MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Puberty Blockers in Gender-Affirming Care: briefing

Date due to MO:	11 June 2024	**Action required by:**	17 June 2024
Security level:	IN CONFIDENCE	**Health Report number:**	H2024043566
To:	Hon Dr Shane Reti, Minister of Health		
Copy to:	Hon Matt Doocey, Associate Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

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Minister's office to complete:

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☐ See Minister's Notes	☐ Withdrawn	

Comment:

Puberty Blockers in gender-affirming care

Security level:	IN CONFIDENCE	**Date:**	11 June 2024
To:	Hon Dr Shane Reti, Minister for Health		

Purpose of briefing

1. To provide information on the upcoming release of three documents relating to use of puberty blockers in gender-affirming care:
   a. The Director General's position statement on the use of puberty blockers in gender-affirming care (the position statement – **Appendix A**).
   b. Impact of puberty blockers in gender-dysphoric adolescents: an evidence brief (the evidence brief – **Appendix B**)
   c. Addendum to the evidence brief (the addendum – **Appendix C**)
2. To provide information about work undertaken to support the release of the documents above including:
   a. options explored within the prescribing environment and settings for puberty blockers to ensure safer prescribing in the care for young people with gender incongruence or gender dysphoria
   b. established a Gender Identity External Advisory Group (the Group)
   c. the communications approach for the release of the documents related to this work.
3. To seek your direction on additional steps to provide tighter control of the prescribing environment for puberty blockers.

Summary

4. The Ministry of Health | Manatū Hauora (the Ministry) has been leading work relating to the use of puberty blockers in gender-affirming care. We have developed an evidence brief and addendum (setting out the evidence available), and a position statement (setting out good practice for the use of puberty blockers as part of gender-affirming care). The Director-General intends to publish the documents on Wednesday 19 June 2024.
5. The position statement sets expectations for the prescription of puberty blockers, including expectations about clinician experience, interdisciplinary care and mental health support.
6. The position statement is a strong and immediate lever to influence prescribing practice through providing the basis for action to be taken under the Health Practitioners

Competence Act 2003 and building expectations for operational policy and service specifications for Health New Zealand – Te Whatu Ora (Health New Zealand).

7. The use of a position statement is similar to approaches taken in comparable countries, where change has been affected through national statements and operational policies.

8. Some countries have limited access to initiation of puberty blockers to those enrolled in clinical trials. There are currently no plans for a clinical trial in New Zealand. The Ministry is monitoring the development of international clinical trials and will use their findings to inform our approach.

9. Regulation of the use of puberty blockers would require Cabinet approval to make regulations under the Medicines Act (1981). While this option would give strong control through specific restrictions on which prescribers may prescribe which medications, it would require legislative process, with long lead in (up to 12 months), including public consultation.

10. Application of a Special Authority to restrict prescribing through Pharmac is unlikely to achieve the full safer prescribing framework being sought. As Special Authority restricts funding only, people could still access these medicines privately, but at their own cost.

11. In addition to the position statement, the Ministry has established an external advisory group to advise on gender identity services and implementation of the position statement. The Ministry will also enhance monitoring of the prescribing of puberty blockers to improve our understanding of how they are being used in the New Zealand context.

12. The Ministry and Health New Zealand are undertaking broader work on gender-affirming care. The Ministry will continue to work with Health New Zealand to further strengthen clinical governance of gender affirming care.

13. Health New Zealand is in the process of developing New Zealand-specific guidelines for clinicians working in this area. We expect the guidelines to be ready by December this year and will provide you with more information at that time if you wish.

