Regulatory Impact Statement: Safe-guarding the use of puberty blockers in young people with gender-related health needs

Coversheet

Purpose of Document	
Decision sought:	Policy decision to proceed work towards considering regulation under section 105 of the Medicines Act 1981 to restrict prescribing of puberty blockers for young people under 18 years.
Advising agencies:	Ministry of Health
Proposing Ministers:	Hon Dr Shane Reti, Minister of Health Hon Matt Doocey, Associate Minister of Health
Date finalised:	9 October 2024 (with subsequent minor editorial changes)

Problem Definition

There has been an increase in use of puberty blockers in gender-affirming care in New Zealand and internationally. However, the evidential basis for their use for gender-dysphoric children and young people is unclear, meaning there is a risk of unintended harm.

Executive Summary

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.

Currently any registered medical practitioner can prescribe puberty blockers. Treatment is initiated by a range of vocationally registered practitioners, most frequently paediatricians, endocrinologists, and general practitioners.

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. Off-label prescribing is common in clinical practice, particularly in paediatric services. When clinicians prescribe off-label they are expected to be working within their scope of practice. Practitioners need to make sure that the person receiving the medicine knows that the medicine is being used for an unapproved use and have an informed conversation with them about the potential risks and benefits, involving family, whānau, or caregivers where appropriate.

A review of evidence for the effectiveness and safety of puberty blockers in young people with gender dysphoria undertaken by the Ministry of Health 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.

The Ministry intends that:

a) the risk of long-term adverse effects from the use of puberty blocking treatment is minimised
b) prescribers and young patients and families are informed about the lack of good quality evidence on puberty blocking treatment outcomes
c) young people presenting with gender-related health needs continue to have access to an interprofessional team and treatments that can meet their wider mental health and social needs.

With these objectives in mind, three options are presented:

a) **status quo**: clinicians continue to make prescribing decisions based on established professional practice and their clinical judgement. This includes assessing patient needs, applying any relevant clinical guidelines, assessing the risk and benefit of any medicines, and considering patient safety and any ethical and legal considerations (including obtaining informed consent).
b) **strengthening clinical guidance and oversight**: the Ministry would publish a Position Statement on the use of puberty-blockers in gender-affirming care, supported by an evidence brief that sets out the limited evidence on long-term impacts of these medicines in gender-dysphoric adolescents. This would be supported by updated clinical guidance and the development of a monitoring framework.
c) **regulating the prescribing of puberty blockers**: restricting the prescribing of puberty blocker medicines for children and young people in the context of gender-affirming care, with limited exceptions including for use in research settings.

Strengthening clinical guidance and oversight will likely achieve the policy intent. However, given the unknown long-term impacts of puberty blocker treatment on a young population and the emerging international evidence in this area, the Ministry considers it prudent to take a precautionary approach, including considering a range of safeguarding measures. Considering the potential for a regulation to be made fits within this approach.

Limitations and Constraints on Analysis

Consultation has not yet occurred on the options included in this analysis. The Ministry anticipates significant interest in the options presented, particularly among groups that would be substantively affected by the option that would regulate the prescribing of puberty blockers. Insights gathered through consultation would inform the refinement of options, including an updated version of this regulatory impact statement if a regulatory option was proposed.

Responsible Manager(s) (completed by relevant manager)

Steve Barnes

Associate Deputy Director-General

Strategy Policy and Legislation

Ministry of Health

9 October 2024

Quality Assurance (completed by QA panel)

Reviewing Agency:	Ministry of Health Quality Assurance panel
Panel Assessment & Comment:	The panel has reviewed the initial Impact Statement titled "Safe-guarding the use of puberty blockers in young people with gender-related health needs", produced by the Ministry of Health and dated 09 October 2024. The Impact Statement is clear, concise, complete, and convincing. The analysis is balanced in its presentation of the information. Impacts are identified and appropriately assessed. The panel notes that consultation would be undertaken as part of the next steps of the development of any further regulatory proposal, after which a formal Regulatory Impact Statement will be prepared.

