In Confidence

Office of the Minister of Health

Office of the Associate Minister of Health

Cabinet

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

Proposal

1 This paper:

1.1 informs Cabinet of the need to safeguard the use of puberty blockers in young people with gender-related health needs, and the release of a Position Statement on this topic by the Director-General of Health;

1.2 seeks agreement to consult on a proposal to regulate the prescribing of puberty blockers in the context of gender-affirming care for people under 18 years, for report to the Cabinet Social Outcomes Committee in early 2025.

Relation to government priorities

2 This proposal supports the Government priority for better public services. It supports the Government Policy Statement on Health's Quality priority by clarifying and reinforcing quality and safety expectations for health services provided for young people with gender-related health needs.

Executive Summary

3 Certain medicines, widely used to treat some cancers and other conditions, can be used to block or delay puberty in children and young people. They are used to treat precocious puberty (puberty that starts much earlier than usual) in children, and approved by Medsafe for this purpose. They are also used to delay puberty in young people with health needs related to gender, an unapproved use that is one of many examples where professional practice and clinical judgement inform prescribing.

4 The Ministry of Health (the Ministry) recently reviewed the effectiveness and safety of puberty blockers in young people with gender dysphoria and found a lack of good quality evidence. An Evidence Brief sets out the findings, unchanged in an Addendum update. In summary, we do not have good evidence to say that these medicines improve the longer-term outcomes for young people with gender-related health needs; nor what the risks from using them in this context are.

5 No particular instances of harm are known of in New Zealand. However, the Ministry is concerned that both prescribers and young patients and families are informed about this lack of evidence, and that any prescribing occurs in the context of broader health

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care for the young person and with informed consent. The Ministry has prepared a Position Statement to this effect, to release together with the Evidence Brief and Addendum. As well, Health New Zealand is updating clinical guidance and the Ministry will improve clinical practice supports and build a monitoring framework.

6 The Ministry considers that the measures referred to above support prescribing of puberty blockers only for those gender-dysphoric children and young people for whom the benefits of accessing these medicines outweigh the potential risks; and with informed consent of the young person and their parents or guardians (unless involvement of parents or guardians would not be appropriate).

7 The Ministry advises that a precautionary approach would include considering whether further safeguarding measures should be put in place in the short-term or held in reserve for the future should more risk information emerge.

8 Based on this advice, our current view is that it is prudent to take a cautious approach in New Zealand. We therefore seek agreement to work towards and consult on a proposed regulation under section 105 of the Medicines Act 1981. Such a regulation would restrict the prescribing of these medicines for the purpose of delaying puberty in the context of gender-affirming care in people under 18 years.

9 In proposing this regulation, we understand the need to preserve access to these medicines for individuals who have them prescribed to treat cancers and other conditions. Subject to consultation outcomes, any proposed regulation would also preserve access for young people with gender-related health needs already receiving puberty blocker treatment; or where its use is part of an approved clinical trial(including multinational trials).

Background

10 Gonadotrophin releasing hormone agonists are a class of medicines given by injection to treat a range of common conditions including breast and prostate cancers and endometriosis, along with a number of other, less common indications. In children, these medicines are used to treat precocious puberty (premature pubertal changes in girls under 8, boys under 9). They are available only on prescription.

11 These medicines are also used to delay puberty in young people with gender incongruence or gender dysphoria (when the experienced gender is persistently different from the sex that was assigned at birth and this has adverse health and wellbeing impacts). In this context, they are known as puberty blockers. Delaying puberty provides young people with additional time to adapt and decide on managing gender incongruence and dysphoria. Puberty resumes when the medicine is stopped.

12 These medicines are approved by Medsafe for use in people under 18 years only for treatment of precocious puberty. No application has been made to Medsafe or other regulators for approval for gender incongruence or dysphoria. Use for this purpose, as part of a suite of health services that include mental health and other supports, has grown internationally over the last 15 to 20 years. Clinical guidelines have been issued based on consolidated clinical experience.

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New Zealand prescribing context

13 In New Zealand, medicine dispensing data shows steady growth in use of these medicines for children and young people aged 10 to 19 years between 2010 and 2022, up to around 200 young people starting treatment each year, followed by a fall-off in 2023. Less than 25 young people typically started treatment each year before that time.

