Regulatory Impact Statement:

Puberty blockers for young people with gender incongruence and gender dysphoria

Decision sought	Analysis produced for the purpose of informing Cabinet decisions on the use of puberty blockers in young people with gender incongruence and dysphoria
Agency responsible	Ministry of Health | Manatū Hauora
Proposing Ministers	Hon Simeon Brown, Minister of Health
Date finalised	July 2025

Briefly describe the Minister's regulatory proposal

This regulatory proposal considers whether further safety measures are needed for the use of puberty blockers in young people with gender incongruence and gender dysphoria. It is prompted by Cabinet's agreement in November 2024 that work should proceed towards considering regulation to restrict prescribing of puberty blockers for young people.

Summary: Problem definition and options

What is the policy problem?

The policy problem is concern that puberty blockers should only be prescribed for young people with gender incongruence/dysphoria for whom the benefits of these medicines outweigh the potential risks.

Puberty blockers is a colloquial term used to describe medicines that delay pubertal changes in children and young people. Over the last two decades there has been an increase in use of puberty blockers in 11–16-year-olds in New Zealand and internationally. This is when they are generally prescribed for gender incongruence (where an individual's experienced gender and their assigned sex at birth persistently do not match) and gender dysphoria (where an individual's gender incongruence has an adverse impact on their health and wellbeing). Despite the overall increase, prescribing has been reducing in New Zealand since it peaked in 2020, with an estimated 100 or fewer young people started on the treatment in 2024.

Puberty blockers have been used for over 30 years to treat precocious puberty, where they are started at a young age (in girls under 8 years and boys under 9 years). When used for gender incongruence/dysphoria, the medicines are prescribed 'off label' because they are used for an unapproved indication. Many medicines are prescribed off-label in paediatrics, with informed consent including discussion about the use being unapproved.

The evidential basis for their use for gender incongruent/dysphoric young people is unclear – neither improved long-term outcomes nor long-term adverse effects have been established.

In November 2024, Cabinet agreed that work should proceed towards considering regulation to restrict prescribing of puberty blockers for young people under 18 years with gender related health needs, including undertaking public consultation.

When public consultation began in November 2024, the Ministry of Health released a Position Statement. The Statement provides a nationally consistent approach to exercising caution in prescribing. It sets expectations of clinicians who initiate puberty blocker treatment for gender incongruence/dysphoria, including that they are experienced in providing gender-affirming care, work as part of an interprofessional team offering a full range of supports, and have the fully informed consent of patients and their parents or caregivers. It outlines further steps to ensure young people have access to comprehensive quality care, including continued active monitoring and commissioning of New Zealand research on long-term clinical and mental health and wellbeing impacts.

Public consultation has been completed. The majority of stakeholders support access to puberty blockers for gender incongruence/dysphoria, through clinical consideration of the risks and benefits for each affected individual, and following consultation with the individual and their caregivers.

The policy problem does not appear to involve a market failure.

What is the policy objective?

The policy objective is to help ensure puberty blockers, when considered in gender-affirming care in New Zealand, lead to:

a. positive health and wellbeing outcomes that are safe for young people with gender incongruence/dysphoria over the long-term

b. health equity for young people presenting with gender incongruence/dysphoria.

There is currently a paucity of quality evidence on the benefits and risks of young people taking puberty blockers for gender incongruence/dysphoria. The Ministry of Health therefore has a monitoring programme to assist with measuring whether the objective is being met. This involves:

a. active monitoring of prescribing, service provision more widely and new information and evidence (both domestically and internationally)

b. regular public reporting every six months of monitoring results and actions

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

d. considering whether to identify trigger points to signal when additional controls are needed and what they should be.

What policy options have been considered, including any alternatives to regulation?

Seven policy options are being considered:

Option One – Status quo/counterfactual: baseline of close Ministry monitoring and adjustment as needed (Options A and B in the related Cabinet paper). Decisions about prescribing puberty blockers would continue to sit with health practitioners working within their scopes of practice, with nationally consistent expectations based on the Ministry of Health's 2024 Position Statement and clinical guidance by Health New Zealand. The Medical Council of New Zealand would continue regulatory oversight of prescribers, and the Council and the Health and Disability Commissioner would investigate complaints. An active monitoring programme would continue, which could include identifying trigger points for additional controls. Option One works as a base for all other options.

Option Two – Non-regulatory options that provide further quality checks on prescribing:

- Option 2a – Enhanced health services and service controls. The services, which may include regional hubs, would bring together all the services needed, including strong specialist clinical governance, psycho-social services and oversight. A series of steps would need to be met prior to prescribing puberty blockers.
  Option 2a can work with all other options except Option Four.
- Option 2b – System action on prescriber controls and supports. Actions across patient management systems would be aligned, structured decisions or consent processes would be created, and guidance across decisions and consent situations for caregivers and young people would be provided. Option 2b can add clarity and legitimacy to other options.

Option Three – Regulatory options that clarify and/or restrict prescribing of puberty blockers

- Option 3a – Regulations to strengthen prescribing requirements otherwise specified. Regulations would require prescribers to be qualified or supervised, information to be collected, and there would be specified oversight. This option can work with Options One, 2a and 2b.
- Option 3b – Regulations to set and enforce new prescribing restrictions. Regulation would prohibit or restrict prescribing and limit who could receive puberty blocker treatment. This option can work with Option One and could work with Option 2a (if service controls are specified as the conditions).
- Option 3c – New specific legislation (Option D in the related Cabinet paper). A bill would be introduced to prohibit or restrict prescribing or limit who can receive treatment. Structures and processes that support restricted prescribing would be created. This option can work with Options One and 2a (if legislation set requirements that could be met through changes to service provisions).

Option Four – A combined regulatory and non-regulatory option where regulations would prohibit new prescribing while making youth gender services more accessible. The prohibition would be immediate and would be supported by alternative medical, psycho-social services (Option C of the related Cabinet paper).

What consultation has been undertaken?

The Ministry of Health undertook consultation from 21 November 2024 to 20 January 2025 on whether further safety measures are needed for the use of puberty blockers in young people with gender incongruence/dysphoria. The consultation involved a series of targeted meetings as well as public submissions.

Targeted meetings were held with representatives of the rainbow and transgender community and support sector, medical practitioner and other professional groups, health regulators, and Commissioners for health and disability, human rights, and children. The public consultation resulted in 5,800 online responses and 2,800 email submissions being analysed.

Almost all participants in consultation meetings and the majority of public responses supported continued access to puberty blockers for gender incongruence/dysphoria. The current safeguards that include psychological assessments and informed consent were considered appropriate. Professional groups supported increased data collection, including monitoring of prescribing practices and health impacts.

Groups considered there is no clear rationale to restrict prescribing through regulation in this context. There were strong concerns about an increase in adverse mental health impacts on young people with gender incongruence/dysphoria, and their families, and wider harm to the transgender community though increased stigma and human rights implications. Restrictions on access, such as who could prescribe, minimal age requirements or participation in clinical trials were generally seen as impracticable or unethical.

A minority group in the public submissions supported further restrictions, including a ban on puberty blockers to protect young people from harm. A lack of evidence of safe use for this group was cited as the main reason for the restrictions along with the potential for later regret. For those that supported restrictions but not a ban, there was support for restrictions on who could prescribe, setting a minimum age for treatment, and requiring patients to be part of a clinical trial.

Is the preferred option in the Cabinet paper the same as preferred option in the RIS?

The Cabinet paper provides no preferred option. It presents four options:

- Option A Current baseline of close monitoring and adjustment
- Option B Baseline plus pre-planned trigger points for further action if required
- Option C Combined option that creates regulations to prohibit new prescribing and establishes alternative gender services
- Option D New specific legislation.

There is no option that we can definitively say advances our objectives. Having regard to this, the Ministry of Health considers Option One (Status Quo / Counterfactual: baseline of close Ministry monitoring and adjustment as needed) (Options A and B in the Cabinet paper) is the best fit overall.

Summary: Minister's preferred option in the Cabinet paper

Costs (Core information)

Outline the key monetised and non-monetised costs, where those costs fall (e.g. what people or organisations, or environments), and the nature of those impacts (e.g. direct or indirect)

The Minister of Health does not have a preferred option. Descriptive costings are therefore provided in this report, with some indications on how the seven options might differ from a cost perspective.

There are two main groups impacted by the review – patients, caregivers and whānau, and practitioners and service providers. For patients, caregivers and whānau, current monetised costs relate to initial visits to general practitioners, private funding where publicly funded services aren't available, transport to centres that provide healthcare services and the costs of puberty blockers where Pharmac does not fully fund them. Long-term costs for those who pursue gender identity change are likely lower where puberty blockers have previously been taken because surgical affirmation surgery is less extensive and carries fewer risks (eg, surgery may not be needed for secondary sex characteristics). For families, there are monetary costs with caring for young people with gender incongruence/dysphoria. Some families may also contribute funds to legal challenges to government policy. Non-monetised costs relate to personal distress and limited health-related quality of life.

More restrictive options could increase costs (eg, via increased need for health services due to increased distress), decrease costs (eg, via fewer young people seeking any treatment) or they may remain much the same.

Current costs for practitioner and service providers include compliance with requirements such as demonstrating experience, training, supervision, service configuration, audits or compliance checks and providing information to regulators or monitors. Service providers also encounter facility costs, but these are small, given facilities are used for multiple purposes and those affected are a very small group of people.

Option 2a would increase costs for service providers, particularly in relation to psychological and social care. This would involve a cost that is currently not budgeted for. Options 2b, 3a, 3b and 3c and Option Four, which are more restrictive than Option One (Status quo and the counterfactual) also require costs that are not currently budgeted for. More restrictions would mean fewer people would present to specialists with requests for puberty blockers, but many would likely require increased levels of healthcare services when compared to Option One. Option Four offers alternative gender services where medical and psycho-social support is provided.

Restrictive approaches where there are no supportive gender healthcare services (Option 2b and 2c), would also likely impact primary health providers, where they would have to manage non-available referral options.

Currently costs to the Ministry of Health relate to policy development work and monitoring. Responsible authorities such as the Medical Council of New Zealand also incur costs ensuring scopes of practice are appropriate and any complaints are investigated. Complaints

to the Health and Disability Commissioner and the Human Rights Commissioner are also important costs.

Developing and implementing regulations under Options Three and Four would require resource for the Ministry of Health. Option 3c would be particularly costly as a bill would need to be developed. There is no current budget for this work.

s 9(2)(h)

Benefits (Core information)

Outline the key monetised and non-monetised benefits, where those benefits fall (e.g. what people or organisations, or environments), and the nature of those impacts (e.g. direct or indirect)

Currently, under Option One, the main non-monetised benefit for patients and their families is improved patient wellbeing. For those who seek treatment but are not prescribed puberty blockers because it is not deemed necessary, there may be some protection from possible unknown treatment harm. Option 2a and 2b may increase these benefits by increasing guidance towards or accessibility of alternative health care and support. Options 3a, 3b and 3c are more restrictive and would provide fewer overall benefits, given the strong demand for puberty blockers from a very small group of people. The benefits for Option Four would be similar to, but greater than Options 3b because it offers alternative gender services for young people with gender incongruence/dysphoria in combination with a prohibition on new prescribing.

For clinicians, non-monetised benefits would be enabling them to make decisions based on their expertise and in consultation with each affected person and their parents, carers and whānau. Non-regulatory options support this more than regulatory options.

The main benefit for regulators and others such as Commissioners is reduction in complaints and investigations because of overall improved wellbeing for children and young people with gender incongruence/dysphoria.

When a child or young person experiencing gender incongruence/dysphoria is not under significant emotional, or psychological and social stress, the people around them – such as whānau (family), caregivers, and peers – are also less likely to experience stress or disruption in their own lives. This more stable and supportive environment is more likely to be achievable when the policies or support systems in place allow for health care options that accommodate the young person's identity and needs.

Balance of benefits and costs (Core information)

Does the RIS indicate that the benefits of the Minister's preferred option are likely to outweigh the costs?

The Ministry of Health concludes there is substantial uncertainty associated with the relative costs and benefits between options.

Despite this uncertainty, it is likely that regulatory options under Option Three and Four would be more costly than non-regulatory options, given the costs associated with

developing and implementing legislation, 9(2)(h)

Option Four would incur costs related to both the creation of regulations and the development of additional gender services. Option One is the least costly.

Implementation

How will the proposal be implemented, who will implement it, and what are the risks?

Given the Minister of Health has no preferred option, detail in relation to implementation would be developed once it becomes clearer on the option/s the Government prefers to consider further or makes a decision on.

Under Option 2a and the non-regulatory component of Option Four, Health New Zealand would lead, although other entities or authorities could also play leading roles. The Ministry of Health would lead under Option 2b, with several, if not all, health entities being involved. Advisory bodies and authorities would also play a role.

If the government decided on a regulatory option under the Medicines Act 1981 (Options 3a and 3b and Option Four), the Ministry of Health would develop and implement the legislation, including any enforcement action. A transition period would apply to allow time for the regulator to develop the necessary infrastructure and those impacted to understand and be able to comply with the regulation. No resource has been allocated to such activities in the Ministry's budget.

If a bill were developed (Option 3c), a longer period of development would be needed, given the need for parliamentary consideration and to develop secondary legislation. The bill would require prioritisation along with other drafting, legislation programme and House business. A transition period would apply.

The more significant the regulatory intervention, the greater the risk of unintended consequences (eg, setting a precedent for exceptions), 9(2)(h)

Limitations and Constraints on Analysis

There is a lack of evidence in New Zealand and internationally on the safety and benefits of using medicines that can block the onset of puberty for young people with gender incongruence/dysphoria. New Zealand and other countries have started active monitoring, and in some cases such as the UK are initiating research, to address the gaps.

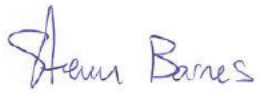
There are constraints on the range of options able to be considered. The emphasis from Government is to safeguard young people from potential harm related to the use of puberty blockers based on limited evidence of possible unknown harm. Many stakeholders supported options that increased access to puberty blockers for those wanting them and in consultation with clinicians and their caregivers.

Given the need to exercise care when consulting with young people and the timeframes available for consultation, the Ministry was unable to consult directly with young people with gender incongruence/dysphoria. There was some consultation with caregivers and whānau in the targeted consultation meetings, and representative groups, medical professionals and

Commissioners for health and disability, human rights, and children have, however, provided relevant input.

I have read the Regulatory Impact Statement and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the preferred option.

Responsible Manager signature:



Steve Barnes
Associate Deputy Director-General
Strategy Policy and Legislation
29 July 2025

Quality Assurance Statement

Reviewing Agency: Ministry of Health	**QA rating:** Meets

Panel Comment:

The Ministry of Health QA panel has reviewed the Impact Statement titled "*Puberty blockers for young people with gender incongruence and dysphoria",* produced by the Ministry of Health and dated July 2025.