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

What are puberty blockers and how are they used?

1. Gonadotrophin releasing hormone agonists (GnRHa) are a class of medicines given by injection to treat a range of sex hormone-related conditions. These medicines temporarily halt the production of sex hormones testosterone, oestrogen, and progesterone.
2. In New Zealand, GnRHas are available as leuprorelin intramuscular injections or goserelin subcutaneous implants.[1] They are approved by Medsafe to treat prostate cancer, breast cancer, endometriosis, uterine fibroids, and central precocious puberty.
3. In children, these medicines are used to treat precocious puberty (premature pubertal changes in girls under 8, boys under 9). This treatment delays further pubertal changes and allows children with precocious puberty to grow along with their peers and achieve a more standard height.
4. These medicines are also used to delay puberty in young people with gender incongruence or gender dysphoria. In this context, they are known as puberty blockers. Delaying puberty provides young people with additional time to elaborate their gender identity without the distress of the fast developing body. They may later choose gender affirming hormone treatment (oestrogen or testosterone) or surgical affirmation.
5. Puberty blockers are being increasingly prescribed for this indication. No application has been made to Medsafe or other regulators for approval.

Gender dysphoria and gender affirming care

6. Gender incongruence is where an individual's experienced gender and their assigned sex (at birth) persistently do not match. Gender dysphoria is where an individual's gender incongruence has an adverse impact on their health and wellbeing.
7. Internationally, there has been a reported increase in the number of children and adolescents describing themselves as gender questioning or identifying as transgender.

[1] Pharmac NZ. GnRH analogues 2023. Available from: https://schedule.pharmac.govt.nz/ScheduleOnline.php?code=A141603

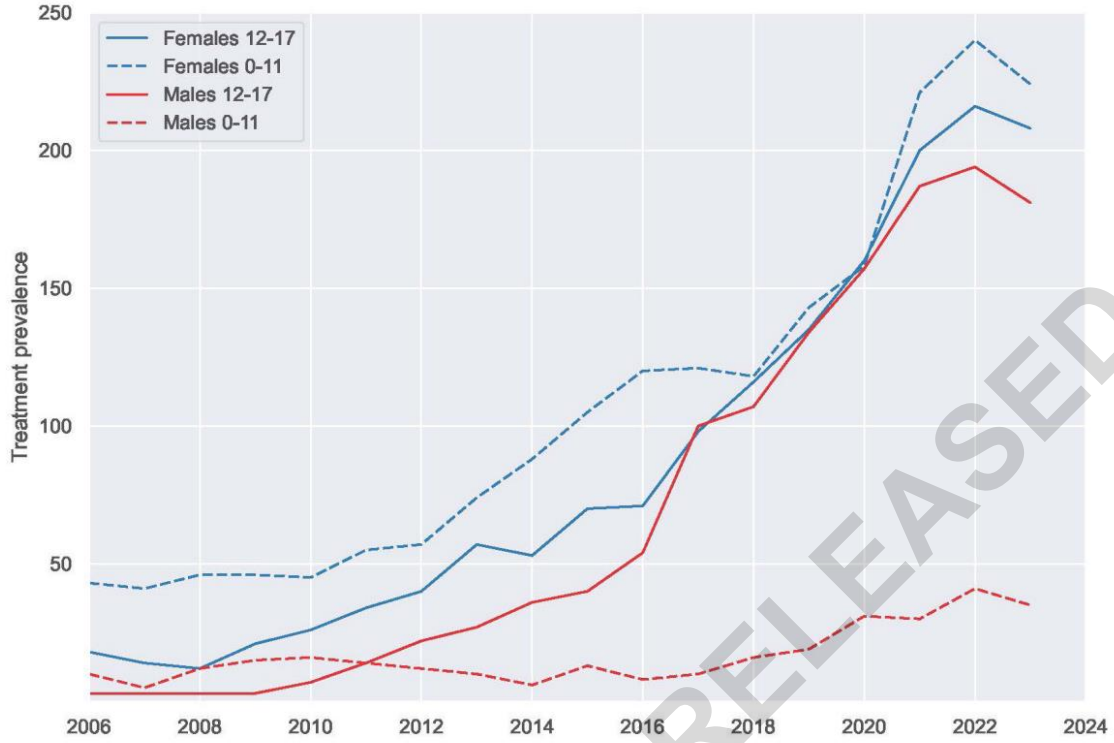
8. In some people, this mismatch can cause severe discomfort, anxiety, depression, and other mental health conditions. Children with gender dysphoria often experience a range of psychiatric comorbidities, with a high prevalence of mood and anxiety disorders, trauma, eating disorders and autism spectrum conditions, suicidality, and self-harm.[2]
9. Access to gender-affirming care is essential to support well-being in people with gender dysphoria. Care may include affirmation in various domains:
    a. Social affirmation may include an individual adopting pronouns, names, and various aspects of gender expression that match their gender identity.
    b. Legal affirmation may involve changing name and gender markers on various forms of government identification.
    c. Medical affirmation may include pubertal suppression for adolescents with gender dysphoria and gender affirming hormones like oestrogen and testosterone for older adolescents and adults. Medical affirmation is not recommended for prepubertal children. Some adults (and less often adolescents) may undergo various aspects of surgical affirmation.

