Briefing for decision

Puberty blockers for young people with gender incongruence and dysphoria: policy options

Date due to MO:	03 April 2025	**Action required by:**	N/A
Security level:	SENSITIVE	**Reference:**	H2025063205
To:	Hon Simeon Brown, Minister of Health		
Copy to:	Hon Matt Doocey, Associate Minister of Health		
Consulted:	Health New Zealand: ☐		
Proactive release:	This **title** is proposed by the Ministry of Health for proactive release: ☐		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved	☐ Decline	☐ Overtaken by events
☐ Needs change	☐ Seen	
☐ See Minister's Notes	☐ Withdrawn	

Comment:

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To:	Hon Simeon Brown, Minister of Health		

Purpose of report

1. This report provides a summary of:
   a. the policy issues with use of puberty blockers for young people with gender incongruence and gender dysphoria
   b. the policy options available to you with their advantages and disadvantages.

Summary

2. A class of medicines are used to block puberty in children and young people with severe and persistent gender incongruence and gender dysphoria. They are known as puberty blockers when referring to this use of the medicines - they are widely used for other common purposes such as treatment of prostate cancer).
3. Although there is a good evidence base for other uses of the medicines, quality evidence is lacking for their use as puberty blockers in gender incongruence and dysphoria. The short-term effects and side effects are well known, together with the longer-term effects for younger children when the medicines are used to treat precocious (very early) puberty. Whether there are longer-term benefits or risks for young people with gender incongruence and dysphoria has not been established to the usual clinical trial standard.
4. With children and young people, there is a duty on health practitioners and other adults providing care to act in their best interests and to uphold their rights. Those rights include being provided with quality healthcare and education, protected from discrimination, able to participate in community life and not subject to experimental treatment without consent.
5. Balancing those rights, providing the best support and striving for best health outcomes can be difficult for parents and health practitioners when faced with the individual needs of young people who have severe and persistent gender incongruence and dysphoria. Significant mental health, social and education concerns are common in this population; these impact both the young person and their family. In November 2024 the Ministry released a Position Statement that set expectations for how new treatment decisions would be made.
6. Governments also have a duty to give effect to and uphold the rights of children. It is in this context that you as Minister of Health are being asked to consider whether Government intervention is needed.

7. While evidence is lacking, concerns have been raised that medically delaying puberty for this group of young people might mean they are less able to decide on their gender identity in future; and that not enough checks and balances are being used by health practitioners and parents, together with the young person, in decisions to treat.

8. On the other hand, rainbow community voices ask that the Government protects their rights to decide for themselves how they wish to live. Such protection would include ensuring quality health care is accessible for all children and young people and that they with their parents should be involved as much as possible in decisions about their own health.

9. 9(2)(g)(i) This report outlines a range of possible responses that take different approaches to protect the rights of children and/or promote their future life outcomes.

10. In November 2024, the Government asked the Ministry to consult on whether further safety measures, such as regulation, are required and what their impacts would be. We have provided a separate report summarising the views received during consultation [H2025063383 refers]. That report will further assist your consideration of the possible responses.

Recommendations

We recommend you:

a) **Note** the policy options to respond to the issue of poor evidence either for or against any long-term benefits or risks from puberty blocker treatment **Yes/No**

b) **Note** that a separate report has been provided on the views received during the Ministry's consultation on whether further safety measures are needed for puberty blocker prescribing and what the impacts of safety measures could be **Yes/No**

c) **Indicate** any preferred option or group of options for which you would like further development or advice:

i) Option A – Baseline of close Ministry monitoring and adjustment as needed **Yes/No**

ii) Option B – Enhanced health services and service controls **Yes/No**

iii) Option C – System action on prescriber controls and supports **Yes/No**

iv) Option D – Regulations to strengthen prescribing requirements otherwise specified **Yes/No**

v) Option E – Regulations to set and enforce new prescribing restrictions **Yes/No**

vi) Option F – Bespoke legislation **Yes/No**

d) **Indicate** which next steps you wish the Ministry to take:

i) Prepare a paper presenting all options for discussion by Ministers **Yes/No**

ii) Prepare a paper presenting your preferred response/s for Cabinet agreement **Yes/No**

iii) Other (please stipulate) **Yes/No**

Steve Barnes
Associate Deputy Director-General
Strategy, Policy and Legislation
Date: 03/04/2025

