cover primary care in conjunction with expert services	Adds detail to Position Statement	Adds to Medical Council view of acceptable practice Adds to any service audit	Due for completion December 2024
PROPOSED NEXT STEPS	3 Monitoring framework	Regular reporting on prescription numbers, age groups, prescriber specialties, service measures, clinical trials, new evidence, etc Set of indicator points at which alterations in settings would start	Enables view across all prescribing Enables alteration in approach in response to emerging evidence or information	Adds information to above enforcement	Earliest 3 months and can be added to over time Commissioned research or population studies can feed in over time
	4 Prescribing and dispensing environment measures	A range of potential actions to shore up the prescribing, dispensing and administration environment, as well as consent and practitioner, public and patient information and learning	Shores up other measures, promotes recommended practice and adds clinical intervention points	Adds information to above enforcement	Estimated 6 months Many measures will require consultation
POSSIBLE IN CURRENT SETTINGS	5 Prescribing supervisory actions	More rigorous prescription monitoring, supervisory and practice audit options, with more robust dispensing information	Shores up other measures, adds intervention points	Adds information to above enforcement	Estimated 6 months plus

	Approach	Description	Effect	Enforceability	Timeframes
REGULATORY LEVER & LEGAL ADVICE REQUIRED	7 S. 105 regulation (Medicines Act 1981)	Regulation under the Medicines Act issued by Governor-General on Cabinet approval. Can regulate prescribing and a wide range of other medicines activities	Would make it illegal to undertake prohibited or restricted activities, with stipulated exceptions	New enforcement regime would be required s 9(2)(g)(i)	Estimated 6 – 10 months though may be shortened by up to 3 months s 9(2)(g)(i) Regulatory impact statement likely required
	8 De novo legislation (a Bill or inclusion in a Bill)	A specific piece of legislation would be enacted to cover this (could be an amendment Act or part of one)	Would make it illegal to undertake prohibited or restricted activities	New enforcement regime would be required	Usually more than 12 months Full legislative process s 9(2)(g)(i)
	9 S. 37 Notice (Medicines Act 1981) 9(2)(h)	Minister of Health can institute restrictions on supply, administration and use of specified medicines. Non-renewable provision, allowing regulation for up to 12 months only.	Cannot limit prescribing Dispensing, administration and use restrictions only	Penalties available - up to $500 fine or 3 months custodial s 9(2)(g)(i)	If this is possible, within 6-8 weeks Only effective for 12 months or less, cannot be renewed

Appendix 2. Earliest timeline for s.105 regulation in three scenarios

	Process or activity	Urgent No contingency	Shortened	Usual
✔	Ministerial decisions on briefing	6 Sept	6 Sept	6 Sept
	Cabinet paper with consultation proposal for decision, and position statement for noting # (Note, expert consultation on position statement to occur during this time)	19 Sept	19 Sept	30 Sept
✔	Ministerial consultation completed	25 Sept **	9 Oct	15 Oct
✔	Lodge	26 Sept	10 Oct	17 Oct
✔	SOU		16 Oct	23 Oct
✔	Cabinet decision	30 Sept	21 Oct	29 Oct
	Announcement & release of Position Statement & Evidence Brief	1 Oct	22 Oct	30 Oct
	Consultation with representative groups	3 to 18 Oct	24 Oct to 6 Nov	4 Oct to 22 Nov
	Briefing on response to consultation, gaining agreement to issue drafting instructions to PCO	31 Oct	21 Nov	16 Dec
✔	Ministerial decisions on briefing	4 Nov	25 Nov	22 Jan
	Cabinet paper for policy decisions			10 Feb
✔	Ministerial consultation completed			25 Feb
✔	Lodge			27 Feb
✔	SOU			6 Mar
✔	Cabinet decision			10 Mar
	Drafting instructions issued to PCO	5 Nov *	26 Nov *	11 Mar
	Cabinet paper for LEG with draft regulation	25 Nov	23 Dec	24 Apr
✔	Ministerial consultation completed	4 Dec *	4 Feb	13 May
✔	Lodge	5 Dec	6 Feb	15 May
	PCO sends certified regulation to Cabinet Office	5 Dec	6 Feb	15 May
✔	LEG	12 Dec	13 Feb	22 May
✔	Signed goatskin to Cabinet Office	12 Dec	13 Feb	23 May
✔	Cabinet decision	16 Dec	17 Feb	26 May
✔	Submit Executive Council documents	16 Dec	17 Feb	26 May
✔	Returned with Governor-General signature	18 Dec	19 Feb	28 May
	Gazette notice issued by Cabinet Office	19 Dec	20 Feb	29 May
	Regulation in effect (if 28 day rule waivered)	23 Dec	24 Feb	
	Regulation in effect after 28 days	6 Feb	20 Mar	27 June

✔ Indicates Minister or office action
\# Fast turnaround at all steps, waiver of regulatory impact statement
** Very short (few days only)
* Shorter than usual

Minister's Notes