Use of puberty blockers in gender-affirming care in New Zealand

10. Currently any registered medical practitioner can prescribe puberty blockers. Treatment is initiated by a range of vocationally registered practitioners, most frequently paediatricians, endocrinologists, and general practitioners.
11. Medicine dispensing data shows sustained growth in use of GnRHas for children and young people since around 2010, although the most recent data suggest a drop in the last year (in 2022, between two and three young people per thousand started on this treatment during their adolescence). The reason for the recent drop in prescribing may be related to increased awareness among clinicians about the risks and benefits of puberty blockers, although it is not possible to attribute a cause at this stage or assess whether the decline may reflect a temporary or longer-lasting change to prescribing.
12. **Figure 1** shows the number of young people prescribed GnRHa each year, however this does not show the reasons for having these medicines prescribed (meaning that some of the prescribing will reflect use for other indications, such as endometriosis and precocious puberty).

[2] Frew, T., Watsford, C., & Walker, I. (2021). Gender dysphoria and psychiatric comorbidities in childhood: a systematic review. *Australian Journal of Psychology*, 73(3), 255–271. https://doi.org/10.1080/00049530.2021.1900747

Figure 1: Number of people aged <18 prescribed GnRHa each year by age group and recorded sex/gender, in New Zealand



Source: Paul, C., Tegg, S., & Donovan, S. (2024). Use of puberty-blocking hormones for gender dysphoria in New Zealand: descriptive analysis and international comparisons. *The New Zealand Medical Journal*, 137(1603), 79–88. https://doi.org/10.26635/6965.6587

Current regulation for prescribing

13. Medicines in New Zealand are approved for particular indications, rather than being approved for any use the prescriber sees fit. Gender dysphoria is not an approved indication for GnRAas, meaning they are prescribed 'off-label' for this purpose. This is permitted by section 25 of the Medicines Act 1981, which allows authorised prescribers to supply any medicine to a patient under their care.
14. Off-label prescribing is common in clinical practice, particularly in paediatric services (generally due to practical difficulties in gathering scientific evidence to support licensing for children). Other examples of medicines prescribed to young people under section 25 are fluoxetine for depression and melatonin for insomnia. In these cases, the medicines are generally being used for the same or similar purposes as in adults. The use of puberty blockers for the purpose of delaying puberty is by its nature only relevant for children and young people.
15. When medical practitioners prescribe a medicine off-label, they are expected to be working within their scope of practice. Practitioners need to make sure that the person receiving the medicine knows that the medicine is being used for an unapproved use and have an informed conversation with them about the potential risks and benefits, involving family, whānau, or caregivers where appropriate.
16. Medical practitioners are expected to meet professional practice and ethical standards and also ensure that they meet the provisions of the Code of Health and Disability Services Consumer Rights. Prescribers are also regulated under the Health Practitioners Competence Assurance Act 2003.