Hon Simeon Brown
Minister of Health
Date:

Puberty blockers for young people with gender incongruence and dysphoria: policy options

Proactive release

11. Note that proactive release of this paper should be deferred until decisions have been made and announced.

Background / context

12. Use of medicines to delay puberty in young people with gender incongruence (personal experience of gender persistently not matching the gender assigned at birth) and gender dysphoria (associated high and persistent distress) is an area of clinical practice with a limited evidence base. High quality evidence is lacking for either benefits or risks in the long-term from this treatment for this population group.

13. No instances of harm have been reported in NZ and the treatment is used infrequently relative to the numbers of young people reporting these conditions. (Fewer than 110 young people started receiving these medicines in 2024 across all reasons for use.)

14. Such an area of clinical practice would normally be governed using the usual range of medicines- and prescribing-related safety settings. These include informed consent of the young person and their parents.

15. However, this particular treatment has become controversial and a focus among groups with very polarised views of transgender identity. Internationally, much and often inaccurate information and opinion has been circulating. The polarity of debate reflects strong feelings rather than evidence (which is lacking either for or against).

International context and developments

16. Use of this treatment grew slowly in many countries over the 2000s. Prescribing patterns have been similar to those in New Zealand with an increase in prescribing since 2010. Uncertainty about reasons for the growth in prescribing, change in the patient group, and in the United Kingdom service provision issues, led to review of the limited evidence base.

17. In the UK, the initiation of puberty blocker treatment for gender incongruence or gender dysphoria in people aged under 18 is effectively prohibited at present. Access was restricted by a clinical policy to stop new prescribing in the National Health Service (NHS) after an in-depth review of services and evidence in England (the Cass review), and legislative action was taken so that prescriptions for new patients could not be dispensed if issued outside the NHS (privately in the UK or in other countries). At the same time, the NHS started establishing new and expanded paediatrician or psychiatrist-led gender identity services and working with researchers on a clinical trial to start within the NHS later this year.

18. Norway, Sweden, and Finland have issued stricter clinical guidance or directives limiting prescription of puberty blockers for this indication (reason for use of the treatment) to research centres or exceptional circumstances. Several US states and the province of

Alberta in Canada have introduced laws to restrict this and other gender-affirming treatments to minors.

19. In other comparable jurisdictions (including most of Europe, Australia, Canada and Japan), prescribing of puberty blockers for gender dysphoria continues to be governed by existing regulatory and professional frameworks. Several jurisdictions have revised clinical guidelines and informed consent protocols in the context of limited evidence for benefits or long-term safety.

20. Appendix 1 provides brief information on the range of responses internationally, and an outline of actions taken in the UK.

Relevant population information

Demographics

21. In Census 2023, 0.7% of New Zealanders 15 years and above were transgender, non-binary or another gender. This population was distributed across all age groups though skewed to younger ages – 1.2% of 15 to 19 year old New Zealanders were in this group.

22. The Youth 2012 survey of 8,500 secondary school students across New Zealand found that 1.2% were transgender and 2.5% not sure of their gender. The Youth 2019 survey of 7,700 students from Auckland, Northland and Waikato found that 1% of students were transgender or non-binary and a further 0.6% unsure of their gender.

23. These population sizes and skews towards younger age groups are broadly similar in other countries that have included questions about gender identity in their census (including Canada and England and Wales in 2021) or a subset of their Census (such as Australia which estimated 0.9% of Australians 16 years and older were transgender and gender diverse).