14 To date, any authorised prescriber can prescribe these medicines for children and young people. In practice, relatively few do. Treatment is initiated by a range of vocationally registered practitioners, most frequently paediatricians, endocrinologists, and general practitioners.

15 The dispensing data cover all indications for these medicines. While the Ministry has limited visibility of prescribing for children and young people with gender incongruence and dysphoria specifically, we assume that gender-related health needs and endometriosis together account for most of the increase in the relevant age range.

Consent to treatment

16 Under New Zealand Law, people 16 years and over are able to make treatment decisions on their own behalf (section 36(1), Care of Children Act 2004). Children under the age of 16 are able to make some treatment decisions based on their competence to make the particular decision, with higher levels of competence needed for more complex procedures. When a child is competent to make a treatment decision, parents or guardians cannot overturn their decision except by disputing competence through the courts. Parents or guardians are responsible for making treatment decisions where the child is not competent, taking into account the child's views to the extent they are able to express them.

17 In practice and under guidelines issued by the Health and Disability Commissioner, practitioners usually involve both children and young people and their parents or guardians in treatment discussions and decisions. For puberty blocking treatment, the support of family, whānau or caregivers is needed both practically (treatment involves regular injections and checkups) and for the young person's development and wellbeing.

Evidence review

18 The Ministry reviewed the evidence on impacts of puberty blockers on clinical and mental health and wellbeing outcomes in 13-18 year olds with gender dysphoria.

19 The quality of the evidence was found to be poor as studies had significant limitations. Knowledge is insufficient on how effective puberty blockers are in improving long-term outcomes or whether there are long-term adverse effects when used in the context of the treatment of gender dysphoria.

20 Evidence on improved mental health and wellbeing outcomes was of poor quality; information is insufficient to draw conclusions on impacts of puberty blocker treatment on outcomes related to depression, anxiety, or suicidal ideation.

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21 In terms of clinical outcomes, there is some evidence that bone density may not increase at expected rate for the person's age or stage of development. However, long-term effects have not been adequately studied.

22 Alongside the Ministry's review of evidence, similar reviews were undertaken in other jurisdictions. The findings of these reviews were consistent with the Ministry's findings and, noting some variation, have informed moves to improve safeguards around prescribing of puberty blockers.

New Zealand health system response

23 The New Zealand health system response follows from the Ministry's evidence review, risk assessment, and consideration of necessary access.

24 No particular instances of harm are known of in New Zealand and numbers of young people receiving puberty blocking treatment for gender dysphoria remain low. However, the Ministry is seeking to ensure that both prescribers and young patients and families are informed about the lack of evidence, and that any prescribing occurs in the context of broader health care for the young person and with informed consent.

Considering the health risks

25 The Ministry has considered all available evidence on the risks and benefits of puberty blocking treatment. Assessment of risk has included the:

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

25.2 continuing emergence of evidence which is still being evaluated internationally;

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

26 As a result, the Ministry's assessment is that immediate safeguards should be put in place so that the potential risks of this treatment are carefully considered and any initiation of its use is reserved only for children and young people for whom its benefits are judged to substantially outweigh these risks; and with informed consent of the young person and their parents or guardians (unless involvement of parents or guardians would not be appropriate).

27 Given the poor evidence on puberty blocking treatment outcomes, supportive care including a range of social and mental health supports should be the starting point. It is important to ensure that access to quality gender affirming care with its wide range of supports continues.

28 The poor evidence of outcomes from puberty blocking treatment does not, however, justify cessation for young patients who have already started puberty blocking treatment. Rather, the lack of evidence should be discussed and consent to treatment reaffirmed before it is continued.

Considering necessary access

29 As well as ensuring that access to quality gender affirming care continues, access to the medicines concerned needs to continue for the thousands of New Zealanders who are prescribed them to treat cancers and other conditions.

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30 The Ministry considers that measures to limit the use of puberty blocking treatment in gender affirming care need to preserve access to these medicines for:

30.1 people who need these medicines to treat a range of conditions outside of their use in gender dysphoria;

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

30.3 use as part of an approved clinical trial (whether based in New Zealand or internationally) that is conducted for the purpose of obtaining information about the safety and efficacy of puberty blocking treatment.

Director-General Position Statement

31 The Ministry has prepared a Director-General Position Statement (attached as appendix 1) to communicate expectations of prescribers and other practitioners involved in providing care for young people with gender incongruence and dysphoria. This statement will be released shortly after Cabinet has considered this paper, alongside the Evidence Brief and Addendum.