17. Regulatory oversight of prescribing is provided by Medsafe (medicines), the Medical Council of New Zealand (prescribing practice), and Pharmac (funding conditions).
18. Consent to medical treatment can be given by legal minors of or over the age of 16 years; this is detailed in section 36 of the Care of Children Act 2004. That Act also outlines the process of referral to the Family Court for rulings when there is disagreement between parties.

Guidelines for use of puberty blockers in gender-affirming care

19. International clinical practice guidelines for endocrine treatment of gender-dysphoric/gender-incongruent persons have been issued by the Endocrine Society.[3] These guidelines provide a framework for the appropriate treatment of these individuals, including evaluation criteria for gender-affirming medical treatment.
20. In New Zealand, the Professional Association for Transgender Health Aotearoa has a 2018 guideline that covers the prescribing of puberty blockers in gender-affirming care.[4] There are also local clinical pathways within primary care and specialist services across New Zealand, but there is not currently a nationally consistent approach. Health New Zealand is currently updating clinical guidance.

International approaches

21. Across related jurisdictions, there are a range of approaches to use of puberty blockers for gender incongruence or dysphoria.
22. The UK, Finland, Norway, and Sweden have recently decided to limit the initiation of new prescriptions of puberty blockers for young people seeking gender-affirming care. These countries have all expressed concerns about the lack of high-quality evidence on outcomes in the use of puberty blockers for gender incongruence and gender dysphoria.
23. Based on the outcomes of the Cass Review,[5] the National Health Service (NHS) England and the NHS in Scotland have paused new prescribing of GnRH analogues for the treatment of gender dysphoria or gender incongruence in children and young people under the age of 18. In June 2024, legislation was passed to prohibit the sale or supply of puberty blockers from UK private prescribers and non-UK registered prescribers. There are narrow exceptions for prescribing under the supervision of a national multi-disciplinary team or a clinical trial.
24. In Scandinavian countries, prescription of puberty blockers is limited to those enrolled in a clinical trial, except in very exceptional circumstances (Sweden) or after non-medical options have been explored and deemed insufficient (Norway and Finland).
25. In most Australian states and territories, the prescription of puberty blockers for people aged under 18 years requires consent from the young person, treating clinician and all parties who have parental responsibility for the young person. Prescribing is 'off-label', which means that the medications are not funded through the Pharmaceutical Benefits Scheme. As a result, prescription is most often through specialist services to enable access to heavily subsidised funding of the medicines through Department of Health and Aged Care investment.

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[3] Hembree, W.C., Cohen-Kettenis, P.T., Gooren, L., et al. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology and Metabolism*, 102(11), 3869–3903. https://doi.org/10.1210/jc.2017-01658

[4] https://patha.nz/Guidelines

[5] https://cass.independent-review.uk/home/publications/final-report/

26. Other countries, such as Canada and the Netherlands, continue to enable the prescription of puberty blockers through clinical processes involving individuals and their families, as part of comprehensive gender-affirming care. However, the Canadian province of Alberta is currently considering banning the use of puberty blockers for young people aged under 16 years, referencing the recent decision made by NHS England.

Assessment of the risk in New Zealand

27. The Ministry has undertaken an evidence brief to review the effectiveness and safety of puberty blockers in young people with gender dysphoria. The evidence on the impacts of puberty blockers on clinical and mental health and wellbeing outcomes, both positive and negative, is scarce. 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.
28. Therefore, we cannot categorically say whether they are safe or unsafe.
29. Due to the lack of evidence, there is a risk of unintended consequences for gender dysphoric children and adolescents. This is a vulnerable population group who face various risks, such as stigmatisation and poor mental health.
30. No instances of harm are known of in New Zealand. However, the Ministry is concerned to ensure 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 informed consent.