Health and wellbeing indicators

24. The Youth 2012 and 2019 surveys found around half of transgender secondary school students had significant depressive symptoms, similar numbers had self-harmed and one in five attempted suicide in the last year. A similar proportion had been unable to access healthcare when they needed it. Nearly one in five experienced bullying at school on a weekly basis and more than half were afraid someone at school would hurt or bother them. About three-quarters reported they had at least one parent who cared about them a lot, and the majority thought that their family got along.

25. The Household Economic Survey 2021 and General Social Survey 2023 reported, for transgender and nonbinary adults, high daily feelings of depression and anxiety, higher levels of disability and after-tax incomes lower by a quarter.

Services for children & young people

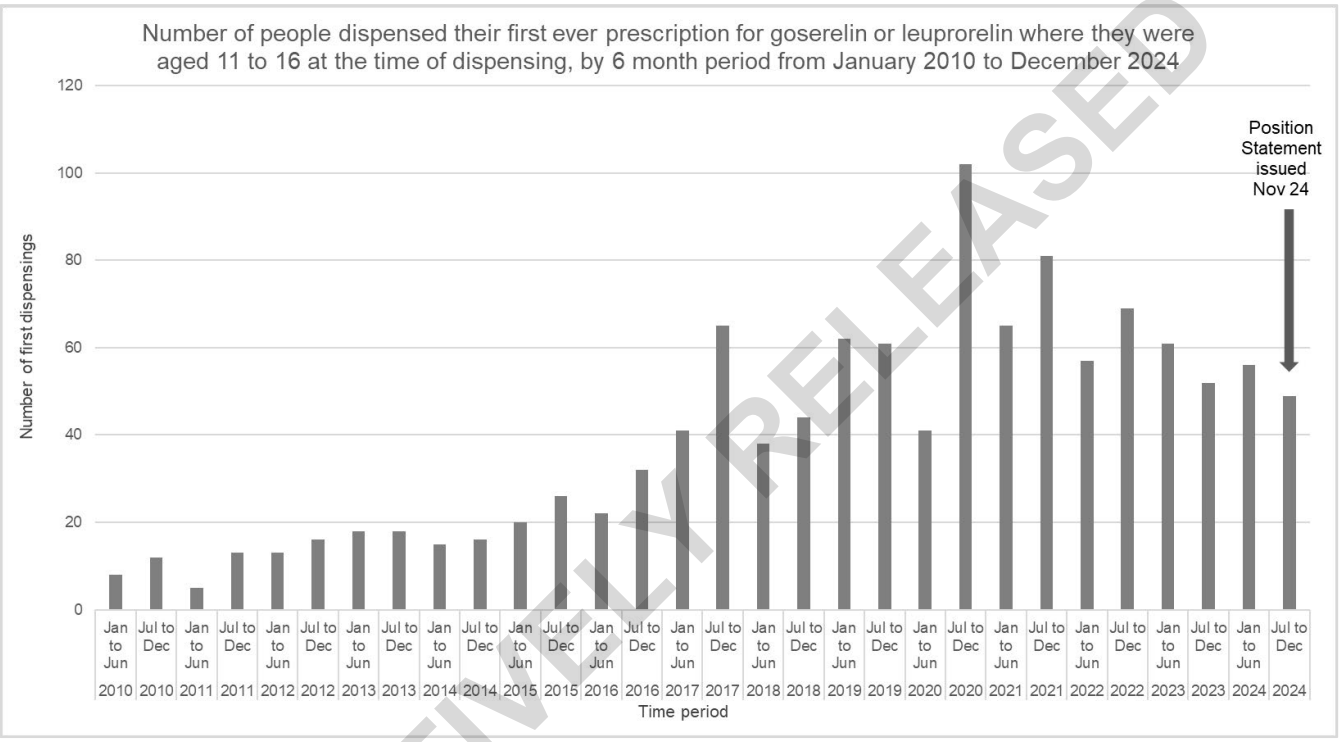
26. Children and young people with health and gender identity concerns can access health care through their family GP, or a youth 'one-stop-shop' or similar service in some locations. If they have significant concerns they may be referred to a specialist paediatric or child and young person mental health or gender affirming care service for full health and psychological assessment and care. Only a small minority meet criteria for puberty blocker treatment, with most young people being supported with psychological and social care.