The panel considers that the Impact Statement **Meets** the quality assurance criteria.

The Impact Statement is clear, concise, consulted, complete and convincing. The analysis is balanced in its presentation of the information. Impacts are identified and appropriately assessed.

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 production of the sex hormones testosterone, oestrogen, and progesterone.

2. In New Zealand, the GnRHa available are leuprorelin intramuscular injections or goserelin subcutaneous implants.[1] They have different indications but overall, these include prostate cancer, breast cancer, endometriosis, uterine fibroids, and precocious puberty (premature pubertal changes in girls under 8 years and boys under 9 years). They are available only on prescription and are funded by Pharmac.

3. Children with precocious puberty can be prescribed leuprorelin to delay further pubertal changes and allow them 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/dysphoria. 'Puberty blockers' is the term used when GnRHa are used to delay puberty. 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) and/or surgical affirmation, or they may decide to retain their birth sex.

What is gender incongruence, gender dysphoria and gender-affirming care?

5. Gender incongruence is where an individual's experienced gender and their assigned sex at birth persistently do not match.[2] Gender dysphoria is where an individual's gender incongruence has an adverse impact on their health and wellbeing.

6. Internationally, there has been a reported increase in the number of children and young people describing themselves as gender questioning or identifying as transgender.

7. In some people, this mismatch can cause severe discomfort, anxiety, depression, and other mental health conditions. Children and young people 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.[3]

8. People with gender incongruence/dysphoria experience much higher levels of psychological distress than the general population. In New Zealand, the Counting Ourselves 2022 Survey, which was completed by 2,631 trans and non-binary people aged

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

[2] https://www.who.int/standards/classifications/frequently-asked-questions/gender-incongruence-and-transgender-health-in-the-icd

[3] 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

between 14 – 86, reported that half of the participants had deliberately injured themselves in the past 12 months. Youth were more likely to have self-injured. Māori, youth and disabled participants were also more likely to have seriously considered suicide in the past 12 months out of the 53% of participants who reported experiencing suicidal thoughts.[4] The survey also found that 77% of participants had scores indicating high or very high psychological distress, which was over six times higher than the level across the general population (12%) in New Zealand. Youth were more likely to report high or very high psychological distress.[5]

9. Gender-affirming care refers to the provision of one or more psychological, behavioural or medical (including hormonal treatment or surgery) interventions designed to support and affirm an individual's gender identity.[6] 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 incongruence/dysphoria, and gender-affirming hormones like oestrogen and testosterone for older adolescents and adults. Medical affirmation is not recommended for prepubertal children. Some adults may undergo various aspects of surgical affirmation.

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

10. The figure below shows the number of young people (11 to 16 years old) who have started treatment with GnRHa each year since 2010. All prescribing of these medicines is captured, so their use to block puberty in gender incongruence/dysphoria will be lower than shown. (The medicines are also used in this age group for other reasons including treatment of endometriosis or uterine fibroids).

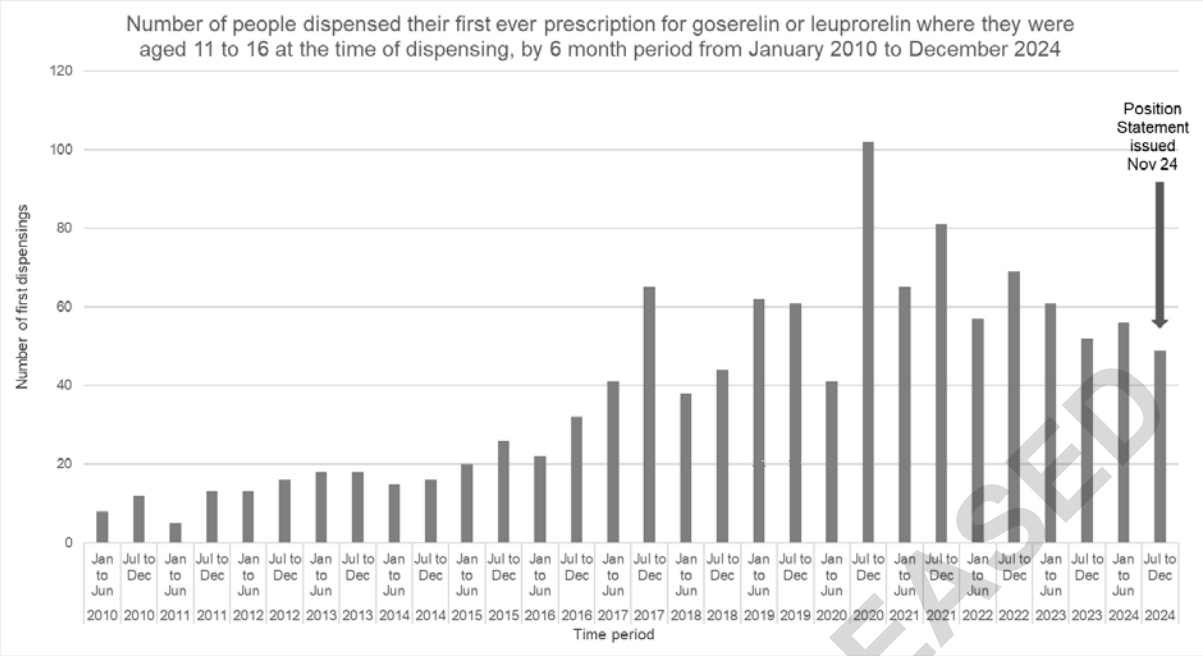
11. Overall, there was a significant increase in dispensing from late 2016 until the peak in the second half of 2020. Since then, there has been a continuing downward trend in initiation of GnRHa, with the number reducing by over 50%. It is noted that around 2020 there was also increasing concern about the use of GnRHa for endometriosis.

12. In 2024, 106 young people (11 to 16 years old) started GnRHa treatment in New Zealand. We can expect that the impacts of any policy changes will be to 100 or fewer young people each year.

[4] Yee, A., Bentham, R., Byrne, J., Veale, J., Ker, A., Norris, M., Tan, K., Jones, H., Polkinghorne, T., Gonzalez, S., Withey-Rila, C., Wi-Hongi, A., Brown-Acton, P., Parker, G., Clunie, M., Kerekere, E., Fenaughty, J., Treharne, G., & Carroll, R. (2025). *Counting Ourselves: Findings from the 2022 Aotearoa New Zealand Trans and Non-binary Health Survey*. Transgender Health Research Lab, University of Waikato, Hamilton, NZ.

[5] Counting Ourselves is a community-led anonymous health survey conducted as part of research out of the University of Waikato. The report provides nationwide insights on the health and wellbeing of trans and non-binary people living in New Zealand, however the survey is self-selected and the data would not meet the same standard as Tier 1 Statistics such as the Census.

[6] Gender incongruence and transgender health in the ICD



13. Information on how many children and young people might be in this wider group who could be indirectly impacted is very approximate. Internationally, approximately 1–2% of children and young people identify as transgender, non-binary or another gender different from the gender they were assigned at birth, and more are unsure of their gender.[7] In New Zealand, 1.2% of 15–19-year-olds recorded themselves as transgender, nonbinary or another gender in the Census 2023.

14. Information including younger age groups comes from the Youth2019 health and wellbeing survey which collected data from 7,891 secondary school pupils (aged approximately 12–18 years) in the Auckland, Waikato and Northland regions. Of the 7,668 who responded to the question regarding gender identity, 1% (n = 78) reported they were transgender and 0.6% (n = 48) said they were unsure.

What we know about young people who access gender-affirming care in New Zealand

15. A recent study of young people accessing Paediatric Hauora Tāhine (Transgender Health) services in the Te Tai Tokerau region of New Zealand from 1 January 2020 to 30 June 2023 found that out of the 45 young people who received care, 10 (22%) were Māori, 27 (60%) had coexisting mental health diagnoses, 14 (31%) had possible or confirmed autism spectrum disorder. The mean age of referral was 13 (8-15) years.[8]

16. Information received during the consultation indicates that those receiving treatment include the following groups for whom particular consideration is required:

    - young disabled people, including neurodiverse young people. The intersection of disabilities and gender identity can create unique challenges and needs for young people and may require specialised multidisciplinary care and support to

[7] Ministry of Health. (2024). *Impact of puberty blockers in gender-dysphoric adolescents: An evidence brief*. Ministry of Health. https://www.health.govt.nz/publications/impact-of-puberty-blockers-in-gender-dysphoric-adolescents-an-evidence-brief

[8] Catlow C, Goffin S, Cunningham V, Abraham A, Grant C. The Health Needs and Management of Young People Accessing Paediatric Hauora Tāhine (Transgender Health) Services in Te Tai Tokerau. J Paediatr Child Health. 2025 May 23. doi: 10.1111/jpc.70078. Epub ahead of print. PMID: 40405702.

navigate the healthcare system. Younger disabled people may experience unique forms of gender incongruence/dysphoria, which can be a significant source of mental distress and may be compounded by other mental health conditions. Adaptation of health services is required to ensure accessibility

- Māori, where transgender people have traditionally been an accepted part of societies (e.g., takatāpui in Māori). Census 2023 indicates that around 1% of Māori aged 15 years or older identify as transgender, whilst the rate in the total population of New Zealand is 0.7%. In the census, 0.6% of Māori identified as another gender. Whakapapa and kinship connections play an important role in shaping young people's sense of belonging and identity and whānau-centred services are important to achieving equitable health outcomes for Māori
- Pacific Peoples, where transgender people have traditionally been an accepted part of some societies (e.g., fa'afāfine and fa'atama in Samoa and akava'ine or laelae in Cook Islands). Census 2023 indicates around 0.8% of Pacific Peoples aged 15 and over identify as transgender in New Zealand, and 0.4% as another gender
- those living outside main centres where access to gender-affirming care is more difficult to obtain.

Current regulation for prescribing

17. Medicines in New Zealand are approved for particular indications, following application from the company who supplies evidence to support a favourable benefit risk profile and a quality product. Gender incongruence/dysphoria are not approved indications for GnRa, meaning the indications are unapproved and therefore use is colloquially described as 'off-label' for these purposes. This is permitted by section 25 of the Medicines Act 1981, which allows authorised prescribers[9] to supply any medicine to a patient under their care.

18. Off-label prescribing is common in clinical practice, particularly in paediatric services (generally due to practical difficulties in gathering scientific evidence to support approval for children). Other examples of medicines prescribed to young people under section 25 are fluoxetine for depression, and most oncology medicines. 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.

19. When authorised prescribers 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.

20. 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

[9] An 'authorised prescriber' is a nurse practitioner, optometrist, practitioner, registered mid-wife or a designated prescriber.

Services Consumer Rights. Prescribers are also regulated under the Health Practitioners Competence Assurance Act 2003.

21. Regulatory oversight of prescribing is provided by the Ministry of Health (medicine safety), the Medical Council of New Zealand (prescribing practice for doctors) and other relevant authorities under the Health Practitioners Competence Assurance Act 2003, and Pharmac (which in the Pharmaceutical Schedule defines what will be paid for by Pharmac – note Pharmac does not define what can be prescribed, only what will be paid for).

22. The Medical Council's standard of informed consent states that individuals under 16 are allowed to make their own decisions about their care. Whether they will be viewed as though they were an adult would depend on how mature they are to make their own decisions. Generally, if a child or adolescent is able to understand the treatment or procedure they are having and why, along with what would happen if they did not have that treatment or procedure, then they are able to decide for themselves.[10] The Ministry of Health's Position Statement, noted below, specifies that in cases where puberty blockers are prescribed, patients and their care givers must be fully informed regarding the current state of the evidence regarding their benefits and risks.

Guidelines for use of puberty blockers in gender-affirming care in New Zealand

23. In November 2024, the Ministry of Health issued a *Position Statement on the Use of Puberty Blockers in Gender-Affirming Care* following an evidence review on the effectiveness and safety of puberty blockers in young people with gender incongruence/dysphoria.[11] 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

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

24. The Position Statement includes detail on the complexity in providing healthcare for young people with gender incongruence/dysphoria, and the importance of fully informed consent of patients and their caregivers. It outlines further steps to ensure young people have access to comprehensive quality care, including:

    a. enhancing governance and monitoring of gender-affirming care

    b. continued monitoring of emerging evidence

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

25. Following release of the Position Statement, Health New Zealand is developing clinical guidance for practitioners to reflect the Ministry of Health's position on prescribing puberty blockers. In the meantime, a 2018 guideline by the Professional Association for Transgender Health Aotearoa is used, based on 2017 international clinical practice

[10] Medical Council of New Zealand (2021). Informed Consent: Helping patients make informed decisions about their care https://www.mcnz.org.nz/assets/standards/55f15c65af/Statement-on-informed-consent.pdf

[11] Position Statement on the Use of Puberty Blockers in Gender-Affirming Care | Ministry of Health NZ

guidelines for endocrine treatment of gender-dysphoric/gender-incongruent persons that were issued by the Endocrine Society.[12] These guidelines provide a framework for the appropriate treatment of these individuals, including evaluation criteria for gender-affirming medical treatment. They are consistent with the Position Statement but lack detail.

International approaches

26. Alongside the Ministry's review of evidence, similar reviews have been undertaken in other jurisdictions.

United Kingdom

27. In the United Kingdom (UK), a decision was made in December 2024 to prohibit the supply of puberty blockers for the treatment of gender incongruence/ dysphoria indefinitely in people aged under 18 years. The exceptions are prescribing under the supervision of a national multi-disciplinary team or a clinical trial.

28. The prohibition followed targeted consultation, advice on patient safety from the independent Commission on Human Medicines and a review in April 2024 on gender identity services and evidence in England (the Cass Review[13]). The Cass Review, which found there was insufficient evidence to demonstrate the safety of puberty blockers for this population, resulted in a temporary ban from May 2024 which was made permanent in January 2025. The indefinite prohibition will be reviewed in 2027.

29. Since November 2024, the NHS in England has set up additional gender care services for young people and announced funding for a clinical trial that may start by the end of 2025.

Scandinavia

30. Some Scandinavian countries have limited the initiation of new prescriptions of puberty blockers for young people seeking gender-affirming care. In Sweden, puberty blocking treatments can only be used in a clinical trial except in very exceptional circumstances; in Norway and Finland they may be used after non-medical options have been explored and deemed insufficient. Denmark has similarly made a shift with non-regulative supportive counselling preferred over puberty blockers, hormones, or surgery. These countries have all expressed concerns about the lack of high-quality evidence on outcomes in the use of puberty blockers for gender incongruence/dysphoria.