What is the policy problem or opportunity?

31. As described above, there has been an increase in use of puberty blockers in gender affirming care in New Zealand and internationally. However, the evidential basis for their use for gender-dysphoric children and young people is unclear, meaning there is a risk of unintended harm. This has led some countries to take a more precautionary approach.
32. Under the status quo, there is a concern that both prescribers and young patients and families are not fully aware of the lack of evidence on the long-term impacts of puberty blockers. This should be made evident to support informed consent.
33. The Ministry's assessment is 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 children and young people for whom its benefits are judged to substantially outweigh these risks; and with informed consent of the young person and their parents or guardians as appropriate.

What objectives are sought in relation to the policy problem?

34. There are three objectives sought in relation to the policy problem:
    a. **Objective One**: to minimise the risk of long-term adverse effects from the use of puberty blocking treatment.
    b. **Objective Two:** to ensure prescribers and young patients and families are informed about the lack of good quality evidence on puberty blocking treatment outcomes.
    c. **Objective Three:** to ensure young people presenting with gender-related health needs continue to have access to an interprofessional team and treatments that can meet their wider mental health and social needs.
35. Objective One is concerned with population-level risks from puberty blocking treatment, while Objective Two is concerned with balancing potential risks at the patient level.

Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

36. There are three criteria that will be used to compare options to the status quo:
    a. **Minimising health risks**: the extent to which the option minimises the risk of long-term adverse effects from puberty blocking treatment via appropriate and consistent prescribing.
    b. **Supporting informed consent and informed practice**: the extent to which the option improves the knowledge of prescribers, patients, and their families about the lack of evidence on puberty blocking treatment outcomes.
    c. **Health protection and equity**: the extent to which the option safeguards the health and wellbeing of young people with gender-related health needs, and supports health equity.

What scope will options be considered within?

37. The scope of options has not been limited by previous policy decisions taken by Ministers. The Ministry has undertaken policy work to assess potential safeguarding measures that could be taken in the short-term or reserved for the future. This work has informed options included in this assessment.
38. The Ministry has considered all available evidence on the risks and benefits of puberty blocking treatment and has formed a view that immediate safeguards should be put in place so that the potential risks of puberty blocking treatments 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.
39. The Ministry has publicly stated that it intends to release a Position Statement and associated evidence brief, which forms part of Option Two, below.
40. The options have been developed prior to consultation with groups that may be affected by any safeguarding actions, which may have limited the identification of potentially feasible options, including non-regulatory options. There will be consultation prior to further advice being provided to Ministers and Cabinet.
41. Options presented broadly align with international responses to safeguarding the prescribing of puberty blocking medicines, noting that there is some international variation.

What options are being considered?

Option One – Status Quo

42. Under the status quo, prescribing of puberty blocking medicines would continue within existing regulatory frameworks.
43. As outlined above there is currently not a nationally consistent approach for the prescribing of puberty blockers in gender affirming care.
44. Clinicians are currently authorised to make prescribing decisions based on established professional practice and their clinical judgement. This includes assessing patient needs, applying any relevant clinical guidelines, assessing the risk and benefit of any medicines, and considering patient safety and any ethical and legal considerations (including obtaining informed consent). Clinicians are bound to adhere to professional practice, which continues to develop in this area of medicine.

Option Two – Strengthening clinical guidance and oversight

45. Option Two builds on the current state with a package of interventions to provide additional guidance and oversight of the prescribing of puberty blocking medicines in gender affirming care. Under this option all regulatory aspects of the status quo would remain unchanged. Decisions about prescribing would continue to sit with health practitioners but with the addition of specific expectations for initiating prescribing and supporting measures.
46. This option includes:
    a. the Ministry issuing a Position Statement on the use of puberty-blockers in gender affirming care, supported by an evidence brief that set out the limited evidence on long-term impacts of these medicines in gender-dysphoric adolescents. These items have been prepared and are scheduled to be published
    b. the publication of Health NZ's clinical guidance, which is currently under development, and
    c. the Ministry developing a monitoring framework that collects 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.
47. It is intended that the Ministry's Position Statement will create a nationally consistent approach for prescribing that is more cautious than the status quo. The Position Statement urges caution in prescribing and sets the expectation that clinicians who initiate puberty blockers 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 health needs.
48. As a national best practice guideline, the Position Statement will provide a firm basis for regulatory oversight of prescribers by the Medical Council of New Zealand or investigation by Health and Disability Commissioner.