27. Current service coverage and arrangements are varied around New Zealand, with lengthy wait times and gaps in availability in many districts.

Puberty blocker prescribing in New Zealand

28. Chart 1 below shows trends in starting treatment with puberty blocker medicines for the relevant age group (11 to 16 years old). All prescribing of these medicines is captured, so their use to block puberty in gender incongruence and dysphoria will be a little lower than shown. (The medicines are also used in this age group for other reasons including treatment of endometriosis or uterine fibroids).

Chart 1. New prescribing of puberty blocking medicines for 11- to 16-year-olds, all uses, 2010 to 2024



New Zealand response to date

29. The Ministry has issued a Position Statement on the Use of Puberty Blockers in Gender-Affirming Care (the Position Statement) together with its evidence review, *Impact of Puberty Blockers in Gender-Dysphoric Young people: An Evidence Brief*. The Position Statement sets expectations of clinicians for use of puberty blockers in young people, that clinicians should exercise caution in prescribing, and that those who initiate puberty blockers should be:

    a. experienced in providing gender-affirming care, and

    b. part of an interprofessional team offering a full range of supports to young people presenting with gender related issues.

30. The Position Statement includes detail on the complexity in providing healthcare for young people with gender-related health needs and the importance of fully informed consent of patients and their care givers. It outlines further steps to ensure young people have access to comprehensive quality care, including enhancing governance and monitoring of gender-affirming care, continued monitoring of emerging evidence, and

commissioning New Zealand research on long-term clinical and mental health and wellbeing impacts of puberty blockers in young people.

31. In November 2024, the Government asked the Ministry to consult on whether further safety measures, such as regulation, are required and what their impacts would be. A report on responses to the consultation on puberty blockers [H2025063383] is provided separately.

Range of possible Government responses

32. You have asked for information on the responses that could be taken by the Government.

Limitations on possible responses

33. The medicines in question are widely used for other purposes and funded by Pharmac – it is not practical to take actions that would limit their overall availability. In adults, they are a mainstay of prostate cancer treatment and used to treat a range of conditions including other cancers; and in children to treat precocious (very early) puberty and a few rare conditions.

Policy Options

34. Six options are identified below and set out in greater detail in Appendix Two.

Option A – Baseline of close Ministry monitoring and adjustment as needed

35. This option provides a baseline to which any other option or options can be added, whether early on or in the future if prescribing problems occur or new evidence emerges. This option is most like Australia (with the exception of Queensland which has temporarily halted prescribing while it investigates service issues within the State) and Japan.

36. Since the release of the Position Statement in November, the Ministry has been developing its active monitoring programme and examining what research could effectively be undertaken in New Zealand. Health NZ has been tightening its models of service provision. This baseline option involves:

    a. Active monitoring of prescribing, service provision more widely and new information and evidence

    b. Regular reporting of monitoring results and actions

    c. Managed responses to new concerns, information and evidence following identified trigger points for additional action

    d. Observational research development to contribute learning about patient experiences and outcomes in this New Zealand population group.

Option B – Enhanced health services and service controls

37. This option involves Health NZ taking a strong lead in consolidating or enhancing its services and their support, oversight or control of health care for young people with gender-related health needs, promoting a full range of psychological and social services. This option is most like European Union countries, where most of western Europe has enhanced services, and where Norway, Sweden and Finland have introduced service

controls on puberty blocker prescribing. It is similar in part to the UK where the NHS is setting up new and enhanced gender identity services.