United States

31. In May 2025, 27 states in the United States had restrictions on gender-affirming care in transgender youth.[14]

Other comparable countries

32. Other countries, including Australia, Canada, and most European 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

[12] 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

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

[14] What Is Gender-Affirming Care, and Which States Have Restricted it? | Best States | U.S. News

by a multidisciplinary team first and foremost, with puberty blocking treatment remaining an option.

33. 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.

34. In January 2025, the Queensland state government issued a healthcare directive prohibiting any new prescribing of puberty blockers for gender incongruence/dysphoria in people under 18 years for 12 months, pending a services review. This was triggered by an investigation of clinical governance at a particular sexual health service.

35. The Canadian province of Alberta has passed (but not yet enacted) a Bill banning the use of puberty blockers for young people aged under 16 years, referencing the recent decision made by NHS England. An injunction application is being considered.

World Health Organization

36. The World Health Organization is currently developing a guideline on the health of trans and gender-diverse people.[15] This new guideline will provide evidence and implementation guidance on health sector interventions aimed at "increasing access and utilization of quality and respectful health services by trans and gender-diverse people". The guideline will focus in 5 areas: provision of gender-affirming care, including hormones; health workers education and training for the provision of gender-inclusive care; provision of health care for trans and gender-diverse people who suffered interpersonal violence based in their needs; health policies that support gender-inclusive care, and legal recognition of self-determined gender identity.

Assessment of the risk in New Zealand

37. The Ministry undertook an evidence brief to review the effectiveness and safety of puberty blockers in young people with gender incongruence/dysphoria.[16] 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 very limited evidence on longer-term effects on bone density or other health outcomes including mental health outcomes.

38. This is a vulnerable population group who face various risks, such as stigmatisation and poor mental health.

39. 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. This approach is consistent with the international approaches described above.

[15] WHO announces the development of a guideline on the health of trans and gender diverse people

[16] Impact of Puberty Blockers in Gender-Dysphoric Adolescents: An evidence brief | Ministry of Health NZ

Difficulties in acquiring evidence

40. The kind of robust evidence of long-term safety and efficacy that large-scale clinical trials aim to generate is unlikely to become available for puberty blockers in the medium term. It is neither feasible nor ethical to conduct this type of trial for this treatment, so evidence is largely limited to studies that observe young people receiving treatment. This limits their comparability and the reproducibility of the evidence they generate.

41. Large long-run observational studies (such as the UK clinical trial under development) offer an alternative. They require trust and confidence of patients and families, including an ability to protect patient information. This is more difficult to achieve where there is societal controversy around gender expression.

Assessment of the impact of restrictions on puberty blockers internationally

42. It is too early to evaluate the impacts from other jurisdictions where access to puberty blockers has been restricted. However, there is evidence of increased mental distress among gender incongruent young people in such jurisdictions.

43. A recent population study in the USA supports the connection between restrictions on gender-affirming care and increased suicides amongst transgender and gender-diverse young people.[17] It found that in states that introduced laws such as restrictions on puberty blockers and hormone therapy, suicide rates increased among transgender and non-binary young people in the first year of access restrictions, compared to states that did not introduce such laws. Another study found increases in self-reported anxiety and depression among people who identified as non-heterosexual and/or gender incongruent in states that had introduced laws restricting access to puberty blockers.[18] These studies were conducted in an American context and therefore are only partially relevant to the New Zealand context. They show association between outcomes and regulatory actions, rather than impacts of puberty blocker treatment. While these studies are not included in the Ministry's evidence review (which focused on the impacts of puberty blockers at an individual level rather than the impacts of regulatory changes), they nevertheless indicate that caution is warranted in considering any similar regulatory approaches.

Relevant International Conventions and Covenants

United Nations Convention on the Rights of the Child

44. Under the United Nations Convention on the Rights of the Child (UNCRC), all children have a right to their 'highest attainable standard of health' and to facilities for the rehabilitation of health (Article 24).[19] The aim is to strive towards no child being deprived of their right of access to health care services. UNCRC was ratified by New Zealand in 1993.

45. UNCRC also provides that the best interests of the child shall be a primary consideration in all decisions (Article 3):

---

[17] Lee, W.Y., Hobbs, J.N., Hobaica, S. *et al*. (2024). State-level anti-transgender laws increase past-year suicide attempts among transgender and non-binary young people in the USA. *Nat Hum Behav,* 8, 2096–2106. https://doi.org/10.1038/s41562-024-01979-5

[18] Last, B.S., Tran, N.K., Lubensky, M.E., Obedin-Maliver, J., Lunn, M.R. and Flentje, A., 2025. US State Policies and Mental Health Symptoms Among Sexual and Gender Minority Adults. JAMA Network Open, 8(5), pp.e2512189-e2512189.

[19] United Nations. Convention on the Rights of the Child | OHCHR

> The concept of the child's best interests is complex and its content must be determined on a case-by-case basis . . . Accordingly, the concept of a child's best interests is flexible and adaptable. It should be adjusted and defined on an individual basis, according to the specific situation of the child or children concerned, taking into account their personal context, situation and needs. For collective decisions – such as by the legislator –, the best interests of children in general must be assessed and determined in light of the circumstances of the particular group and/or children in general. In both cases, assessment and determination should be carried out with full respect for the rights contained in the Convention and its Optional Protocols.[20]

46. Another principle is the right of the child (who is capable of forming his or her own views) to be heard in any proceedings that affect them (Article 12 of the Convention), including those who are very young, have a disability, or belong to a minority group[21], even if the child's views may not always be completely followed:

> Any decision that does not take into account the child's views or does not give their views due weight according to their age and maturity, does not respect the possibility for the child or children to influence the determination of their best interests.[22]

47. Articles 7 and 8 (child's right to protect and preserve their identity), 13 and 14 (freedom of expression, thought and belief – including the right to seek and receive information of all kinds) and 17 (right to be informed and have access to information relevant to you) are also all relevant for children and young people with gender incongruence/dysphoria.

48. The policy proposal engages the rights and freedoms guaranteed under UNCRC due to the potential for policy options to affect access to puberty blockers for young people with gender incongruence/dysphoria in a way which impacts their wellbeing. The Human Rights Commission and the Children and Young People's Commission have raised concerns that additional regulations may impact on these young people's rights including the right to health, the best interests of the child, freedom from discrimination and freedom of expression under more restrictive measures. This highlights the need to carefully weigh the limitations in evidence with the potential wellbeing outcomes of policy options to ensure the protection of young people's rights. The Child Impact Assessment (Appendix One) expands on the rights implications of various policy settings.

International Covenants

49. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which New Zealand ratified, also recognises the right to the highest attainable standard of health, encompassing both physical and mental wellbeing.

50. Principles of non-discrimination and equality are also referred to in the International Covenant on Civil and Political Rights (ICCPR) which was ratified by New Zealand in 1978.

---

[20] United Nations Convention on the Rights of the Child: Committee on the Rights of the Children. 'General comment No. 14 (2013) on the right of the child to have his or her best interests taken as a primary consideration (art. 3, para. 1)*': para 32. General comment no. 14 (2013) on the right of the child to have his or her best interests taken as primary consideration (art. 3, para. 1)

[21] Ibid., para 54

[22] Ibid., para 53.

Domestic Human Rights Legislation

New Zealand's Human Rights Act 1993

51. Prohibited grounds of discrimination under the Human Rights Act include, but are not limited to, sex, age (once a person is 16 years of age), disability and ethnic or national origins (section 21). The Human Rights Commission interprets section 21(1)(a) on sex to include gender identity.[23] In 2006, the acting Solicitor General reached the same view in a publicly-available legal opinion.

52. The Human Rights Commission has noted that restricting access to puberty blockers could constitute differential treatment of transgender and cisgender young people. 9(2)(h)

New Zealand Bill of Rights Act 1993

53. Section 19 of the New Zealand Bill of Rights Act (BORA) affirms the right to freedom from discrimination on the grounds of discrimination in the Human Rights Act. 9(2)(h)

Te Tiriti o Waitangi

54. The principles of Te Tiriti o Waitangi guarantee the protection and promotion of Māori self-determination or tino rangatiratanga, and require the Crown to commit to achieving equitable health outcomes for Māori.

How will the status quo evolve in New Zealand?

55. Status quo is expected to change with time as the Position Statement continues to be implemented. By the end of February 2025, there were indications that prescribers are showing greater caution in line with the expectations of the Position Statement. The Ministry of Health has ascertained that some paediatric endocrinologists have informed patients they can no longer prescribe puberty blockers as they are not confident that young people have sufficient access to psycho-social services, or because they themselves are not working directly in an interdisciplinary team. This has occurred in at least three centres: Wellington, Christchurch, and Dunedin.

[23] Te Kāhui Tika Tangata | Human Rights Commission (2020). PRISM-Human-Rights-issues-relating-to-Sexual-Orientation-Gender-Identity-and-Expression-and-Sex-Characteristics-SOGIESC-in-Aotearoa-New-Zealand-A-report-with-recommendations-PDF.pdf

56. Continued changes will result from:

    a. working with Health New Zealand to enhance governance and monitoring of gender-affirming care. Health New Zealand is currently working to implement clinical guidance based on the Position Statement

    b. continuing to monitor emerging evidence and review the international context in relation to the use of puberty blockers

    c. commissioning New Zealand-based research on the impacts of puberty blockers in young people with gender incongruence/dysphoria

    d. considering system-wide issues to gender-affirming care, with advice from the Gender Identity Services External Advisory Group.

What is the policy problem or opportunity?

57. The policy problem is concern that puberty blockers should only be prescribed for young people with gender incongruence/dysphoria for whom the benefits of these medicines outweigh the potential risks.

58. Over the last two decades, there has been an increase in use of puberty blockers for gender incongruence/dysphoria in children and young people in New Zealand and internationally. The evidential basis for this indication, is however, unclear, meaning there is a risk of unintended harm that might outweigh the benefits of the treatment.

59. In November 2024, Cabinet agreed to consider regulation to restrict prescribing of puberty blockers for young people under 18 years with gender related health needs.

60. This policy problem does not appear to involve a market failure.

61. The policy is in the context of puberty blocker medicines being available (and funded by Pharmac) for use in children. They are approved for treatment of precocious puberty and additionally used ‘off-label’ for several uncommon conditions; many medicines are prescribed off-label in children.

62. Prescribing of puberty blockers has been reducing in New Zealand since it peaked in 2020, with an estimated 100 or fewer young people started on the treatment last year.

63. The majority of stakeholders support access to puberty blockers through clinical consideration of the risks and benefits for each affected individual, and following consultation with the individual and their caregivers.

64. Non-regulatory options have been explored, with recent changes occurring in November 2024 when a Ministry of Health Position Statement was released. The Statement provides a nationally consistent approach to prescribing, with expectations of clinicians to exercise caution in prescribing, and to be experienced in gender-affirming care and part of an interprofessional team offering a full range of supports. The Position Statement also includes the importance of fully informed consent of patients and their caregivers. It outlines further steps to ensure young people have access to comprehensive quality care, including continued active monitoring and New Zealand research on long-term clinical and mental health and wellbeing impacts.

What objectives are sought in relation to the policy problem?

65. The objectives are to help ensure any use of puberty blockers, when considered in gender-affirming care in New Zealand, leads to

    - positive health and wellbeing outcomes that are safe for young people with gender incongruence/dysphoria over the long term
    - health equity for young people presenting with gender incongruence/dysphoria

What consultation has been undertaken?

66. The Ministry ran a consultation from 21 November 2024 to 20 January 2025 on whether further safety measures are needed for the use of puberty blockers in young people with gender incongruence/dysphoria.[24]

67. The consultation involved a series of targeted meetings with groups representing those likely to be substantially affected by any further safety measures. These groups included the rainbow and transgender community and support sector, medical practitioners and other professional groups, health regulators, and Commissioners for health and disability, human rights, and children.

68. The Ministry also provided an opportunity for public submissions which resulted in over 8,500 submissions being analysed. Submissions were received both from people likely to be directly affected by restrictions and from members of the public more broadly.

69. Cabinet asked the Ministry to seek feedback on the necessity and impact of proposed regulation, how such regulation might be framed for clarity and effectiveness, which groups of young people should be able to access puberty blockers, and any potential implementation issues.

70. All groups that participated in the targeted meetings and most public responses supported continued access to puberty blockers for gender incongruence/dysphoria. Key points expressed included that:

    a. current safeguards such as psychological assessments and informed consent are sufficient safety measures
    b. restrictions on access, such as who could prescribe, age requirements or participation in clinical trials would be impracticable or unethical
    c. many medicines are prescribed off-label before risks are fully identified and evidential uncertainty can be managed within clinical practice
    d. restrictions will cause adverse mental health impacts for these young people, wider harm to the transgender community and human rights implications.

71. A minority of public submissions supported further restrictions, including a ban on puberty blockers to protect young people from harm. This group cited a lack of evidence for safe use as their main concern. For those that supported restrictions but not a total

[24] Ministry of Health (2025). Safety measures for the use of puberty blockers in young people with gender-related health needs: Consultation summary.

ban, there was support for restrictions on who could prescribe, setting a minimum age for treatment, and requiring patients to be part of a clinical trial.

72. Groups representative of rainbow and transgender communities expressed strong concerns about the public consultation, including that raising this issue as a public debate politicises a medical issue and implicitly legitimises anti-transgender views.

73. The Ministry was unable to directly consult with young people outside of the public submissions processes as the available timeframes were insufficient to design and deliver consultation sessions that would be appropriate for this population. Māori and Pacific Peoples were also not consulted directly beyond the public submissions. Further consultation with these groups would be beneficial for improving the implementation of whichever option is progressed.

Section 2: Assessing options to address the policy problem

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

74. The criteria chosen to assess how the options reflect the objectives are:

    a. **Effective**: the extent to which the option promotes the health and wellbeing of young people with gender incongruence/dysphoria through analysis of the risks and benefits for prescribing puberty blockers

    b. **Efficient**: the extent to which the objective is achieved without unnecessary time and resource costs for the Crown, and is adaptive to emerging evidence

    c. **Responsive**: the extent to which the option supports decisions in the best interests of each child or young person

    d. **Health equity**: the extent to which young people with disabilities, Māori, Pacific Peoples and people living in rural areas receive the same access to treatment for gender incongruence/dysphoria as those with the same presentations

    e. **Trust and confidence**: the extent to which New Zealanders trust and are confident in the health system to look after their health needs and health needs among their families, whānau and communities, now and in the future.

75. Greater weighting should be placed where options are effective and responsive, and there are improvements in health equity as these criteria best meet the objectives.

What scope will options be considered within?

76. The scope of options covers non-regulatory and regulatory approaches. They range from prescribing puberty blockers to young people with gender incongruence/ dysphoria in accordance with a clinical and monitoring framework to legislation that prohibits new prescribing of puberty blockers.