Minimises health harms

49. Under this option, prescribing of puberty blockers will be more cautious and limited to certain contexts. It is expected that the overall volume of prescribing will decrease.
50. At the population-level, this is expected to decrease the risk of unintended harms from puberty blocking treatment. However, this option does not fully address the potential for longer-term unknown risks to vulnerable individuals.

Supporting informed consent and informed practice

51. This option would support informed consent by raising awareness among practitioners and patients about the lack of evidence on puberty blocking treatment outcomes.

Health protection and equity

52. In the absence of clear evidence for long-term treatment outcomes, this option is intended to protect young people with gender-related health needs. Under this option, individuals at lower risk of poor health outcomes are less likely to be offered puberty blocking treatment. It is likely that this this group will perceive that a treatment option is being reduced or removed, which may lead to distress. This risk may be mitigated with careful messaging to emphasise the safety rationale and the other actions being taken to build health, including mental health, services for all New Zealanders including for young people with gender-related needs.

Option Three – Regulating the prescribing of puberty blockers

53. This option would build on the interventions under Option Two with a legal framework for prescribing of puberty blocking medicines in gender affirming care. In developing this option the Ministry has explored the legal mechanisms that would provide a practical and feasible way to regulate the prescribing of puberty blockers.
54. The Ministry considered whether it would be possible to restrict the supply, administration or use of puberty blockers. 9(2)(h)

55. Drafting a de novo bill specific to the purpose of regulating the prescribing of puberty blockers in gender affirming care also considered and discounted as unnecessary as another regulatory lever was available.
56. 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. 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.
57. The making of regulations under the Medicines Act has been identified as an appropriate tool for regulating prescribing. This would require the development of clear criteria by which health practitioners could prescribe puberty blockers to different patients.
58. Consultation will be required to ensure that the need for regulation is justified, and any resulting regulation is clear for health practitioners and health service users.

Minimises health harms

59. This option would address the potential for longer term unknown risks to vulnerable groups by significantly restricting prescribing, with few patients meeting criteria to start treatment with puberty blocking medicines in gender affirming care. This is dependent on the regulation being drafted.

Supporting informed consent and informed practice

60. As per Option Two, this option is considered to support informed consent by raising awareness among practitioners and patients about the lack of evidence on puberty blocking treatment outcomes. As a law change the visibility will be high.
61. It is expected that in many cases, prescribing would not be an option available to the clinician. This removes the opportunity for a patient to consent to unknown risks.
62. This option may be seen by some, including the medical profession, as unnecessary interference in clinical decision-making. There are many examples of prescribing that is unevidenced or where evidence has changed, and well-accepted ways of changing practice over time. Regulating prescribing practice this way is outside the norm.

Health protection and equity

63. As per Option Two, this option is also intended to protect the health of young people with gender-related health needs. The perceived removal of an option for some patients is likely to cause distress. Patients may perceive regulating access in this way as blunt and disproportionate. It could lead to reduced help seeking by young people with gender-related health needs, and resulting harms.

64. Compared to Option Two, a law change will be much less flexible and less able to respond to changing evidence around harms.

How do the options compare to the status quo/counterfactual?