38. It is Health NZ's function to fund and deliver health services that meet the needs of New Zealanders. Ministers can ask that action is taken to shore up services and address the needs of this population but do not have powers to direct how this is done.

39. A range of interventions is possible and most will have resource implications (such as specialist clinicians spending time in supervising others rather than in direct patient care). Given the issues Health NZ is facing currently with fully staffing frontline child and young person health services, additional resources or repurposing from other areas of health spending may be required.

40. The types of service enhancements and controls that Health NZ could consider include:

    a. Establishing consistent access to a broader range of social and psychological services (similar to the UK NHS)

    b. Establishing a national service and/or centre of excellence to provide for decision-making nationally (similar to Finland)

    c. Mandating a national clinical decision structure with particular experts to approve treatment decisions

    d. Mandating multidisciplinary second opinion requirements

    e. Establishing peer review meetings or case discussion requirements nationally or within regions.

41. These enhancements and controls would mainly impact publicly subsidised services (including those delivered in a primary care setting). In practice, this covers all current puberty blocker prescribing. While in theory a private service could be set up, a number of disincentives currently operate. Private social and psychological services face fewer barriers but cost limits access.

Option C – System action on prescriber controls and supports

42. This option involves health entities and authorities, together or separately, implementing mechanisms that improve prescribing. Most such work will have resource implications (such as time to develop and agree proposals or enhance IT systems). This option is most like Denmark where firmer consent requirements are in place.

43. Possible approaches include:

    a. Establishing a health system joint work programme to further reinforce a uniform high bar for puberty blocker prescribing

    b. Aligning all related prescribing information, guidance, settings and support systems (this could include, for example, aligning provisions administered by Pharmac with service pathways established by Health NZ and patient management systems used in primary care)

    c. Developing tools and guidance to support, for example, assessment processes, clinical decisions, patient and family discussions or social and psychological treatment delivery

d. Enhancing prescribing safety and quality more widely, such as by developing processes or supports to assist clinicians or parents and carers with difficult or complex prescribing situations for children young people.

Option D – Regulations to strengthen prescribing requirements otherwise specified

44. The Minister of Health could make regulations under section 105(1)(d) of the Medicines Act to restrict prescribing puberty blockers for treatment of gender incongruence and gender dysphoria in one or more of the following ways:

    a. Prohibit initiation of this treatment where it does not meet the expectations set out in the *Position Statement on the Use of Puberty Blockers in Gender-Affirming Care* as published on the Ministry website (including any revisions from time to time)

    b. Require prescribers to have obtained qualifications, undertaken training or demonstrated competence that are specified under section 105A(1)(a) to (c) before they can initiate treatment – specified from time to time by notice in the *Gazette*

    c. Require prescribers to undertake this prescribing under the supervision of a particular practitioner (such as an office holder) or specified class of practitioner under section 105A(1)(d) – the scope, requirements and conduct of the supervision could provide for monitoring and assurance

    d. Stipulate prescription requirements (such as annotations on prescriptions) and require records to be submitted by dispensers and/or by prescribers.

45. The regulations would reinforce requirements otherwise in effect (such as those in options B and/or C) to make them more visible and weighty for prescribers, with specific offences and penalties. This option in effect is most like Norway, Sweden and Finland, though they have achieved a high bar for prescribing without using regulations.

46. This would be the first time such regulations were made in respect of a particular use of a class of medicines.

Option E – Regulations to set and enforce new prescribing restrictions

47. The Minister could also make regulations under s105(1)(d) to further restrict prescribing of the medicines for the purpose of blocking puberty in treatment of gender incongruence and gender dysphoria in 11-16 year olds. Such regulations would, in effect, limit who could receive the treatment as well as who could prescribe it. They could include the following:

    a. Prohibit, limit, restrict or impose conditions on prescribing that initiates the treatment for new patients

    b. Prohibit, limit, restrict or impose conditions on all prescribing (and/or on administration, sale or supply).