Recommendations

We recommend you:

a) **Note** that the Ministry intends to publish the evidence brief, addendum and position statement on the use of puberty blockers in gender-diverse youth on 19 June 2024 **Yes/No**

b) **Note** that the position statement sets expectations for the prescription of puberty blockers, including expectations around clinician experience, the use of multidisciplinary care and mental health support. **Yes/No**

c) **Note** that the position statement will have an immediate effect to improve the safety of the prescribing of puberty blockers, and that it does not preclude taking additional steps in the future should evidence indicate that greater control is required. **Yes/No**

d) **Direct** the Ministry to:

Provide further advice on the process to introduce regulation of puberty blockers under the Medicines Act (1981) **Yes/No**

Engage with Pharmac to pursue Special Authority through the Pharmaceutical Schedule **Yes/No**

Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date: 10/6/24

Hon Dr Shane Reti
Minister of Health
Date:

Puberty Blockers in gender-affirming care

Background

14. The use of puberty blockers has increased in recent years leading to questions about appropriate prescribing.

15. Puberty blockers are a class of drug which are gonadotrophin hormone analogues (GnRHa) that suppress the development of puberty. They are used to address early puberty, endometriosis, polycystic ovary syndrome and some hormone-sensitive cancers (some breast and prostate cancers). They are also used in gender-diverse youth to delay puberty. Examples of the most common GnRHa used in New Zealand are goserelin and leuprorelin.

16. In recent years, the use of GnRHa in young people in New Zealand has increased significantly, though numbers treated remain small. There has been a steady increase in prescribing over the past 15 years. Although we do not have data on the reason for prescribing puberty-blockers, we believe it is primarily driven by increased in gender-diverse youth.

17. The increases in prescribing patterns being seen in New Zealand are mirrored in other comparable countries.

18. Other countries are taking a variety of approaches to increase controls around the use of puberty blockers. These range from reinforcing guidance regarding informed consent, introducing operational policy and service specifications requiring interprofessional approaches, linking the initiation of puberty blockers to participation in clinical trials, to introducing specific legislation. Detail regarding individual countries' approaches is included in the addendum to the evidence brief.

19. There are strong and varied views on the appropriateness and/or safety of the use of puberty blockers in adolescents with gender dysphoria. These views are varied across health professionals, rainbow communities and the general public.

20. Gender-affirming care is a relatively new field, and New Zealand healthcare professionals would benefit from updated New Zealand-specific clinical guidance. This work is underway, being led by Health New Zealand and is expected to be published before the end of 2024.

The Ministry's approach to leading improvements in prescribing and care for gender diverse young people

An evidence review

21. In response to these concerns the Ministry undertook an evidence review to inform the Ministry's approach and position. The evidence brief examined up-to-date scientific evidence regarding the impact of puberty blockers on clinical and mental health and wellbeing outcomes in adolescents with gender dysphoria.

22. Overall, the quality of the evidence was low, with studies presenting a high risk of bias and significant limitations.

23. There is some evidence, that for young people taking puberty blockers, their bone mineral density is lower than what is expected for the individual's age or stage of pubertal development, when compared to a control group.

24. Other international analyses and reports have been released since the initial completion of our evidence brief. A further review of additional publications between October 2023 to May 2024, including the final Cass Report was undertaken and is available in an addendum.

25. Our overall assessment is that the new evidence published since September 2023 is not different from that included in the evidence brief. Therefore, the conclusions drawn in the evidence brief remain.

Improving the prescribing environment

26. Given the evidence brief findings, changing international context and ongoing concerns being raised regarding the use of puberty blockers, the Director General is intending to release a position statement on the use of puberty blockers.

27. The position statement sets clear practice expectations for the prescription of puberty blockers, including expectations about clinician experience, interdisciplinary care and mental health support in the context of holistic clinical care for young people presenting with gender dysphoria or gender incongruence.

28. Specifically, the position statement is a strong and immediate lever to influence prescribing practice. It has effect in the following ways:

    a. ability to take action under the Health Practitioners Competence Assurance Act 2003 (HPCA) in response to significant variations in practice from those described in the position statement

    b. influence the prescribing environment by building the expectations of the Position Statement into Te Whatu Ora | Health NZ operational policy and service specifications.