77. The scope does not include increasing access to puberty blockers amongst gender incongruent/gender dysphoric young people. The paucity of research and therefore lack of safety evidence suggests a more cautionary approach is required.

78. The options have been developed following public consultation.

79. Options presented broadly align with international responses to safeguarding the prescribing of puberty blocking medicines, noting that there is international variation.

What options are being considered?

An option considered but not proceeded with

80. The Ministry of Health considered a lower intervention option for puberty blockers (eg, the option could revert back to an earlier status quo with no Position Statement and no active monitoring). This option, which could lead to greater prescribing, was not considered appropriate, given the importance of a nationally consistent approach, multi-disciplinary teams, informed consent and monitoring.

81. The following options are considered:

    - Option One – Status quo/counterfactual: baseline of close Ministry monitoring and adjustment as needed (Options A and Option B in the related Cabinet paper as explained below)
    - Option Two – non-regulatory options that provide further quality checks on prescribing:
        - Option 2a – Enhanced health services and service controls
        - Option 2b – System action on prescriber controls and supports
    - Option Three – Regulatory options to clarify and/or restrict prescribing of puberty blockers
        - Option 3a – Regulations to strengthen prescribing requirements otherwise specified
        - Option 3b – Regulations to set and enforce new prescribing restrictions
        - Option 3c – New specific legislation (Option D in the related Cabinet paper)
    - Option 4 – Regulations to prohibit new prescribing while making youth gender services more accessible (Option C in the related Cabinet paper)

Option One – Status quo/counterfactual: baseline of close Ministry monitoring and adjustment as needed

How it would work

82. Option one (Options A and Option B in the related Cabinet paper) 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. Likewise, certain features of the baseline could be removed if evidence emerged to more clearly indicate puberty blockers were beneficial and safe.

83. Under the status quo (option A in the Cabinet paper), decisions about prescribing puberty blocking medicines would continue to sit with prescribers. Specific expectations for initiating prescribing would continue to be based on the Ministry of Health's Position Statement and clinical guidance by Health New Zealand. This nationally consistent approach would continue to provide a firm basis for regulatory oversight of prescribers by the Medical Council of New Zealand or investigation by the Health and Disability Commissioner.

84. Prescribers are currently authorised to make prescribing decisions based on established professional practice and their clinical judgement. This includes working as part of an interprofessional team offering a full range of supports to young people presenting with gender related issues. Clinicians must:

    a. assess patient needs

    b. apply any relevant clinical guidelines and adhere to professional practice, which continues to develop in this area of medicine

c. assess the risks and benefits of any medicines for the patient to determine the appropriateness use of puberty blockers

d. advise the patient of the lack of research on the safety of the medicines for young people with gender incongruence/ dysphoria

e. consider any ethical and legal considerations, including obtaining informed consent.

85. As part of option one, the Ministry of Health will continue to progress its active monitoring programme and examine what research could effectively be undertaken in New Zealand. This involves:

a. active monitoring of prescribing, service provision more widely and new information and evidence, and regular review

b. regular reporting every six months of monitoring results and actions

c. observational research development to contribute learning about patient experiences and outcomes in this New Zealand population group. This work is not a clinical trial but may still produce information that adds to understanding of benefits and risks.

86. The counterfactual also includes potentially developing trigger points for further action to ensure a rapid response can be implemented where needed (Option B in the Cabinet paper). For example, if a service was not delivering according to the expectations set out in the Position Statement, or new evidence arose internationally, the pathway to manage the issue would be pre-determined. Pre-planning in this way would include signalling when a move to add another option was warranted.

87. Option One is more cautious than, but otherwise similar to, Australia (with the exception of Queensland which has temporarily halted prescribing while it investigates service issues within the State), Canada (except the province of Alberta) and Japan.

Assessing Option One against the criteria

88. Option One is effective and responsive as it enables clinicians to assess the risks and benefits for each person to promote their health and wellbeing, using their expertise and in consultation with that person, their caregiver/s and whānau. The Ministry of Health's Position Statement sets a national approach and safeguards access to protect against potential treatment harm. It also ensures a small group receives treatment where benefits have been reported, even though the evidence of mental health benefit is not strong. The anticipated clinical guidance from Health New Zealand is expected to help implement the Position Statement and support positive health outcomes.

89. Enforcement of good clinical practice by the Medical Council investigating and prosecuting complaints helps protect health and wellbeing. Additionally, active monitoring enables the Ministry to identity signals of possible problems at an early stage and make adjustments. If pre-planned trigger points are identified in the counterfactual, the adjustments would be implemented more quickly than if no pre-planning were undertaken.

90. Prescribing under Option One is more cautious than it was prior to November 2024. It has not been accompanied by improved service access so there is a risk it may be leading to

negative patient outcomes in instances where puberty blockers are not provided and there is a consequent decrease in health and wellbeing through a decline in mental health.

91. This option has mixed efficiencies. s 9(2)(h)

Complaints are currently being considered by the Health and Disability Commissioner and the Human Rights Commissioner on related issues.

92. There are, however, efficiencies as non-regulatory settings can be easily adjusted in response to new information from active monitoring (both from within New Zealand and internationally), or regulatory options can be added. This is dependent on monitoring and research resources being available so any constraints will limit the long-term effectiveness.

93. There are likely health inequities under Option One despite the Position Statement. The following groups are identified as most negatively impacted, given they may face barriers to healthcare and poorer health outcomes in general:

- Younger disabled people, particularly those who are neurodiverse
- Māori and Pacific People where transgender people have traditionally been an accepted part of some societies
- Those living outside main centres where access to gender services is more difficult to obtain.

94. The Child Impact Assessment (Appendix One) appended provides further detail on why and how these groups are likely impacted.

95. In terms of trust and confidence in the health system, Option One largely retains trust and confidence as it continues the main health system settings with guidance by the Ministry of Health and clinical decision-making remaining with clinicians in discussion with patients and families. Those who cannot access puberty blocker medicines may have less trust and confidence in the system than formerly.

Option Two – non-regulatory options that provide further quality checks on prescribing

96. Option Two aims to improve prescribing of puberty blockers by increasing quality checks on clinical practice. It includes the following non-regulatory options:

Option 2a – Enhanced health services and service controls

Option 2b – System action on prescriber controls and supports.

Option 2a - Enhanced health services and service controls

How it would work

97. Considered access to puberty blockers would continue under Option 2a. This option involves Health New Zealand (or other suitable entities or authorities) taking a strong lead in ensuring services for young people with gender incongruence/dysphoria align with the Position Statement.

98. The services, which may include regional hubs, would be based on a care model, bringing together all the services needed, including strong specialist clinical governance and psycho-social services. A series of steps would need to be met prior to prescribing puberty blockers. This could include improved clinical decision-making and transparency through closer oversight or feedback to clinicians. Examples include second opinion requirements, peer review meetings or case discussion requirements. With such considered care, a small number of young people may meet the requirements for being prescribed puberty blockers.

99. The intended health services would be analogous to the KidsFirst model in South Auckland.

100. This option is most similar to 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 also similar in part to the UK where the National Health Service is setting up new and enhanced gender identity services. At present there is no initiation of puberty blocker treatment, however this is likely to change within these new services once a clinical trial is underway and providing clinical outcome information.

Assessing Option 2a against the criteria

101. Option 2a differs to Option One because it is a specific structured service delivery model. In contrast, Option One provides more freedom for clinicians to decide on the structure and operation of multidisciplinary teams (eg, a network of general practitioners rather than specialists could work together with a psycho-social service).

102. Considered puberty blocker prescribing and further clinical consistency across New Zealand would be both effective and responsive as the approach favours working in the best interest of the child.

103. Services that restrict access significantly further through clinical service controls could, however, prove less effective if they resulted in increased distress and mental health needs amongst those affected. This is not, however, intended.

104. Option 2a is less efficient compared to Option One due to resource implications. It would be critical that wait-times to access the services are reasonably short, given the limited time available for someone with gender incongruence/dysphoria to use puberty blockers. While in theory a private service could be set up, a number of disincentives currently operate. For instance, private social and psychological services face fewer barriers but cost limits access.

105. Enhanced services and service controls would improve health equity for children and young people with gender incongruence/dysphoria, although it is unlikely they would be uniformly available across all regions of New Zealand.

106. Trust and confidence would, at a minimum, be retained although it would likely improve through the service meeting the needs of more young people, as long as this adds to total service availability. Addressing cultural and other issues would be important in delivering accessibility of services for some parts of the community.

Option 2b – System action on prescriber controls and supports

How it would work

107. This option involves health entities and authorities, together or separately, implementing mechanisms that improve prescribing. Most of this work would have resource implications (such as time to develop and agree proposals or enhance IT systems).

108. 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 New Zealand and patient management systems used in primary care (for example, clinicians could report their prescribing to their service provider, who could then provide it to the Ministry of Health for monitoring purposes)

    c. developing tools and guidance to support, for example, assessment processes, clinical decisions, patient and family discussions or social and psychological treatment delivery (eg, a GP in a remote area would be able to easily find referral services and support when presented with a case)

    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 young people. This includes providing examples and case studies on informed consent, given the complexities that arise when parents have differing views to those wanting treatment.

109. Option 2b can add clarity and legitimacy to other options. This option is most like Denmark where firmer consent requirements are in place.

Assessing Option 2b against the criteria

110. Option 2b would promote better prescribing decisions, and therefore help improve health and wellbeing, although there is some risk of adverse health outcomes for some individuals if prescribing were too restricted and mental health deteriorated. It would likely be effective but not as responsive as status quo.

111. Option 2b is efficient in providing clarity and promoting joint governance across entities. Monitoring information from all entities would also be very useful in making further improvements. However, likely resource constraints may limit the speed of progress, and joint governance can result in longer timeframes to agree on priorities, approaches or final decisions. If key entities, advisory bodies or authorities do not endorse the results, efficiencies will be lost. 9(2)(h)

112. The clarity provided by a health system joint work programme would provide greater health equity compared to Option One for children and young people with gender incongruence/dysphoria.

113. This option would increase trust and confidence in the health system, provided joint governance across entities worked smoothly together. Any further restrictions on

accessing puberty blockers compared to Option One would, however, likely decrease trust and confidence, especially among health system workforce.

Option Three – Regulatory options to clarify and/or restrict prescribing of puberty blockers

114. Option Three aims to clarify and/or restrict prescribing of puberty blockers via the following regulatory options:

    Option 3a – Regulations to strengthen prescribing requirements otherwise specified

    Option 3b – Regulations to set and enforce new prescribing restrictions

    Option 3c – New specific legislation

Option 3a – Regulations to strengthen prescribing requirements otherwise specified

How it would work

115. 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/ 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.

116. The regulations would reinforce requirements otherwise in effect (such as those in Options 2a and/or 2b) to make them more visible and weightier for prescribers, with specific offences and penalties.

117. Option 3a can work with Options One, 2a and 2b. This option is most like Norway, Sweden and Finland, though they have achieved a high bar for prescribing without using regulations.

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

Assessing Option 3a against the criteria

119. Option 3a would formalise the rules for prescribers to reinforce the Position Statement and/or set new expectations. Requiring the provision of information would support the Ministry's monitoring of prescribing with more detailed information, thereby helping to improve health outcomes. However, prescribers generally comply with Position Statements so there would likely be little or no improvement in health outcomes from this

perspective. There is also a medium risk of adverse health impacts due to increased distress from legislation that could limit who can prescribe puberty blockers. The ability to respond to each individual could be reduced by the smaller pool of prescribers compared to non-regulatory options.

120. 9(2)(h)

121. It would require considerable resource to develop the regulations and a new resource to enforce it, which are currently not accounted for in the health budget. Delays in new qualifications, supervision and reporting could lead to high initial restriction and lead to ineffectiveness and inefficiencies. Furthermore, it would be inflexible when new information resulted in the need for change as amendments to the regulations would be needed.

122. No improvements to health equity are envisaged as the regulations would not specifically address inequities.

123. Option 3a risks lowering trust and confidence in the health system by signalling interference with the usual settings for clinical decision-making. However, the extent to which trust and confidence are lowered may be minor if the regulations are seen as fitting in with usual decision-making processes.

Option 3b – Regulations to set and enforce new prescribing restrictions

How it would work

124. 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/dysphoria in 11-16 year olds. This option is much more restrictive than option 3a as 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).

125. This would be the first time such regulations were made for any specific medicines in New Zealand. 9(2)(h)

126. This option can work with Option One and could work with Option 2a (if service controls are specified as the conditions). This option is most like the UK provided service enhancements are also made via Option 2a.

127. The restrictions would remain in effect until the regulations were revoked or disallowed by Parliament or changed by Order in Council.

Assessing Option 3b against the criteria

128. Option 3b would protect young people from the potential for harm from puberty blockers because their access would be significantly curtailed. However, with little, if any, access

to puberty blockers there would likely be a negative impact on mental health from not having access to a medicine that a prescriber and individual think would be beneficial. There is also a very small possibility that individuals could purchase puberty blockers online where the reliability of the products is uncertain and can result in harm, as reported in the UK.[25] Overall, this option would be less effective than status quo and not responsive.

129. Like Option 3a, this option would be less efficient than Option One due to:

    a. the time and resource needed to develop and enforce regulations

9(2)(h)

The penalties that are possible under the Medicines Act 1981 would likely be seen as less significant than the existing safeguards. For example, the maximum penalty available under the Medicines Act is a prison term not exceeding three months (which is unlikely to be levied in this case) or a fine not exceeding $500, whereas existing penalties through the Medical Council can include the permanent revocation of the right to practice medicine.

130. 9(2)(h)

131. There would likely be no improvements in health equity overall, given the regulations would not specifically address inequities. Seeking health services would continue to be an issue for the group, particularly for young people with disabilities, Māori, Pacific Peoples and those living in rural communities.

132. Perceptions of Government interference with clinical decision-making would likely reduce trust and confidence in the health system. s 9(2)(h)

Option 3c – New specific legislation

How it would work

133. Under Option 3c (Option D in the related Cabinet paper), a Bill specifically designed to limit prescribing of puberty blockers could be designed, drafted and introduced. It could amend the Medicines Act as required, and include specifications not provided for currently. New provisions could, for example, stipulate:

[25] Concerns as cross-sex hormones available online for just £11 a month | Transgender | The Guardian

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).

134. The usual caveats around timeframes and priority (for design, drafting, consultation and consideration) would apply.

135. This option could work with Options One and 2a (if legislation set requirements that could be met through changes to service provisions).

136. This option is most like certain US States and the new law proposed for enactment in the province of Alberta in Canada.

Assessing Option 3c against the criteria

137. A bill that prohibits or significantly restricts access to puberty blockers has a high risk of adverse health outcomes for young people with gender incongruence/dysphoria due to negative impacts on mental health. s 9(2)(h)

    There is also the very small possibility of individuals using the hidden economy to access puberty blockers as discussed under option 3b.