48. This would be the first time such regulations were made for any medicines in New Zealand. This option is most like the UK if service enhancements are made via Option B.

49. The restrictions would remain in effect until the regulation was revoked or disallowed by Parliament or changed by Order in Council. Consultation and process requirements apply, with associated timeframes s 9(2)(g)(i)

Option F – Bespoke legislation

50. A Bill specifically designed to limit prescribing of puberty blockers could be designed, drafted and introduced. It would amend the Medicines Act as required, and include specifications not provided for currently. New provisions could, for example, stipulate:

    a. assessment and documentation requirements designed to limit prescribing to those patients for whom rigorous clinical assessment criteria have been met and reviewed with multidisciplinary input

    b. informed consent requirements including adaptation for patient and family capacity, needs and circumstances

    c. monitoring and assessment during treatment and review periods

    d. a new requirement for indication statements on prescriptions for the purposes of reporting and monitoring (as exists in the UK).

51. The usual caveats around timeframes and priority (for design, drafting, consultation and consideration) would apply. 9(2)(g)(i)

52. This option is most like certain US States and the province of Alberta in Canada.

Comparing policy options

53. Detail on the six policy options is provided in Appendix 2. The options vary in whether their primary focus is protection from possible treatment harm or addressing health needs. They also vary according to closeness of fit with the usual ways for managing clinical decision-making. Making regulations or introducing legislation in order to manage clinical decision-making in relation to a particular medicine or class of medicines has not occurred before, except for controlled drugs under the Misuse of Drugs Act.

54. For comparison, Appendix 3 provides examples of other clinical and prescribing situations where special consideration is given to balancing risks and benefits, ensuring informed consent and assuring safety and quality.

Risks and management

55. The Ministry's review of evidence *Impact of Puberty Blockers in Gender-Dysphoric Adolescents: An evidence brief* and ongoing follow-up found limitations in the quality of evidence for both the benefits and risks (or lack thereof) of using puberty blockers. Studies have not adequately demonstrated benefits, including benefits to mental health, nor long-term adverse effects; benefits and/or long-term adverse effects may still exist.

Risks to patients and families

56. 9(2)(g)(i)

57. Accessible, supportive and proactive healthcare is required for effective responses, including mental health responses, to patients and families experiencing distress. However, care is not always available, timely or welcoming for all who seek it. Even where services are available, there can be barriers including affordability.

58. Health NZ will shortly issue updated clinical guidance on gender-affirming care. The guidelines will describe the clinically appropriate care for the wide health needs of young people and reinforce the expectations set out in the Ministry's Position Statement.

Legal risks [Legally privileged]

s 9(2)(h)

Next steps

63. A report on views received during the consultation on puberty blockers [H2025063383] has been provided separately. It will require consideration along with this report in considering possible responses.

64. Further detailed advice will be required for any of the possible responses you wish to consider further. This will include assessment of impacts on health, human rights, child wellbeing, resource requirements and health service delivery.

ENDS.

APPENDIX 1. Additional information on international responses

Table 1: Approaches to puberty blockers across jurisdictions

Government regulatory intervention	National/State health system controls	Usual clinical guidance and professional standards approaches
Ban – certain US States, province of Alberta (Canada)	Temporary pause in prescribing – State of Queensland, Australia	Many countries including Australia, Japan and most European countries.
Ban outside national health system control – UK	Limit use to research settings or high clinical risk – Norway, Sweden, Finland	
Other regulatory approaches, eg, stipulating consent requirements – Denmark, certain US States	Issue Position Statement – NZ	