32 The Position Statement sets expectations that treatment should be initiated only by prescribers who are experienced, working within their scope of practice, meeting professional practice and ethical standards, and working as part of an interprofessional team offering a range of supports and services. Prescribers are expected to inform patients about the lack of evidence for long-term effects from these medicines.

33 The practical effect of the Position Statement will be that a far smaller number of prescribers will be able to prescribe puberty blockers, and this will take effect immediately.

34 Issue of the Position Statement will set out clear expectations for health practitioners and put immediate additional safeguards in place to protect children and young people from any potential harm. It will provide a firm basis for regulatory oversight of prescribers by the Medical Council of New Zealand. It will uphold the rights of children and young people not to be subjected to medical or scientific experimentation without consent and not to be subject to discrimination (including on the basis of sexual orientation or preferences or gender), as well as other legal rights.

Other measures underway

35 Health New Zealand is updating clinical guidance. Current clinical guidance (issued in 2018) is consistent with the Position Statement but brief. The updated guidance will include clinical pathways and is planned for completion in the coming months.

36 The Ministry is developing a monitoring framework to support adaptation to future evidence and trends. This will collect information to monitor puberty blocker prescribing and use as well as broad population outcomes. Diverse elements are being considered, from population studies to complaints investigation outcomes.

37 The Ministry has started examining other actions in the clinical practice and dispensing environment that could further shore up safe prescribing. This will include assessing international practices and tools as they are being developed. Tools to better

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assess health needs or risks, and information resources to support informed decision making, may be adaptable for New Zealand use.

Are further safeguarding measures needed?

38 The Ministry considers, and Health New Zealand agrees, that the measures described above support prescribing of puberty blockers only for those gender-dysphoric children and young people for whom the benefits of accessing these medicines outweigh the potential risks. These measures are designed to:

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

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

38.3 retain flexibility for future adjustment as additional evidence accrues.

39 The Ministry advises that, taking a precautionary approach, it is prudent to consider whether further safeguarding measures should be put in place in the short-term, or whether any safeguarding measures should be held in reserve for the future should more risk information emerge. For example, it seems that prescribing has reduced somewhat in 2023and 2024, which may indicate adjustment in clinical practice in light of the international concerns.

Proposal

40 Our view is that it is prudent to take a cautious approach in New Zealand. We are proposing to regulate to restrict the prescribing of these medicines for the purpose of delaying puberty in people under 18 years.

Making a regulation under section 105 of the Medicines Act 1981

41 Section 105 of the Medicines Act allows the Governor-General to make regulations that cover a wide range of purposes related to prescribing and other medicines-related activities. These regulations are made by Order in Council on the advice of the Minister of Health after consultation with organisations representative of those likely to be substantially affected.

42 We are seeking agreement to proceed with work towards considering whether to make regulations under the Medicines Act. Such regulations would likely restrict prescribing, administration, and supply of gonadotrophin releasing hormone agonists for people under 18 years to delay puberty in the context of gender affirming care.

43 A six- to ten-month period is the usual minimum required to develop, consult, and implement through to such regulations coming into effect. Given the importance of minimising possible harm to young people, we are seeking agreement to progressing work on proposed regulations with a degree of urgency, while ensuring that all consultation requirements are met, and risks are minimised.

44 Our intent for such regulations would be to pause new prescribing of puberty blocking medicines for use in gender affirming care, except for use in approved clinical trials, including multinational trials. Access to the same medicines would continue for

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young people who have already started this treatment and for people who are prescribed the medicines for other reasons. This intent will be considered during consultation.

45 Making a regulation will require the development of clear criteria by which health practitioners could prescribe what products for which people, and exclusions defined. Consultation with expert groups will be important to ensure the need for regulation is justified, and that any resulting regulation is clear, without unintended impacts and able to be updated in light of emerging evidence.