138. Option 3c is also less efficient than Option One and any of the other regulatory options due to the significant resource needed to develop and enact a bill and secondary legislation and the new resource to implement it. This is the most inflexible option, given any required changes due to new information would require another bill to be developed.

139. 9(2)(h)

140. As with Option 3b, there would likely be no improvements in health equity, given the bill and secondary legislation would not specifically address inequities.

141. Trust and confidence in the health system would likely fall.

Option 4 - Regulations to prohibit new prescribing while making youth gender services more accessible

How it would work

142. Option 4 combines both non-regulatory and regulatory approaches. It is the only combination option considered because it aligns with an option (Option C) in the related Cabinet paper.

143. For the regulatory component, regulations under section 105(1)(d) of the Medicines Act would be put in place to provide for an immediate prohibition on new prescribing of puberty blockers for young people presenting with gender incongruence/dysphoria.

144. The non-regulatory component would provide alternative services. A structured service delivery model would incorporate medical, psychological and social support for youth gender services.

145. The Ministry of Health would continue to monitor in the way described under Option One. This would include keeping abreast of any new international evidence and service models, particularly when planned clinical trials in the United Kingdom start reporting and are completed. Reporting to the Minister of Health on any changes in evidence could initiate a change in policy, including revoking the regulation.

146. Option 4 is similar to the effect of the UK's current prescribing controls. However, once their clinical trials are running, this option will be more restrictive as it will not provide any access to puberty blockers through a trial. Like the UK, emerging evidence on safety (for example, from clinical trials) could lead to future changes to regulatory settings.

Assessing Option Four against the criteria

147. Option Four, like the other regulatory options, offers less benefit under each criterion when compared to Option One. While it puts safety and caution first, based on a lack of evidence of safety or benefit, the approach is unlikely to be as effective as status quo because it removes the practitioner's ability to consider and respond in the best interests of the individual. This could be alleviated to some degree through patients attending the alternative services but may not resolve the medical issue that young people with gender incongruence/dysphoria are presenting for. Like Option 3b and 3c, people that desperately want to delay puberty while they consider their identity may try to purchase products online where there are safety issues with the quality.

148. A change to the prohibition on prescribing under Option Four may occur with the emergence of high-quality evidence (for example, from clinical trials) that demonstrates the benefits and an acceptable level of risk. While the UK is developing a clinical trial the results are not expected to be available for a number of years and any results would need to be considered in a New Zealand context.

149. There are efficiency issues due to having to develop and enforce new regulations 9(2)(h)

150. 9(2)(h)

151. The option would be less responsive to the interests of each person as there would be no access to puberty blockers where clinically indicated.

152. Health equity issues would not improve, nor would trust and confidence in the health sector, given regulation of a particular medicine for a particular health problem would be regulated for the first time. Access to the alternative health services could help provide some trust and confidence because individuals would be cared for by specialists. However, without the availability of puberty blockers, this effect would likely be minor. The need to develop additional gender services may result in the reallocation of resources from other higher-priority areas of health.

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

Non-regulatory options

	Option One – Status Quo / Counterfactual: baseline of close Ministry monitoring and adjustment as needed	Option Two – Non-regulatory options that provide further quality checks on prescribing	
		Option 2a – Enhanced health services and service controls	Option 2b - System action on prescriber controls and supports
Effective	0 Protects from possible treatment harm while enabling clinicians to prescribe to improve health, after considering the risks and benefits for the patient, and consultation with those affected. Active monitoring, including developing trigger points for actions, would enable adjustments to be made in a timely manner where necessary. There are health risks for those not able to access puberty blockers (which has reported benefits for mental health even though the evidence of benefit is not strong).	+ A care model with service specifications would improve outcomes. Greater clinical consistency across New Zealand could also improve access if it attracts more clinicians into work in this service area. However, if service enhancements include mandated peer review/second opinions, this could introduce more barriers to access and delays, causing distress and mental health impacts for some patients.	0 Strengthened and more consistent prescribing decisions would be as effective as the status quo, given there is no good evidence for or against effectiveness of puberty blockers. Access may improve if clarity increases for clinicians, or may decrease if the requirements are seen as placing additional clinical burden and fewer clinicians are attracted into this work.
Efficient	0 Some inefficiencies 9(2)(h) Complaints are currently being considered by the Health and Disability Commissioner and the Human Rights Commissioner on related issues. A non-regulatory approach is efficient as adjustments can be made to prescribing settings as needed (such as in response to new information).	- - s 9(2)(h) More resource would require costs not currently budgeted for. This could be offset if the increased services (eg, psychological and social support) resulted in less demand overall in the long term.	- s 9(2)(h) There are resource implications (time and costs) that are not currently budgeted for.

Responsive	0 Generally able to respond with decisions that are in the best interest of the individual, noting a more cautious approach to the use of puberty blockers has been adopted since introduction of the Position Statement	+ Wrap-around services that included psycho-social healthcare would improve responsiveness. Enhanced services with peer review would also improve decisions that were in the best interest of the affected individual.	- A health system joint work programme could improve decision making for each individual. However, it is likely that a uniform high bar to accessing puberty blockers would limit the ability to act as responsively for each child or young person.
Health equity	0 A nationally consistent approach through the Position Statements provides clarity and assists with health equity. However, there are likely more negative impacts with accessing healthcare services for: • neurodiverse young people • Māori and Pacific People where transgender people have traditionally been an accepted part of some societies • those living outside main centres where access to gender affirming care is more difficult to obtain. • In many cases, the above groups won't access services because they do not feel valued by the system and/or do not feel there is a cultural fit for them.	0 A care model with greater psycho-social support could improve health equity for trans and gender diverse young people, especially if services are provided consistently across regions and in accessible, culturally safe and responsive formats. (Improvements could mostly occur in main urban centres unless otherwise provided for.) However, additional resource invested in this area could amplify health inequities for the broader population of young people if it pulls resource away from other important service areas like youth mental health.	+ A health system joint work programme would provide greater clarity and uniformity across New Zealand. This could improve health equity for those children and young people with gender incongruence/dysphoria in alignment with, and without drawing resources away from, other important service areas for addressing health inequities.
Trust & confidence	0 Those wanting and treated with puberty blockers are likely to trust and have confidence in the health system. Those who cannot access the medicines will likely have less trust and confidence in the system.	0 Services with a holistic care model and consistency across New Zealand would likely increase trust and confidence. However, if these services are seen as attracting resource at the expense of other deserving areas of health, trust and confidence in the system could fall.	0 A health system joint work programme could increase trust and confidence but could also have the opposite effect if it further restricted access to puberty blockers.

Overall assessment	**0**	**0**	-

Regulatory options. The following regulatory options are compared to Option One (status quo / counterfactual), as described in the above table.

	Option Three – Regulatory options			**Option 4 - Regulations to prohibit new prescribing while making youth gender services more accessible**
	Option 3a – Regulations to strengthen prescribing requirements otherwise specified	**Option 3b – Regulations to set and enforce new prescribing restrictions**	**Option 3c – New specific legislation**	
Effective	- Formalising the rules for prescribers and reinforcing current health settings that enable careful access to puberty blockers where needed protect against potential harm. However, prescribers have good compliance with Position Statements so there would likely be little or no improvements from this perspective. Those with gender incongruence/dysphoria would likely be more distressed due to limitations on who can prescribe, leading to poorer mental health.	- - Rules for prescribers and who could receive treatment would provide little, if any, access to puberty blockers, which while aiming to protect against potential harm, would not provide the benefits prescribers would want to provide. It would cause significant distress to those with gender incongruence/dysphoria and likely reduce help-seeking. It could also result in some turning to the hidden economy to access hormones illegally.[26] This option has a high risk of adverse health outcomes.	- - Setting out prescribing requirements in primary legislation would reinforce current health settings and depending on design, could enable careful access to puberty blockers where needed (although there is no evidence of harm from prescribing under Option One). However, those with gender incongruence/dysphoria would likely be more distressed due to the uniqueness of enacting primary legislation for such a purpose, with similar results as under Option 3b.	- A prohibition on new prescribing would protect against potential harm. However, this option has a high risk of adverse health outcomes (similar to options 3b and 3c) due to possible negative impacts on mental health, despite medical and psycho-social support through the alternative services. The lack of access to puberty blockers would not treat the indication in many of the cases.

[26] Concerns as cross-sex hormones available online for just £11 a month | Transgender | The Guardian

Efficient	- Less efficient due to: • time and resource needed to develop and enforce regulations, which is not currently budgeted for • 9(2)(h) • inflexible regulations. New information could result in the need for legislative amendment/s.	- - Less efficient due to: • time and resource needed to develop and enforce regulations, which is not currently budgeted for • 9(2)(h) • inflexible regulations. New information could result in the need for legislative amendment/s.	- - Less efficient due to: • very significant time and resource needed to develop and enact a bill, and then implement it. Such resources are not currently budgeted for • very inflexible as new information could result in the need for another bill • 9(2)(h)	- - Less efficient due to: • time and resource needed to develop and enforce regulations, and develop the services, which are not currently budgeted for • 9(2)(h)
Responsive	- While it would set out in regulation good clinical practice that is based on weighing up the risks and benefits for each individual, the legislation would likely decrease the pool of health practitioners who can prescribe puberty blockers. The ability to respond to each individual could therefore be somewhat curtailed.	- - Less responsive due to multiple constraints on the ability to make decisions in the best interest of each child or young person.	- - Less responsive due to one or more constraints on the ability to make decisions in the best interest of each child or young person.	- - Less responsive due to an inability to make decisions in the best interest of each child or young person.
Health equity	0 No improvements for health equity as the regulations would	- - No improvements for health equity as the regulations would not specifically address inequities. Restricting	- - No improvements for health equity as the regulations would not specifically address inequities. Restricting	- - No improvements for health equity as the regulations would not specifically address inequities. The alternative services would likely

	not specifically address inequities.	prescribing of puberty blockers to only secondary care specialists would likely create inequitable access if services were not available in all regions.	prescribing of puberty blockers to only secondary care specialists would likely create inequitable access if services were not available in all regions.	create inequitable access if services were not available in all regions.
Trust & confidence	- - Less trust and confidence in the health sector, given children and young people with gender incongruence/dysphoria would likely feel the system wasn't serving their needs. Regulatory exceptions also risk undermining the system.	- - Significantly less trust and confidence in the health sector. A particular treatment using a medicine would be regulated for the first time in New Zealand. There are many examples of other medicines used with a similar amount of evidence and/or even with much greater evidence of harm, without regulation. Regulatory exceptions also risk undermining the system.	- - Significantly less trust and confidence in the health sector. A particular treatment using a medicine would be regulated for the first time in New Zealand. There are many examples of other medicines used with a similar amount of evidence and/or even with much greater evidence of harm, without regulation. Regulatory exceptions also risk undermining the system.	- - Significantly less trust and confidence in the health sector. A particular treatment using a medicine would be prohibited through regulation for the first time. There are many examples of other medicines used with a similar amount of evidence and/or even with much greater evidence of harm, without regulation. Regulatory exceptions also risk undermining the system. If the alternative services were seen as attracting resources at the expense of other deserving areas of health, trust and confidence in the system could fall.
Overall assessment	-	- -	- -	- -

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

153. The Ministry of Health considers Option One (Status Quo / Counterfactual: baseline of close Ministry monitoring and adjustment as needed) is the best fit for the policy objectives.

154. There is no evidence base to know the likely impact of other options, given they have not been previously tried in this type of context. Also, the steps already taken have not yet had time to be fully embedded and therefore time is needed to evaluate their impact fully.

Is the Minister's preferred option in the Cabinet paper the same as the agency's preferred option in the RIS?

155. The Minister of Health does not have a preferred option. The Ministry of considers Option One (Status quo/counterfactual: baseline of close Ministry monitoring and adjustment as needed) best meets the policy objectives for the reasons described above. Option Two is considered less feasible in a fiscally tight health environment.

What are the marginal costs and benefits of the preferred option in the Cabinet paper?

156. This section provides descriptive costings for all options, given the Minister of Health does not have a preferred option. Quantifying costs on all options would be challenging 9(2)(h) and resource intensive. Quantitative and qualitative analysis could, however, be undertaken if one or two options were preferred.

Costs

Regulated parties

157. There are two types of groups impacted by the review: patients and their caregivers and whānau; and practitioners and service providers.

Patients, caregivers and whānau

158. Current monetised costs for individuals and their caregivers and whānau relate to initial visits to general practitioners, private funding where services aren't available in a timely manner, transport to centres that provide healthcare services and the costs of puberty blocker medicines. 9(2)(h) .

159. There are also long-term costs that relate to whether puberty blockers are prescribed, and the pathway taken later in terms of gender identity. Of those who later pursue transgender changes, the costs for the individual/caregiver/whānau would likely be lower where puberty blockers have previously been taken compared to those who were not prescribed puberty blockers. This is because puberty blockers function to effectively pause puberty to delay any further development of (potentially irreversible) secondary sex characteristics such as breast growth, voice deepening, facial structure changes, Adams'

apple development and facial hair. Pubertal suppression, therefore, may obviate or lessen the need for future surgical interventions.[27]

160. Additionally, there are likely monetary costs associated with caring for children and young people with gender incongruence/dysphoria (eg, loss of income due to caring for those who are unable to attend school or employing additional help in the home, as well as carers potentially seeking support services for their own needs).

161. Non-monetised costs relate to personal distress and not enjoying living in the way healthy individuals and families do due to dealing with the impacts of distress and outcomes for the child or young person.

162. More restrictive options could increase or decrease monetary costs, or they may remain much the same. Costs that might increase include privately paying for psychological care due to increased distress and in the absence of services not being immediately available; increased trips to healthcare services where they are available, trips to Australia or other countries to access puberty blockers; purchasing unsafe puberty blocking medicines online; and contributing to legal challenges.

163. Monetary costs that might decrease could relate to fewer children and young people seeking any treatment.

164. A balance between the above cost increases and decreases could mean that costs remain essentially the same.

Practitioners and service providers

165. Workforce costs relate to specialist care (eg, paediatricians, endocrinologists, psychologists and their associated nurses and administrative people) as well as general practitioners and their support staff (where children and young people with gender incongruence/dysphoria first present), and other social services. There are also costs associated with developing clinical guidance under Health New Zealand to support the Ministry of Health's Position Statement.

166. Current costs for practitioners and service providers include compliance with requirements such as demonstrating experience, training, supervision, service configuration, audits or compliance checks and providing information to regulators or monitors. Service providers also encounter facility costs, but these are small, given facilities are used for multiple purposes and those affected are a very small group of people.