Table 2: Timeline of UK regulation of puberty blockers

Timeline	What happened
October 2019	A legal claim is lodged against the NHS Gender Identity Development Services (GIDS), initiating the Bell v Tavistock court case
September 2020	NHS England commissions the Cass Review to independently examine the NHS gender identity services for children and young people
December 2020	The High Court ruling in the Bell v Tavistock case states that children under 16 are unlikely to be able to give informed consent to starting puberty blockers
September 2021	The Court of Appeal overturns the Bell v Tavistock ruling, allowing clinicians to decide if under-16s can consent to puberty blockers
March 2022	The interim report of the Cass Review is published
July 2022	The NHS announces the closure of the Tavistock clinic with regional centres to be set up as replacement. This followed the interim findings of the Cass Review which highlighted concerns about the Tavistock's model of care
August 2023	NHS England initiates a 90-day public consultation period on the use of puberty blockers
March 2024	NHS England stops the routine prescription of puberty blockers for under-18s
April 2024	The final Cass Review report is published; two new gender care services open
May 2024	The UK government introduces emergency regulations to restrict the prescribing and supply of puberty blockers to under-18s outside the NHS, except those enrolled in clinical trials. The ban was set to last from June to September 2024
June 2024	The emergency ban on puberty blockers for under-18s comes into effect
August 2024	The NHS announces additional new specialist regional hubs for gender care
December 2024	The UK government announces that the ban on puberty blockers outside the NHS would be made indefinite

Appendix 2. Comparison of policy options

Policy option	Description	Effects - stand alone	Effects - additive	Implementation	Implementation risks	Impact risks	International comparison
A Baseline of close monitoring and adjustment • Monitor prescribing, services, new information and evidence • Report six-monthly • Pre-plan action trigger points • Plan NZ research	Keep abreast of trends in NZ and internationally. Intervene or add other options if and when needed. Observational research on NZ patient experiences and outcomes	Firm basis for Medical Council to investigate/ prosecute complaints. Tracking of prescribing trends over time Adjustment of settings in response to new information Add other options as needed	Base for all other options. Strategic approach to other options and when to use them	Already underway Ministry lead Health NZ important contributor Medical Council and Health & Disability Commissioner	Resource constraints may limit research funding.	9(2)(g)(i)	More cautious than but otherwise similar to Australia, Canada, Japan In time, will contribute to international knowledge through observational research
B Enhanced services and service controls • Increase alternative services • Create national centre • Or structured decisions • Or supervision/oversight	Consolidation and/or enhancement of youth gender services. Choose from range of ways to tighten and improve clinical decision-making. Closer oversight of or feedback to clinicians	Couples reduction in puberty blocker prescribing with increased availability of alternative psychological or social services	Can work with all options. 9(2)(g)(i)	Health NZ lead Other entities or authorities may lead	Resource constraints or competition for attention may limit speed and/or extent of implementation. Tension for clinicians between direct patient care and time for administration, supervision & support	9(2)(g)(i)	Similar to most of western Europe Similar to UK minus its regulation of private provision National centre similar to Finland
C System action on prescriber controls and supports • Align actions across health patient management systems • Create structured decision or consent process • Guidance across decision & consent situations for parents and children	Collective attention across health entities, advisory bodies, commissioners Menu of options within this approach Looking at root causes of problems and how they can be addressed	Range of parties work collectively to address issues. Upstream effects that promote better prescribing decisions. Can be wider than puberty blockers or gender services. Promotes buy-in to work programme overall	Can add clarity and legitimacy to other options and lower their impact risks. Promotes joint governance across entities for this and other options Likely to add useful monitoring information	Ministry lead Involvement of several if not all health entities Advisory bodies and authorities Programmatic approach should lead to accelerated improvement gains over time	Resource constraints may limit speed of progress. Many take longer to agree priorities, approaches or final decisions. Key entities, advisory bodies or authorities may not endorse results	9(2)(g)(i) 9(2)(h)	Denmark firmed up consent requirements for puberty blocker prescribing
D Regulations to strengthen otherwise specified requirements • Require prescribers to be qualified or supervised • Require information provision • Require specified oversight	Regulations under Medicines Act s105(1)(d) Choose from a range of options to require prescribers to follow specific expectations, including training, supervision and reporting	Formalises expectations on prescribers, to reinforce existing requirements (eg the Position Statement requirements) and/or set new expectations	Can work with Options A, B and C Requiring the provision of information would support the Ministry's monitoring of prescribing with more detailed information	Ministry lead (regulatory process and enforcement of regulation) Involvement of multiple health entities/regulators Enforcement will require new resource	9(2)(g)(i)	9(2)(g)(i) 9(2)(h)	Similar to Norway, Sweden and Finland, although they have achieved a high bar for prescribing without using regulations
E Regulations for new prescribing restrictions • Prohibit or restrict prescribing • Limit who can receive puberty blocker treatment	Regulations under Medicines Act s105(1)(d) Choose to either prohibit, limit, restrict or impose conditions on either new prescribing or all prescribing	Likely to significantly curtail prescribing	Can work alone added to baseline option A Could work with Option B (eg, if service controls are specified as conditions)	Ministry lead (regulatory process and enforcement of regulation) Involvement of multiple health entities Enforcement will require new resource	Penalties in the Medicines Act are less significant than existing safeguards (eg through the Medical Council)	s 9(2)(g)(i) s 9(2)(h) s 9(2)(h) s 9(2)(g)(i)	Similar to UK if coupled with Option B (enhanced services) and research programme
F New specific legislation • Prohibit or restrict prescribing, or limit who can receive treatment • Create structures and processes that support restricted prescribing	Bill to amend the Medicines Act specifically designed to limit prescribing of puberty blockers (eg specific assessment criteria, informed consent processes, patient monitoring)	Likely to significantly curtail prescribing Might require indication statements on prescriptions	Can work with Options A and B (if legislation set requirements that could be met through changes to service provision)	Ministry lead (legislative process and enforcement of regulation) Involvement of multiple health entities Resource needed to implement and enforce	High resource and opportunity costs for Ministry, Parliamentary Counsel, Parliament Penalties would remain minor unless amended through legislation	9(2)(h)	Some states in the United States and Alberta, Canada