Consultation proposal

46 We are seeking agreement to the Ministry commencing consultation on this proposal. Consultation would seek feedback on:

46.1 whether there is a need to create such a regulation and its likely impacts;

46.2 how the proposed regulation is framed to provide clarity of intent and effect;

46.3 the effectiveness of the proposed regulation in minimising impacts and preserving access to these medicines for those groups being considered to need treatment with these medicines;

46.4 which groups of young people with gender-related health needs, if any, should be able to access puberty blocking treatment;

46.5 any implementation, administration or enforcement issues or risks and their prevention or management;

46.6 any potential unintended impacts for people, health practitioners, health service providers, health regulators or others, and their prevention or management

47 The Medicines Act requires that consultation occurs with organisations or bodies that are representative of persons likely to be substantially affected by the regulations. Consequently, consultation would occur with groups representative of:

47.1 medical practitioners and relevant specialist medical practitioners;

47.2 health services providing care for young people with gender-related health needs;

47.3 gender diverse young people, including rangatahi Māori and Pacific young people;

47.4 families and whānau of gender diverse children and young people;

47.5 health regulators.

48 In addition, the Ministry will invite public submissions via survey questions on its Health Consultation Hub web page. Given the high level of public interest in this issue we anticipate that many people will submit on this proposal, including parents and families.

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Risks and mitigation

Risks related to clarity in drafting

49 9(2)(h)

50 Consultation with expert groups will endeavour to identify and mitigate risks. Feedback from the consultation would help to determine details of how a regulation would be drafted, if this is the path chosen. This would include determining implementation issues such as how prescribing could be initiated and maintained (eg, whether this may be limited to certain specialist medical professions).

Health risks

51 Gender incongruence is not a health issue per se. However, young people with gender-related concerns are, as a group, at higher risk of poor health, including mental health, outcomes. Some reasons for this higher risk include their higher rates of social exclusion, discrimination, victimisation, trauma, and abuse.

52 9(2)(g)(i)

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Social and justice risks

54 9(2)(g)(i)

Trust and confidence risks

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9(2)(g)(i)

57 9(2)(g)(i)

58 9(2)(g)(i)

Legal risks [legally privileged]

59 9(2)(h)

60 9(2)(h)

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62 9(2)(h)

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Implementation

63 A short but feasible timeframe for development and finalisation of a proposed regulation that keeps within legal and process requirements is set out below:

Milestone/Activity	Indicative timeframe
Announcement & release of Position Statement with Evidence Brief and Addendum	21 November
Consultation with representative groups & public	22 November to 20 January

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Consultation and impact analyses completed	10 February
Lodgement of SOU paper for policy decisions	6 March
Issue of drafting instructions to PCO	24 March
Lodgement of LEG paper with draft regulation	24 April
Publication of Gazette notice	8 May
Regulation in effect (with 28-day rule)	5 June

Other options considered

64 We have considered other options to add strength to the measures already underway. Their major disadvantage is length of time to effect them; it would be difficult to progress them sufficiently within 12 months, let alone within the timeframe for creating a section 105 regulation.

Prescribing supervisory actions

65 More rigorous prescription monitoring, supervisory and practice audit options could be developed, once more robust dispensing information than is currently collected is in place. Potentially, this could help build good practice as well as provide early alerts and intervention for outliers in prescribing patterns.

66 These actions would be designed to ensure that medical practitioners follow best practice and that children and young people experiencing gender incongruence and dysphoria receive appropriate treatment. 9(2)(g)(i)

De novo legislation

67 A Bill (which could be an amendment Bill or provisions inserted in a related Bill) could be drafted specific to the purpose of safeguarding the use of puberty blockers in gender affirming care. This option would require House time and would need to be progressed in the context of the Government's wider legislative programme and priorities. 9(2)(g)(i)

Cost-of-living implications

68 This proposal has no direct cost-of-living implications for families with children who have gender-related health needs and/or are trans or gender-diverse. Alternative services will continue to be accessible.

Financial implications

69 This proposal has no direct financial implications. Financial implications of monitoring and enforcing the proposed regulation will be examined as it is developed.

Legislative implications

70 The proposed regulation is provided for under section 105 of the Medicines Act 1981.

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Impact analysis

Regulatory Impact Statement

71 The Ministry of Health quality assurance panel has reviewed the initial Impact Statement titled "Safe-guarding the use of puberty blockers in young people with gender-related health needs" and dated October 2024.

72 The panel considers the Statement is clear, concise, complete, and convincing, and notes that consultation will be undertaken in the next stages of the policy process.

Climate Implications of Policy Assessment

73 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal, as the threshold for significance is not met.

Population implications

74 9(2)(g)(i)

Human rights

75 9(2)(h)

76 9(2)(g)(i)

77 Any impacts on human rights will be considered, together with a Bill of Rights Act analysis and any relevant consultation results, before proceeding with any regulation.