29. Ministry officials recently met with Dr Hilary Cass, author of the UK report and recommendations from her independent review of gender identity services for children and young people. The recent changes to prescribing practice in NHS England are being effected through operational policy, as opposed to regulation/legislation. The use of a Position Statement and its influence is similar to the NHS approach. Whilst the UK and some other countries are looking to establish multi-centre clinical trials across countries, we understand from Dr Cass that these clinical trials have not yet been commenced.

Options for further regulation of puberty blockers

30. Medicines used as puberty blockers in the context of providing gender-affirming care are used for other conditions. Any consideration of restricting the prescribing of these medicines for the indication of puberty blockers needs to ensure access for other indications is not adversely impacted.

31. Four potential options were investigated within the prescribing environment for improving the prescribing settings for Puberty Blockers to ensure safer prescribing in the care for young people with gender incongruence or gender dysphoria. Of these, only

three options were progressed for further investigation, s 9(2)(h)

A summary of all options explored is included in **Appendix D**.

Controls available through Medicines Act 1981

32. Placing restrictions on which prescribers can prescribe these particular medicines can only be achieved at this time by making regulations under the Medicines Act 1981 (the Act).

33. Regulation can be made under the Act after consultation with organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations.

34. While this option would give strong control through specific restrictions on which prescribers may prescribe which medications, it would require legislative process, with long lead in (up to 12 months), including public consultation and advice to Cabinet. s 9(2)(g)(i)

Pharmac: application of Special Authority as a mechanism

35. The primary function of Special Authority criteria in the pharmaceutical schedule is to target funding. Criteria are used to identify patient groups and indications where funded treatments will be most cost effective.

36. Puberty blockers are relatively inexpensive and there is no economic reason to restrict their use. The only consequence of prescribing that occurred outside of the restrictions of any Special Authority would be the patient being charged for the medicine at the pharmacy. Effectively this would mean that people could access these medicines privately, so long as they were willing and able to pay for them.

37. As prescribing outside the Special Authority is still possible, this mechanism may not effectively achieve the full safer prescribing framework we are seeking.

The Gender Identity External Advisory Group

38. We have established an External Advisory Group to provide independent advice to the Director-General Health on gender identity services.

39. The purpose of the Group is to provide independent external advice to the Director-General of Health on current issues relating to gender identity services.

40. The Group will work closely with the leadership of the Ministry to offer advice relating to:

    a. implementation of the Ministry's position statement on the use of puberty blockers in gender-affirming care (the position statement) developed including next steps

    b. review of existing information about prescribing patterns and gender-affirming care service provision.

Communications plan

41. We expect the position statement to generate significant media, sector and community interest. The Ministry has developed a detailed communications plan to support the release of the position statement and evidence brief. We are providing a focussed communications plan (**Appendix E**) to support Minister's offices post-release. It includes:

    a. key messages

    b. intended Ministry of Health media release

    c. reactive lines for Ministers

    d. will commission New Zealand research to determine the long-term clinical and mental health and wellbeing impacts of puberty blockers in young people with gender incongruence or gender dysphoria.

Next steps

42. In addition to setting immediate expectations for care, the position statement sets out the following actions which will provide assurance that care provided to those presenting with issues related to their gender identity is of high quality. To support implementation and evaluation of the Position statement, the Ministry:

    a. is working with Health New Zealand to enhance clinical governance structures across gender related services. Clinical governance will require monitoring of the range of services required including wraparound support, as well as the use of medicines to ensure the safe and evidence-based delivery of gender-affirming care

    b. will enhance the monitoring of prescribing, with measures and monitoring put in place to assess the impact of the position statement. This includes ongoing evaluation of any need to introduce additional regulatory measures in the future should evidence indicate that greater control is required

    c. will monitor progress of development of Health New Zealand's updated guidance development to support clinicians providing gender-affirming care, expected to be completed by the end of 2024.

    d. will continue monitoring of international literature for emerging evidence on puberty blockers and gender-affirming care more generally

    e. will commission New Zealand based research on the use of puberty blockers for gender affirming care.

    f. will convene the expert advisory group for a first meeting on 20 June 2024

    g. will publish the evidence brief, addendum and position statement on the 19 June 2024.

ENDS.