Appendix 3. Additional information other clinical and prescribing situations used as comparison examples

Table 3: Comparitive examples of safety approaches in other decision-making processes involving special clinical and prescribing situations

Example	Concern	How it is handled
Fluoxetine for childhood depression	Fluoxetine is a Selective Serotonin Reuptake Inhibitor (SSRI) medicine used to treat depression. There are both risks and benefits identified for its use in children.	Approved by Medsafe for adults 18 years and over, and can be prescribed for children with guidance in the NZ Formulary for Children.
Methylphenindate for ADHD	Used to treat ADHD but also misused as a recreational drug and had been restricted for that reason. Methylphenindate has both substantial benefits for children with ADHD, along with potentially significant rare adverse effects.	The Government asked Medsafe, Pharmac and the Ministry to look at reducing restrictions in order to improve access. Renewal criteria were removed by Pharmac in 2024 to make it easier to continue receiving the medication.
Clozapine for treatment resistant schizophrenia	Clozapine is an antipsychotic used to treat schizophrenia with both high potential benefits and life-threatening adverse reactions, and a patient group not always able to consent to treatment or to reliably report emerging health problems.	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.
Welfare guardianship	Welfare guardianship involves a court-appointed individual making decisions about a person's personal care and welfare when they lack the capacity to do so themselves.	Governed by special processes under the Protection of Personal and Property Rights Act 1988
End of life choice	Development of the End of Life Choice Act involved ethical, moral, and legal considerations regarding assisted dying.	The End of Life Choice Act 2019 legalised assisted dying under strict criteria with safeguards in place such as requiring agreement from at least two medical practitioners, and ensuring the patient is competent in making a fully informed decision.
Care of children	Protecting the welfare and best interests of children and ensuring their views be taken into account in matters affecting them.	Governed by special processes under the Care of Children Act 2004.