Key:

++	much better than status quo	0	about the same as the status quo	-	worse than the status quo
+	better than the status quo			- -	much worse than the status quo

	Option One – Status Quo	Option Two – Strengthening clinical guidance and oversight	Option Three – Regulating the prescribing of puberty blockers
Minimises health risks	0	+ Reducing access limits potential long-term risks from puberty blocking treatment for vulnerable groups.	++ By significantly restricting prescribing, the potential long-term risks for vulnerable groups are minimised (dependent on the regulation being drafted).
Supporting informed consent and informed practice	0	++ Raising awareness among practitioners and patients about the lack of evidence on puberty blocking treatment outcomes is considered to support informed practice and consent.	+ As per Option Two, however in most cases this would remove an option for clinical decision-making and remove the opportunity for a patient to consent to unknown risks.
Health protection and equity	0	+/- As evidence on the outcomes of puberty blocking treatment is sparse, it is difficult to predict long-term effects.	+/- As per Option Two, however, there will be less flexibility to respond to changing evidence on around harms.
Overall assessment	0	++ This option will reduce potential long-term risks for vulnerable groups and support informed consent and informed practice.	++ This option takes a precautionary approach by minimising potential long-term risks for vulnerable groups. However there is a lack of flexibility to respond to emerging evidence.

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

65. Across the options considered Option Two (strengthening clinical guidance and oversight) is likely to achieve the policy objectives. The Ministry notes that this option is particularly beneficial in supporting informed consent and informed practice as it provides information and guidance to health practitioners and patients and their families.
66. The Ministry notes, however, that:
    a. There are unknown long-term impacts of puberty blocker treatment on a young population
    b. There is emerging evidence which is still being evaluated internationally
    c. There is limited evidence about the New Zealand population, including Māori and Pacific peoples.
67. In this context, the Ministry considers it prudent to consider whether further safeguarding measures should be put in place in the short-term, or whether any safeguarding measures should be held in reserve for the future should more risk information emerge. For example, it seems that prescribing has reduced somewhat in 2023 and 2024, which may indicate adjustment in clinical practice in light of the international concerns.
68. Consultation will be important in considering further measures including a potential regulation. Consultation would consider:
    a. whether there is a need to create such a regulation and its likely impacts;
    b. how the proposed regulation is framed to provide clarity of intent and effect;
    c. the effectiveness of the proposed regulation in minimising impacts and preserving access to these medicines for those groups being considered to need treatment with these medicines;
    d. which groups of young people with gender-related health needs, if any, should be able to access puberty blocking treatment;
    e. any implementation, administration or enforcement issues or risks and their prevention or management;
    f. any potential unintended impacts for people, health practitioners, health service providers, health regulators or others, and their prevention or management.
69. The insights gathered through this consultation will inform the refinement of options, including an updated version of this regulatory impact statement if a regulatory option was proposed.

Section 3: Delivering an option

How will the new arrangements be implemented?

70. The interventions to provide additional guidance and oversight of the prescribing of puberty blocking medicines under Option Two are underway. The Director-General Position Statement will be published as soon as practicable, alongside the evidence brief and an addendum. Health NZ plan to complete updated clinical guidance in December 2024. The Ministry will continue to develop a monitoring framework for prescribing and use of puberty blockers and outcomes for young people.
71. Under Option Two, the Position Statement is expected to provide a firm regulatory basis for the Medical Council of New Zealand and the Health and Disability Commissioner. Enforcement action would likely follow from complaint or notification about inappropriate prescribing. It is expected that a reasonably high level of compliance will be achieved, as medical practitioners are held to high professional standards.
72. Under Option Three, as a prescribing practice issue, implementation will be the responsibility of the same parties, with support from the Ministry for legal action.
73. The process for making regulations under Section 105 of the Medicines Act will require consultation with affected groups, including medical practitioners, health service providers, gender diverse young people and health regulators.
74. It is important that any communications are sensitive and emphasise the safety rationale and the other actions being taken to build health, including mental health, services for all New Zealanders including for young people with gender-related needs.

How will the new arrangements be monitored, evaluated, and reviewed?

75. The Ministry is developing a monitoring framework for use and prescribing of puberty blockers as well as broad population outcomes for cohorts of young people. It is expected that this will provide more clarity than current medicines dispensing data by collecting 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).