[27] Salas-Humara C, Sequeira GM, Rossi W, Dhar CP. Gender affirming medical care of transgender youth. *Curr Probl Pediatr Adolesc Health Care.* 2019 Sep;49(9):100683. doi: 10.1016/j.cppeds.2019.100683. Epub 2019 Nov 15. PMID: 31735692; PMCID: PMC8496167.

167. In the long term, workforce and facilities costs depend on whether puberty blockers are prescribed, and the path taken later in terms of gender identity, as described in the following table[28] [29] [30] [31]:

Are puberty blockers prescribed?	What further care is followed?	Long-term costs
Yes	Gender affirming hormones (GAH) are taken and gender affirmation surgery is undertaken	Pharmaceutical and surgery related costs, and ongoing psychological and social support. Long-term costs are lower when puberty blockers are taken as less extensive gender affirmation surgery is needed (eg, they delay the development of (irreversible) secondary sex characteristics, and obviate the need for future gender affirmation surgeries)
Yes	GAH are taken	Pharmaceutical costs and ongoing psychological and social support
Yes	None. Puberty blockers discontinued as gender incongruence/dysphoria abates	No evidence-based long-term costs, although psychological and social support may be needed at various points
No	GAH are taken and gender affirmation surgery is undertaken	Pharmaceutical and surgery related costs, and ongoing psychological and social support. Long-term costs are higher when puberty blockers are not taken as more extensive gender affirmation surgery is needed (eg, surgery relating to secondary sex characteristics)
No	GAH are taken	Pharmaceutical costs, and ongoing psychological and social support
No	None	No costs in the long term. Costs would only relate to gender incongruence/dysphoria in the short term

[28] Elkadi J, Chudleigh C, Maguire AM, Ambler GR, Scher S, Kozlowska K. Developmental Pathway Choices of Young People Presenting to a Gender Service with Gender Distress: A Prospective Follow-Up Study. *Children.* 2023;10(2):314.

[29] Salas-Humara C, Sequeira GM, Rossi W, Dhar CP. Gender affirming medical care of transgender youth. *Curr Probl Pediatr Adolesc Health Care*. 2019 Sep;49(9):100683. doi: 10.1016/j.cppeds.2019.100683. Epub 2019 Nov 15. PMID: 31735692; PMCID: PMC8496167.

[30] deVries et al. (2011) Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. Journal of Sexual Medicine, 8(8), 2276-2283.

[31] deVries (2014) Young adult psychological outcome after puberty suppression and gender reassignment. Pediatrics, 134(4), 696-704.

168. In considering how practitioner and service provider costs would be affected under each of the options, Option 2a would initially increase costs while services are consolidated, but costs could be offset if it resulted in less costs in the long term (eg, due to improved mental health).

169. Options 2b, 3a, 3b and 3c, which are more restrictive than Option One (Status quo and the counterfactual) would likely change how current resources are used. More restrictions would mean fewer people would present to specialists with requests for puberty blockers, but many would still require alternative or increased levels of healthcare services (eg, mental health and emergency services) when compared to Option One.

170. Option 4 would also change how current resources are used, with the same short-term costs as Option 2a while alternative services are developed. Some long-term costs could be offset where health improved for those attending the services. However, overall, the prohibition would likely be more costly than status quo for those who want but do not get access to the services or puberty blockers.

171. More restrictive approaches would also likely impact primary health providers, where they would have to manage non-available referral options.

Regulators

172. Depending on the option chosen, regulators' costs relate to responsible authorities under the Health Practitioners Competence Assurance Act 2003 and the Ministry of Health and other government bodies.

173. Current costs for responsible authorities such as the Medical Council of New Zealand relate to prescribing qualifications for prescribing puberty blockers and investigating complaints. There is likely little increase in costs under most of the options, although regulatory options that require supervision of clinicians would be more complex to investigate, where complaints were made.

174. Current costs to the Ministry of Health and other regulatory bodies relate to policy development work and monitoring functions, and two complaints the Health and Disability Commissioner and the Human Rights Commissioner are considering.

175. Developing regulations and implementation by the Ministry of Health (including enforcement) under Options Three and Four would involve substantial work. There would be a cost involved that is not currently budgeted for, particularly under Option 3c where a bill would need to be developed. 9(2)(h)

Others

176. Costs are also associated with other groups, such as:

- the Health and Disability Commissioner and Human Rights Commissioner, where free services for the public are provided, resources are developed, and where applicable, complaints are formally investigated

- those around an affected child or young person who is in significant distress (eg, friends, classroom and school students, club colleagues). There is likely a large flow-on effect of mainly non-monetised costs that are difficult to quantify
- Pharmac funding puberty blockers. Given there is an average of 113 new children and young people (11-16 years) receiving the medicines per year over a period that could be for 5-6 years per person, it is expected that the costs would not impact Pharmac's budget in any substantial way. Options that further limit access to puberty blockers compared to the restrictions already in place under Option One (Status quo and the counterfactual) would likely reduce the cost but would not be enough to influence decision making.

Benefits

Regulated parties

177. The non-monetised benefits from the small group of children and young people with gender incongruence/dysphoria who are prescribed puberty blockers is improved wellbeing. The extended period of pre-pubescence allows the person affected to carefully consider their gender identity. In the longer term, benefits arise whether the individual continues to pursue gender affirming care or ceases taking treatment, given the increased opportunity for the young person and their family to be closely involved in decision-making on their own behalf and over a suitable time period. Options One and 2a best support these benefits.

178. For those who seek treatment but are not prescribed puberty blockers, there may be some protection from possible unknown treatment harm. Options that are more restrictive (Options 2b, 3a, 3b and 3c and Option Four) will particularly best support these benefits.

179. Non-regulatory options would provide more non-monetised benefits for the workforce compared to regulatory options as clinicians would be able to make decisions based on their expertise and in consultation with each affected person and their caregiver and whānau. It is difficult to quantify across the spectrum of options, the monetised benefits for the workforce and facilities, given all the factors that interplay.

Regulators

180. Non-regulatory options would benefit the Ministry of Health by allowing resources to be allocated to other priority work. Similar benefits would be ascribed to government bodies supporting the Ministry of Health in this area.

Others

181. The Health and Disability Commissioner, Human Rights Commissioner would see greater benefits under less restrictive options s 9(2)(h)

182. If a child or young person with gender incongruence/dysphoria is not significantly stressed, those around the affected person would also be less stressed or distracted from other life events. This is more likely to occur under less restrictive options.

183. More restrictive options would mean less money spent on pharmaceuticals, but the overall savings would be low.

Conclusion

184. The Ministry of Health concludes there is substantial uncertainty associated with the relative costs and benefits between options. Despite this uncertainty, it is likely that regulatory options under Option Three and Four would be more costly than non-regulatory options, given the costs associated with developing and implementing legislation,9(2)(h) Status quo is the least resource intensive.

Section 3: Delivering an option

How will the proposal be implemented?

185. The Minister does not prefer a particular option.

186. Implementation of the Ministry of Health's preference for Option One (status quo and counterfactual) is already underway and described in the options section. Should additional policy options to Option One be decided on now, whether for development in case future implementation is triggered or for implementation at this stage, these will be progressed as soon as practical.

Option Two

187. Under Option 2a, Health New Zealand would lead, although other entities or authorities could also play leading roles. For Option 2b, the Ministry of Health would lead, with several, if not all, health entities being involved. Advisory bodies and authorities would also play a role.

Regulatory options

188. If the government decided on a regulatory option under Option Three, the Ministry of Health would develop and implement the legislation, including any enforcement action. Prioritisation against the current drafting programme will be needed to deliver the regulation. No funding has currently been allocated to this work.

189. In general, regulations can take 6-18 months to develop, depending on the complexity of the work and as stated above, government priorities. A transition period would also apply to Option Three to allow time for the regulator to develop the necessary infrastructure and resources to implement the regulations. For Option Four, there would be no transition period.

190. If a bill were developed (Option 3c), a longer period would be needed, given the need for parliamentary consideration and the development of secondary legislation following enactment of the bill. The bill would require prioritisation along with other drafting, legislation programme and House business. Many bills take two years to enact, with another 6-15 months needed to develop secondary legislation. A transition period would also be needed.

191. There are significant risks with developing legislation to safeguard the use of puberty blockers. These have been identified throughout this document, with the risk of unintended ill health, 9(2)(h)

How will the proposal be monitored, evaluated, and reviewed?

192. The Ministry has a monitoring and six-monthly reporting programme in place and will add to this once policy decisions are made. Implementation of Option One (status quo/counterfactual) involves developing a detailed monitoring and adjustment plan. This will include considering whether to develop pre-planned trigger points at which additional actions, such as those detailed in Options 2a through 3b, would be recommended.

193. For all options, a review would be conducted three years following the policy decision made by Cabinet, except for Option Four where the Director-General of Health would

report to the Minister of Health when the outcomes of any clinical trials are available. The review would consider the findings of an anticipated 2027 review of the UK prohibition on the supply of puberty blockers for the treatment of gender incongruence/dysphoria in people aged under 18 years. This review would be informed by a two-year trial in the UK that will examine the evidence for a range of clinical care, including the use of puberty suppressing hormones. The evidence will cover physical, social and emotional wellbeing aspects. This initial UK review would not provide sufficient evidence to prompt any changes under Option Four as it is only one aspect of UK's approach to gathering evidence on safety.

Appendix One. Child Impact Assessment

Improving the wellbeing of children and young people in New Zealand – Child Impact Assessment Tool

The Child Impact Assessment (CIA) Tool aims to help government and non-government organisations in New Zealand to assess whether policy proposals will improve the wellbeing of children and young people.

It will enable organisations to explicitly examine the impact of their policy proposals and take appropriate steps based on this analysis. Undertaking a CIA supports our obligations under the United Nations Convention on the Rights of the Child and will help ensure that the best interests of the child are a primary consideration (Article 3) and that the views of children are respected and given due weight (Article 12).

1. Complete the Screening Sheet

Initial analysis of a proposal and its impacts on children and young people up to the age of 18.

2. Based on the Screening Sheet analysis, are the impacts assessed to be distinct and significant?

No Impacts are neither distinct nor significant: **Screening Sheet analysis is sufficient.**

Yes Impacts are distinct and significant: Carry out the full CIA analysis**:**

- Step 1: Proposal details
- Step 2: Data collection, evidence gathering, stakeholder consultation
- Step 3: Summary of impacts

Note: This template has been adapted for use by New Zealand officials from the Scottish Government model: *Child Rights and Wellbeing Impact Assessment (CRWIA*). This usage and adaptation is allowed by the Scottish Government through the Open Government Licence for public sector information. This encourages the use and re-use of public information where the Scottish Government is the copyright holder. This licence allows usage by other jurisdictions providing there is acknowledgement of the source of the information, and that the information is not used in a misleading context. The Ministry of Social Development has worked with the Office of the Scottish Commissioner for Children and Young People in adapting this template and acknowledges their assistance.

Screening Sheet

1. What is the proposal?

The aim is to help ensure puberty blockers, when considered in gender-affirming care in New Zealand, lead to:

a. positive health and wellbeing outcomes that are safe for young people with gender incongruence (where an individual's experienced gender and their assigned sex at birth persistently do not match) and gender dysphoria (where an individual's gender incongruence has an adverse impact on their health and wellbeing) over the long-term

b. health equity for young people presenting with gender incongruence and gender dysphoria.

Puberty blockers can allow young people with gender-related health needs time to understand their gender identity, without the distress of the fast-developing body. This is because they halt the production of sex hormones testosterone, oestrogen, and progesterone.

There has been an increase in the use of puberty blockers in gender-affirming care in New Zealand and internationally over the last two decades. The lack of clarity on the evidence for their use for gender-incongruent/dysphoric children and young people, means there is a risk of unintended harm as well as uncertainty about benefits over the longer term. This has led some countries to take a more precautionary approach.

The Ministry of Health (the Ministry) has determined that while evidence on the effectiveness and long-term safety of puberty blockers is still developing, their use in gender-affirming care should be approached with caution. These treatments should only be prescribed to children and young people when the benefits and risks have been fully evaluated by experienced multidisciplinary teams, and with informed consent from both the young person and their caregivers.

The Government is considering policy options for use of puberty blockers in young people with gender incongruence and dysphoria. It is timely to review impacts of policy options on children and young people given the increase in the use of puberty blockers over the past two decades and the need to ensure the safety and wellbeing of children and young people.

Seven policy options have been considered in the Ministry's Regulatory Impact Statement (RIS) ranging from status quo (with additional enhancements) to full regulation. Some options support access to health services, with access to puberty blockers carefully managed. Others seek restrictions to further protect the targeted group from the risk of potential harm. All options therefore directly impact children and young people with gender incongruence and gender dysphoria.

Implementation will depend on the option or combination of options chosen by the Government.

2. What are the impacts on children and young people of this proposal?

In 2024, 106 young people aged 11 to 16 years old started puberty blocker treatment in New Zealand. While the reasons for taking the treatment are not known (it may be used for indications such as endometriosis in this age group), it is expected that the majority used it for gender dysphoria. We can expect that the impacts of any policy changes will be to 100 or fewer children and young people each year. However, indirect impacts may also occur for a larger number of children and young people for whom availability of a treatment option might have been a perceived benefit even if they did not receive the treatment.

Information on how many children and young people might be in this wider group who could be indirectly impacted is very approximate. Internationally, approximately 1–2% of children and young people identify as transgender, non-binary or another gender different from the gender they were

assigned at birth, and more are unsure of their gender.[32] In New Zealand, 1.2% of 15-19 year-olds recorded themselves as transgender, nonbinary or another gender in Census 2023. Information including younger age groups comes from the Youth2019 health and wellbeing survey which collected data from 7,891 secondary school pupils (aged approximately 12–18 years) in the Auckland, Waikato and Northland regions. Of the 7,668 who responded to the question regarding gender identity, 1% reported they were transgender and 0.6% said they were unsure.

The nature of the impacts on young people will depend on the option or combination of options chosen.

A potential positive impact with limiting access to puberty blockers is protection from potential harm, particularly in relation to bone health and metabolic parameters. The evidence is, however, limited and yet to be confirmed. The Ministry heard through the public submissions that there are fears amongst some members of the public that those prescribed puberty blockers for gender dysphoria are too young to make such decisions and there could be a risk of unknown harm or regret later in life. In this instance, further safety measures may curb these potential impacts.

There are strong concerns from young people with gender incongruence/dysphoria and those that support or represent them that regulatory changes may have negative impacts. They consider restrictions will increase psychological distress and harm (e.g. self-harm and suicide, harm from taking unsafe puberty blocking medicines sourced online, and harm from using other unsafe approaches to delay puberty). There are also concerns about wider harm to the transgender community, human rights implications and specific impacts for rangatahi (young) Māori.

Equity issues associated with reducing access to puberty blockers include the potential to exacerbate poor access and health outcomes experienced by groups within the broader population of young people who experience gender incongruence/dysphoria. These groups include younger disabled people, rangatahi Māori, Pacific young people and those living outside main centres.