Use of external resources

78 No external resources, contractors or consultants have been or are proposed to be engaged in the development of the proposal.

Consultation

79 Health New Zealand, Pharmac, the Parliamentary Counsel Office, the Crown Law Office and the Department of the Prime Minister and Cabinet, and the Ministry for Regulation have been consulted on this paper.

Communications

80 Following Cabinet decisions:

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80.1 we propose to announce the Government's intention to look into regulating the prescribing of puberty blockers in young people with gender-related health needs;

80.2 the Director-General of Health will release the Position Statement together with the Evidence Brief and Addendum;

80.3 the Ministry of Health will proceed towards consultation with the representative groups described in paragraph 48.

Proactive Release

81 We intend to defer proactive release of this paper and the associated Regulatory Impact Statement until full consideration is given to the proposal and the outcomes, including any regulation, have been put in place.

Recommendations

The Associate Minister of Health and the Minister of Health recommend that the Committee:

1 note that a Ministry of Health evidence review found a lack of good quality evidence for the long-term effectiveness or safety of puberty blocking treatment for gender dysphoria, as set out in an Evidence Brief and Addendum;

2 note that the Director-General of Health will shortly issue a Position Statement on the use of puberty blockers in treatment of young people with gender-related health needs, to accompany publication of the Evidence Brief and Addendum;

3 note that the practical effect of the Position Statement will be that a far smaller number of prescribers will be able to prescribe puberty blockers in gender-affirming care, and that this will take effect immediately;

4 note that Health New Zealand is updating clinical guidance and the Ministry will improve clinical practice supports and build a monitoring framework;

5 note that the Ministry considers that the measures described in recommendations 2 to 4, above, support prescribing of puberty blockers only for those gender-dysphoric young people for whom the benefits of these medicines outweigh the potential risks;

6 note that the Ministry further advises that a precautionary approach would include considering whether further safeguarding measures should be put in place in the short-term or held in reserve for the future should more risk information emerge;

7 note that we consider it prudent to take a cautious approach to further safeguard the prescribing of puberty blockers for people under 18 years, without delay;

8 note that section 105 of the Medicines Act 1981 provides for regulations related to prescribing and other medicine-related activities to be made by Order in Council, on the advice of the Minister of Health after consultation with organisations representative of those likely to be substantially affected;

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9 s 9(2)(g)(i)

10 agree that work should proceed towards considering regulation under section 105 of the Medicines Act 1981 to restrict prescribing of puberty blockers for people under 18 years;

11 agree that consultation will consider:

11.1 whether there is a need to create such a regulation and its likely impacts;

11.2 how the proposed regulation is framed to provide clarity of intent and effect;

11.3 the effectiveness of the proposed regulation in minimising impacts and preserving access to these medicines for those groups being considered to need treatment with these medicines;

11.4 which groups of young people with gender-related health needs, if any, should be able to access puberty blocking treatment;

11.5 any implementation, administration or enforcement issues or risks and their prevention or management;

11.6 any potential unintended impacts for people, health practitioners, health service providers, health regulators or others, and their prevention or management;

12 agree that, subject to consultation outcomes, any proposed regulation should preserve access to treatment with puberty blockers for:

12.1 people who need treatment with these medicines for a range of indications outside of their use in gender dysphoria;

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

12.3 use as part of an approved clinical trial (whether based in New Zealand or internationally) that is conducted for the purpose of obtaining information about the safety and efficacy of puberty blocking treatment;

13 agree that the Ministry of Health should consult on any proposed regulation with groups representative of:

13.1 medical practitioners and relevant specialist medical practitioners;

13.2 health services providing care for young people with gender-related health needs;

13.3 gender diverse young people, including rangatahi Māori and Pacific young people;

13.4 families and whānau of gender diverse children and young people;

13.5 health regulators;

13.6 and provide an opportunity for public submissions;

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14 agree in principle that development of any proposed regulation should proceed within short but feasible timeframes that are in keeping with legal and process requirements;

15 note that a report on the results of consultation and impact analyses will be submitted to the Cabinet Social Outcomes Committee in March 2025;

16 note that we expect any regulations will be submitted to the Cabinet Legislation Committee for consideration in May 2025.

Authorised for lodgement

Hon Dr Shane Reti	Hon Matt Doocey
Minister of Health	Associate Minister of Health

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