Some studies show improvements in the mental health and wellbeing of gender-dysphoric adolescents when dispensed puberty blockers, however these generally rely on small, localised cohorts, making it difficult to extrapolate to other, larger cohorts. There is also a lack of high-quality evidence specific to the New Zealand context which limits the applicability of insights to the New Zealand population.

3. What are the likely impacts on Māori children and young people of this proposal?

Data on the number of rangatahi Māori seeking puberty blockers for gender-related health needs is not available.

The principles of The Treaty of Waitangi (Te Tiriti) guide the priorities for equitable health outcomes for Māori. Restrictions on the rights of rangatahi Māori and their whānau to make informed decisions about medicines may affect the Crown's obligations to achieve equitable health outcomes for Māori.

Concern was expressed through the Ministry's consultation that restrictive policy options may foster a negative social climate towards gender diversity in the community. This could have impacts on the ability of rangatahi to comfortably express themselves and their gender identity. Concerns were also raised that Māori already experience barriers to accessible and culturally safe healthcare and that a reduction in access to puberty blockers for rangatahi Māori with gender-related health needs could exacerbate this.

[32] Ministry of Health. (2024). *Impact of puberty blockers in gender-dysphoric adolescents: An evidence brief*. Ministry of Health. https://www.health.govt.nz/publications/impact-of-puberty-blockers-in-gender-dysphoric-adolescents-an-evidence-brief

4. Have children and young people had a say and their voice heard in this proposal?

Given the need to exercise care when consulting with young people and the timeframes available for consultation, the Ministry was unable to consult directly with young people with gender incongruence/dysphoria. There was some consultation with caregivers and whānau in the targeted consultation meetings, and representative groups, medical professionals and Commissioners for health and disability, children, and human rights have provided relevant input.

Young people with gender-related health needs and others supporting them responded to the public consultation. Of 5,840 analysed online submissions, 13% identified as young people with gender-related health needs, 20% identified as their families, 5% as their health practitioners and 7% were others working to support them. Further responses from children and young people were also received through email submissions. Whilst the public consultation did receive submissions from rangatahi Māori and their whānau, there are limits within this analysis of the effects any proposed changes might have on Māori and Pacific Peoples due to limited direct consultation.

Depending on the policy direction chosen, further consultation with Māori, Pacific People and young people who are likely to be affected by proposed changes would be beneficial for improving whichever option is progressed.

5. Do the impacts identified require further analysis?

The impacts identified above are significant and distinct to a particular group of children and young people, indicating that a full CIA is required and completed below.

Child Impact Assessment: Step 1
Proposal details

1. Summarise the proposal

The proposal's aim is to help ensure that the use of puberty blockers, when considered in gender-affirming care in New Zealand, leads to positive health and wellbeing outcomes that are safe and equitable for young people with gender incongruence and gender dysphoria over the long-term. Given the unclear evidence on the risks or benefits, the Ministry recommends that these treatments be prescribed only after thorough consideration by experienced practitioners and with informed consent. Seven options are proposed and listed below. Option 1 involves enhanced and close monitoring by the Ministry as a baseline. Other options can be used separately or together to build on the baseline.

- Option 1 – Status quo/counterfactual: baseline of close Ministry monitoring and adjustment as needed
- Option 2a – Enhanced health services and service controls
- Option 2b – System action on prescriber controls and supports
- Option 3a – Regulations to strengthen prescribing requirements otherwise specified
- Option 3b – Regulations to set and enforce new prescribing restrictions
- Option 3c – New specific legislation
- Option 4 – Regulations to prohibit new prescribing while making youth gender services more accessible

---

2. What is the broader, cross-sector context of this proposal?

Background context and previous Ministerial decision-making

In 2023-24, the Ministry conducted a review of the evidence on the risks and benefits of using puberty blockers for young people with gender-related health needs. Puberty blockers are taken by a small number of young people in New Zealand.

The Ministry's review occurred in the context of an increase in the use of puberty blockers in New Zealand and internationally over the last two decades, though data including prescribing for all indications suggests this trend has turned downward in New Zealand more recently. A lack of evidence has prompted some countries to take a more precautionary approach to prescribing. In November 2024, the Ministry released a *Position Statement on the Use of Puberty Blockers in Gender-Affirming Care* (the Position Statement) alongside its evidence review *Impact of Puberty Blockers in Gender-Dysphoric Adolescents: An evidence brief*. The Position Statement sets expectations of clinicians, highlights the importance of informed consent and outlines further steps to ensure young people have access to quality care. At the time of the Position Statement's release, Cabinet directed the Ministry to conduct a consultation about whether further safeguarding measures such as regulations are necessary.

How the proposal may impact on and/or be impacted by broad social, political and cultural issues and on issues of particular relevance to children and young people

Throughout the consultation, groups representing transgender and rainbow youth raised that gender-diverse young people already face poorer mental health and wellbeing outcomes in New Zealand, due to gender minority stress and stigma. They considered that any approach to reduce services or support for this group is likely to intensify these issues. For Māori and Pacific People, this could be exacerbated further due to the additional barriers these groups already experience in accessing appropriate care.

It is likely that options involving unconventional healthcare decisions that restrict puberty blockers specifically for young people with gender incongruence/dysphoria could appear to contribute to a negative social climate towards transgender healthcare and transgender people more broadly. Such a climate could worsen social and wellbeing outcomes for the transgender community and gender-diverse young people.

The proposal in relation to other existing and/or planned governmental policies, work programmes and commitments

- This proposal supports the Government priority for better public services by clarifying and reinforcing quality and safety expectations for health services.

3. Does the proposal advance children's rights and comply with the Children's Convention, including the general principles?

Throughout the consultation, the Ministry heard from various professional organisations and agencies concerned with upholding children's and young people's rights. Groups raised concern that options which reduce access to puberty blockers for young people with gender-related health needs may be an infringement on their rights.

The Children and Young People's Commission raised that additional regulations would likely restrict the legitimate access of some children to the gender-affirming health care they need to experience their holistic rights, including the right to health. Under the United Nations Convention on the Rights of the Child (UNCRC), to which New Zealand is a party, all children have a right to their highest attainable standard of health, and should not be deprived of their right of access to health care services. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which New Zealand ratified, also recognises the right to the highest attainable standard of health, encompassing both physical and mental wellbeing. Policy options that ensure changes to access are precautionary and proportionate will more likely align with UNCRC and ICESCR by carefully weighing the current limitations in evidence with the potential risk of exacerbating mental distress through restricting access.

Article 3 of the UNCRC emphasises that the best interests of the child must be the primary consideration in all decisions affecting them. During the consultation, the Ministry received strong views from varying perspectives on what might be the best interests of each child seeking puberty blockers for gender dysphoria. Some public submissions which opposed their use, argued that children experiencing gender-related distress should receive psychological support rather than treatment with medicines, citing concerns about long-term risks and the capacity of young people to make such decisions. In contrast, groups that the Ministry met with in the targeted consultation widely supported continued or improved access to puberty blockers as part of gender-affirming care in instances where this is in the clinical best interests of the individual child. The Children and Young People's Commission emphasised in their submission that the current referral pathway is guided by comprehensive interdisciplinary assessment and informed consent. The submission recommends strengthening this pathway to ensure consistency of access supported by robust clinical guidance rather than introducing regulations.

Article 12 of the UNCRC emphasises that children have the right to express their views freely in all matters affecting them, and these views should be given due weight according to the child's age and maturity. In the context of healthcare, this means that children should be involved in decisions about their medical treatment. If regulation were to be designed which reduces the involvement of young people in decisions which affect their health and wellbeing related to puberty blockers, this could stand in contention with the principles of the convention.

Article 23 of the UNCRC underscores the right of children with disabilities to receive specialised care

and support that not only upholds their dignity and fosters self-reliance but also ensures meaningful inclusion in all aspects of life. This includes access to education, healthcare and opportunities for social, cultural, and spiritual development – enabling each child to reach their fullest potential. Given emerging evidence indicates there may be higher rates of neurodiversity (such as Autism Spectrum Disorder and Attention-Deficit/Hyperactivity Disorder) among transgender individuals[33], decisions about access to puberty blockers should consider Article 23 and ensure neurodiverse transgender youth receive care that supports both their gender-related needs and overall cognitive, emotional, and social development.

The Health and Disability Commissioner raised that in considering further regulation of puberty blockers it is important to take into account the right to an appropriate standard of care and the right to give informed consent under the Code of Health and Disability Services Consumers' Rights. The Human Rights Commission further highlighted the following articles of the UNCRC that are particularly relevant in the context of access to care for young people experiencing gender dysphoria including:

- Article 3 – best interests of the child
- Article 2 – freedom from discrimination
- Articles 7 and 8 – child's right to protect and preserve their identity, meaning the Government should assist them to do so
- Articles 13 and 14 – freedom of expression, thought and belief – including the right to seek and receive information of all kinds
- Article 17 – right to be informed and have access to information relevant to you
- Article 24 – right to health and health services

The Human Rights Commission also noted that restricting access to puberty blockers could constitute differential treatment of transgender and cisgender young people. 9(2)(h)

Under the Human Rights Act 1993 it is unlawful to discriminate against someone because of their sexual orientation or sex, including their gender identity, gender expression, or sex characteristics. Section 19 of the New Zealand Bill of Rights Act (BORA) similarly affirms the right to freedom from discrimination. 9(2)(h)

9(2)(h)

[33] Engel, L., *et al*. (2023). Assessment of Quality of Life of Transgender and Gender-Diverse Children and Adolescents in Melbourne, Australia, 2017-2020. *JAMA network open* 6(2): e2254292. https://dx.doi.org/10.1001/jamanetworkopen.2022.54292

Child Impact Assessment Tool: Step 2
Data collection, evidence gathering, stakeholder consultation

1. What evidence do you have of how your proposal will impact on children and young people?

The Ministry's evidence brief summarises a literature review on the latest national and international evidence of the safety and long-term impacts of puberty blockers on adolescents. It found a paucity of studies and limitations in the quality of evidence for both the benefits and risks (or lack thereof) of the use of puberty blockers in gender-affirming care. It is difficult to conduct the kind of large-scale clinical trials that are normally used to evaluate effectiveness and safety. The review found some evidence for potential side effects (eg, slower accumulation of bone density) and low-quality evidence on benefits to mental health and wellbeing.

The Ministry is closely monitoring emerging evidence and the targeted consultation meetings have helped to provide a qualitative steer on what the impacts of further safeguarding measures may be.

If further evidence were to indicate long-term negative effects from taking puberty blockers for gender incongruence/dysphoria, the impact on children and young people under the status quo option would be on a small group. This is because the current approach seeks to ensure through the Position Statement that clinicians only prescribe the medicines after carefully weighing up the risks and benefits and through informed consent with those affected and their caregivers and whānau.

Professional organisations consulted by the Ministry highlighted that puberty blockers are an important treatment option for preventing distress amongst gender-dysphoric young people. Organisations supporting the rainbow community expressed concerns for worsening distress and suicidality if puberty blocker treatment is delayed based on their experience working with the community. If further evidence of the clinical benefits comes to light, then maintaining the status quo or improving access could help avoid the risks of declining mental health that might otherwise result from restrictive measures.

A recent population study in the USA supports the connection between restrictions on gender-affirming care and increased suicides amongst transgender and gender-diverse young people.[34] It found that in states that introduced laws such as restrictions on puberty blockers and hormone therapy, suicide rates increased among transgender and non-binary young people in the first year of access restrictions, compared to states that did not introduce such laws. Another study found increases in self-reported anxiety and depression among people who identified as non-heterosexual and/or gender incongruent in states that had introduced laws targeting gender minorities, including gender-affirming care restrictions.[35]

These studies were conducted in an American context and therefore are only partially relevant to the New Zealand context. They show association between outcomes and regulatory actions, rather than impacts of puberty blocker treatment. While these studies would not meet the selection criteria used in the Ministry's evidence review of the impacts of puberty blockers (which focused on the impacts of puberty blockers at an individual level rather than the impacts of regulatory changes), they nevertheless indicate that caution is warranted in considering any similar regulatory approaches.

[34] Lee, W.Y., Hobbs, J.N., Hobaica, S. *et al.* (2024). State-level anti-transgender laws increase past-year suicide attempts among transgender and non-binary young people in the USA. *Nat Hum Behav*, 8, 2096–2106. https://doi.org/10.1038/s41562-024-01979-5

[35] Last, B.S., Tran, N.K., Lubensky, M.E., Obedin-Maliver, J., Lunn, M.R. and Flentje, A. (2025). US State Policies and Mental Health Symptoms Among Sexual and Gender Minority Adults. *JAMA Network Open, 8*(5), pp.e2512189-e2512189.

2. What are the most significant impacts that the proposal will have on children and young people?

As discussed above, many submissions and groups in the Ministry's consultation expressed concern that an increase in rates of psychological distress and self-harm among this group could be expected if access to puberty blockers is restricted further. Submitters noted that this is because young people with gender dysphoria can experience distress from undergoing puberty which does not align with their gender identity. Though there have been studies conducted which support the correlation between access to gender-affirming care and improved mental wellbeing outcomes, the Ministry's evidence brief found that the quality of evidence remains limited.

Concerns were raised that young people may access puberty blockers through unsafe means, such as obtaining them online without a prescription from black or grey markets. The Ministry heard there is a risk that young people may turn to alternative approaches to delay puberty, which could pose health risks. Accessing unregulated medicines or using alternative approaches may be medically unsupervised, resulting in incorrect dosages and harmful side effects.

Concerns were also raised in the public consultation that if access to puberty blockers is limited or denied, those who continue to want to transition as adults may undergo more extensive surgical affirmation surgery in adulthood which carries risks.

In the consultation, medical practitioners and providers suggested that if access to puberty blockers were to be restricted by regulation, specific monitoring for harms experienced by the young people impacted should be implemented. This includes monitoring for increased incidences of self-harm. The Professional Association for Transgender Health Aotearoa (PATHA) advised that mitigating impacts would be best achieved through maintaining the status quo, as puberty blockers are currently prescribed in line with best practice.

As discussed in the rights analysis above, options which further restrict access to puberty blockers may also impede young people's autonomy, and their right to have a say in healthcare decision-making at both individual and systemic levels.

In their submission, the Royal New Zealand College of General Practitioners noted that puberty blockers are a relatively new and politicised treatment, which has led to confusion and concern among the public and health professionals about potential effects on bone health, psychological/social harm, and disruptions to cognitive development. However, they stress that these concerns alone are not sufficient to deny individuals' access and right to care. The College emphasises the absence of compelling evidence indicating any harm, noting that regulation is being considered without any publicly documented complaints or reports of mistreatment from patients who have received this treatment.

Given the lack of evidence, the Ministry has developed a monitoring and reporting programme to better understand prescribing trends and to mitigate the potential of unknown impacts.

3. How will the policy proposal impact on different groups of children and young people?

Which groups of children/young people are impacted:

Any proposed changes to the use of puberty blockers will affect young people with gender incongruence or dysphoria for whom puberty blockers are clinically indicated. These young people are primarily aged between 11 to 16 years. In 2024, 106 young people aged 11 to 16 years old started puberty blocker treatment in New Zealand and it is expected that the majority used it for gender

dysphoria.

Differential impacts within this group:

- Māori:
    - Data is not available on the proportion of Māori young people that experience gender incongruence/dysphoria, but Census 2023 indicates that around 1% of Māori aged 15 years or older identify as transgender, compared to the rate of 0.7% in the total population of New Zealand across all ethnic groups. In the census, 0.6% of Māori identified as another gender. The Youth19 Rangatahi Smart Survey reports that 0.9% of Māori secondary school respondents in their survey sample identified as transgender, and 0.9% were unsure of their gender identity.
    - Māori experience barriers to healthcare and poorer health outcomes. The proposal has the potential to either address these inequities by improving services and support or, conversely, to disrupt whānau-based decision-making through regulation that reduces the options Māori have for accessing care. This could disrupt access to care and exacerbate inequities. Ways to address care inequities should be considered regardless of the policy option selected.
    - The Ministry heard through the consultation that it is also important that policy options recognise and support the role of diverse gender identities within Te Ao Māori.
- Pacific Peoples:
    - Data is not available on the proportion of young Pacific people who experience gender incongruence/dysphoria, but Census 2023 indicates around 0.8% of Pacific Peoples aged 15 and over identify as transgender in New Zealand, and 0.4% as another gender. The Youth19 survey reports that 0.9% of Pacific high school students in the survey identified as transgender. In the absence of direct consultation with Pacific Peoples experiencing gender incongruence or dysphoria, it is difficult to determine exactly how this policy will impact Pacific children, adolescents, families, and their communities.
    - Pacific communities in New Zealand experience barriers to culturally safe and accessible healthcare and this could be exacerbated under policy options which reduce access.
    - The Ministry heard through the consultation that it is important that policy options aim to address the current inequities and also recognise the role of cultural gender identities which exist among some Pacific cultures including fa'afafine, fakaleiti, fa'atama, vakasalewalewa, akava'ine and laelae.
- Younger disabled people:
    - The intersection of disabilities and gender identity can create unique challenges and needs for young people. Younger disabled people may experience unique forms of gender dysphoria, for example young people with Autism Spectrum Disorder (ASD) may have limited self-awareness to comprehend gender concerns, challenges with ambiguity, or difficulties communicating feelings about their gender.[36] This can be a source of mental distress and may be compounded by mental health conditions. It is important to ensure that their needs are considered and that access to gender-affirming care is not discriminatory or limited due to disability.
    - Those currently receiving treatment for gender-related health needs include neurodiverse young people (with conditions like ASD and Attention-Deficit/Hyperactivity Disorder) who

[36] Strang, J. F., Meagher, H., Kenworthy, L., de Vries, A. L. C., Menvielle, E., Leibowitz, S., Anthony, L. G. (2016). Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents. *Journal of Clinical Child & Adolescent Psychology*, 47(1), 105–115. https://doi.org/10.1080/15374416.2016.1228462

may require specialised support to navigate the healthcare system. The Royal New Zealand College of General Practitioners highlighted the correlation between gender dysphoria with ASD and other neurodivergent conditions which increases the need for access to multidisciplinary care. Accessing this care and support can be particularly important for alleviating dysphoria and improving mental health amongst these groups and their families.

- Rurally isolated groups:
    - Many groups, including health professionals, indicated in the consultation that restrictions on prescribing puberty blockers could deepen existing access inequities across New Zealand. For example, restricting access to puberty blockers to only secondary care specialists could result in inequitable access as these services are not available in all regions.

Associated impacts on whānau, parents and caregivers

Throughout the consultation, many parents, caregivers and whānau expressed their concerns about access to puberty blockers becoming further reduced. The Ministry heard that policy options that restrict access to puberty blockers may leave caregivers feeling distressed and helpless about how to support their young person in receiving healthcare for gender dysphoria. This sense of powerlessness can strain family dynamics and emotional wellbeing if caregivers are unable to alleviate their child's distress.

Impact and rationale behind focusing on certain groups of young people

The proposal focuses on young people experiencing gender incongruence and dysphoria. There has been a lack of robust, long-term evidence supporting the use of puberty blockers for this group and an increase in prescriptions over the past two decades. This has raised debate about the need for enhanced safety measures especially in other countries where there have been complaints of cases of inappropriate prescribing. Whilst no such complaints have been made in New Zealand, the proposal is pre-emptive to avoid harm here by ensuring that the treatment is only received by those young people for whom the uncertain benefits outweigh any possible unknown risks. The rationale behind options which would severely limit or effectively ban puberty blockers only for young people with gender incongruence/dysphoria is more limited, as puberty blockers have been used for over 30 years to treat precocious puberty, which is started at a younger age (in girls under 8 years and boys under 9 years). Additionally, in other areas of paediatric medicine, many medicines are prescribed off-label carrying similar levels of risk and comparable quality of evidence as puberty blockers.

Does the proposal consider whakapapa and respect whanaungatanga of all children and young people?

The Ministry's Position Statement recognises the need for a holistic approach to care for young people with gender-related health needs and involving whānau in healthcare decisions where appropriate. Policy options which uphold informed consent and decision-making between young people, their caregivers and health professionals more closely align with respect for whanaungatanga (kinship or close connection) and acknowledges the responsibilities of caregivers to support the health and wellbeing of young people in their care. More restrictive prescribing controls or regulations could remove options for healthcare decisions to be made collectively between patients, caregivers and healthcare providers.

Should access to puberty blockers reduce, this could negatively impact the ability of young people with gender-related health needs to comfortably express themselves and their gender identity in their community. This could differentially affect rangatahi Māori.

4. Are there particular implications for Māori from the policy proposal?

During the consultation, concerns were raised that potential restrictions on puberty blockers could conflict with the principles of Te Tiriti by undermining Māori rights to determine their own healthcare decisions and gender identities. Options which restrict access to puberty blockers without clear evidence of harm could impact collaborative healthcare decision-making for rangatahi Māori and reduce options for culturally safe and whānau-centred care.

In the consultation, concern was raised that international studies should not be used as a basis for regulatory change in New Zealand, as these are not informed by the context of Te Tiriti, nor do they take into account conceptions of gender identities in Te Ao Māori. New Zealand also has a different population demographic and inequities across the population, particularly impacting Māori, which will be different to international contexts. Among those expressing this viewpoint in the consultation, the current informed consent model was seen as one which upholds the principles of Te Tiriti and supports autonomy in decision-making, thereby maintaining the mana of rangatahi Māori. Policy decisions would therefore best comply with the rights and interests protected by Te Tiriti where they provide options for support and services that are culturally appropriate and safe.

5. What are the impacts of the policy proposal on whānau and the wider hapū, iwi and community?

If the chosen policy option, or combination of options, restricts access to puberty blockers, this may reduce the options available to whānau, caregivers, hapū and iwi to support the wellbeing of young people with gender-related health needs in their care. This can place strain on families and whānau dynamics due to a lack of access to appropriate care.

As mentioned, concerns were raised in the consultation that restrictions could be seen as contributing to a negative social climate towards transgender individuals in the wider community, potentially increasing a sense of marginalisation for these young people and their whānau.

During the consultation, organisations working with gender-diverse youth and their whānau in the community shared feedback reporting an increase in harassment and misinformation about children and young people's gender identity. Groups report this is causing tension within communities and support networks, including families/whānau, schools, churches, and sports groups and consequently a deterioration in mental health among youth experiencing gender incongruence or dysphoria.

6. Have you ensured that the views of children and young people are part of the evidence base of your CIA? Have you consulted with diverse groups of children and young people?

Children and young people's perspectives were gathered mainly through public consultation where 13% of the 5,840 online responses identified as a young person with gender-related health needs. Further responses were also received from young people in the email submissions.

The Ministry had planned to hold two moderated webinar-style sessions specifically for young people, their families, and those who provide care to them. These sessions did not proceed in response to concerns raised by stakeholder groups. The Ministry also explored the possibility of engaging with young people via focus groups facilitated by the Children's Commissioner, but the available timeframes were insufficient to design and deliver sessions that would be appropriate for this population. As such, children and young people were not directly consulted outside of the public submissions processes.

7. How have you consulted with other stakeholders to identify the potential impacts of the proposal beyond your agency?

What consultation has been undertaken?
The Ministry's targeted meetings with various organisations and groups representing people likely to be affected by further safety measures were the primary method for gathering views on the topic. The Ministry also provided an opportunity for public submissions via an online submission form and a dedicated email address.

The consultation sought feedback on the necessity and impact of proposed regulation, how such regulation might be framed and any implementation issues or unintended impacts. The consultation did not consult on the specifics of policy options as no specific regulatory proposal was available at the time of the consultation. Some groups reflected that a lack of clarity of the proposal made it difficult to provide feedback on potential impacts and regulatory design during the consultation.

Have you consulted with different groups of children and young people? Are there different ways for children and young people to provide their viewpoints?
As outlined above, children and young people's perspectives were mainly gathered through public consultation. The Ministry had planned to hold moderated webinar-style sessions and explored the possibility of focus groups facilitated by the Children's Commissioner, but these did not proceed due to concerns and time constraints.

How have you consulted with whānau, hapū and iwi to further consider how your proposal will impact children and young people?
Though the targeted consultation meetings did engage with organisations representative of diverse groups of young people with gender-related health needs, including rangatahi Māori, the Ministry did not meet directly with whānau, hapū and iwi. The Ministry did hear from Māori through the public submissions where a modest number of submissions were received from those identifying as transgender rangatahi Māori, their whānau, and those working in the community with rangatahi Māori. The limited understanding on how policy changes might impact Māori communities is a limitation of this analysis and should be taken into account in decision-making.

What other interested groups have required targeted consultation? How have you consulted with them?
The Ministry held meetings with a wide range of organisations and groups, including:

- Organisations representing the rainbow and transgender support sector: InsideOUT, NZ Parents and Guardians of Transgender and Gender Diverse Children (NZPOTC), OUTLine NZ, Qtopia, Rainbow Support Collective, RainbowYOUTH, and Te Ngākau Kahukura.
- The Professional Association for Transgender Health Aotearoa (PATHA).
- The Gender Identity External Advisory Group.
- Regulatory Authorities: Medical Council, Psychologists Board, and Psychotherapists Board.
- Medical and nursing colleges.
- Professional Societies including the Paediatric Society of New Zealand, Pharmaceutical Society of New Zealand, and New Zealand Society of Endocrinology.
- Commissioners: Offices of the Children and Young People's Commissioner, the Health and Disability Commissioner, and the Human Rights Commission.
- Other government agencies: Pharmac and Health New Zealand.

For the public consultation, the Ministry analysed 5840 online submission form responses and 2768

email submissions. These submissions covered a broad range of perspectives including:

- Young people with gender-related health needs
- Family/whānau members of a young person with gender-related health needs
- Friends of young people with gender-related health needs
- Health practitioners working with young people with gender-related health needs
- People with a role in an organisation that works with young people with gender-related health needs
- Generally concerned citizens
- Parents and grandparents broadly
- General supporters of the trans and gender diverse community
- Members of the transgender community
- Adults with gender-related health needs or such needs in their youth
- Members of other rainbow communities
- Health practitioners in general
- Academics and researchers
- Teachers and others working with young people in general
- Other or not disclosed

The Ministry also met with two groups known to oppose the use of puberty blocking treatment for young people with gender-related health needs: Genspect and Family First. These meetings were held at the groups' requests and insights have been considered as part of the public consultation.

Child Impact Assessment: Step 3
Summary of impacts

8. What are your conclusions about the policy being proposed as a result of your assessment?

The impacts of this proposal will depend on the policy option/s chosen, ranging from more minor impacts in options adjusting service and prescribing settings, to more potentially negative impacts in options that restrict or ban the use of puberty blockers for young people with gender incongruence/dysphoria through regulation.

As highlighted by the professional groups and organisations in the Ministry's consultation, options which restrict or reduce access to puberty blockers for gender-related health needs may have negative outcomes including:

- increased distress, mental illness and self-harm related to a reduction in treatment options
- increased distress or strain on family/whānau and support networks
- impacts to the sense of belonging or acceptance experienced by gender-diverse young people if restrictions contribute to a negative social climate towards the transgender community
- an exacerbation of current access issues for groups such as Māori, Pacific People, young disabled people and rurally-isolated young people
- impacts to collaborative decision-making and whanaungatanga between young people, their family/whānau and their healthcare providers
- impacts to the options available to rangatahi and whānau for culturally safe and accessible care
- rights-based impacts related to the right to be free from sex- or gender-based discrimination and the right to health
- potential health impacts for young people with gender-related health needs should they turn to black or grey markets to access puberty blockers without healthcare provider input.

The Ministry's evidence brief did not identify clear evidence of either benefits or harms.

The main potential positive impact of regulation would be to safeguard against unknown harm should evidence of risks to health and wellbeing become evident in future. The potential for unknown potential side effects and later regret were arguments put forward by a minority of the public submissions and two groups known to oppose the use of puberty blocking treatment. The Ministry's evidence brief did find some evidence for a slower accumulation of bone density as a potential side effect, however no substantial evidence for these other concerns was otherwise found.

Options which maintain or improve the access and options available could help avoid many of the negative impacts above. The Ministry heard in the consultation that puberty blockers are already hard to access, leading to distress even under the status quo. It is expected that policy options which support young people with gender-related health needs to access puberty blockers when clinically indicated, through services meeting the expectations of the Position Statement, should balance the lack of evidence for long-term impacts with best practice informed consent to provide quality care.

9. What are your recommendations about the policy being proposed as a result of your assessment?

This Child Impact Assessment indicates that policy options which restrict access to puberty blockers beyond the status quo would likely have negative impacts on young people with gender-related health needs. The assessment therefore does not support these options from a child-centred perspective.

Policy options which maintain or improve service provision could mitigate these negative impacts. The status quo option has measures in place for informed prescribing to support young people with gender incongruence or dysphoria. Under this option, opportunities to modify prescribing and service provision remain open in the instance that evidence of harm arises. This is supported by the Ministry's ongoing monitoring and reporting of puberty blocker prescribing and any emerging evidence in this field.

Given the difficulties the Ministry faced in consulting directly with young people with gender-related health needs and a lack of consultation specifically with Māori and Pacific Peoples, it is important that these views continue to be sought to inform ongoing decision-making.

s 9(2)(h)