Briefing

Addendum: Puberty Blockers: Regulatory Controls in the UK and New Zealand

Date due to MO:	N/A	**Action required by:**	09 July 2024
Security level:	IN CONFIDENCE	**Health Report number:**	H2024043566
To:	Hon Matt Doocey, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☐		

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☐ See Minister's Notes	☐ Withdrawn	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: Regulatory Controls in the UK and New Zealand

Security level:	IN CONFIDENCE	**Date:**	09 July 2024
To:	Hon Matt Doocey, Associate Minister of Health		

Purpose of briefing

1. In response to your request for further information, this briefing updates previous advice (the advice) provided on 11 June 2024 (Puberty Blockers in gender-affirming care - H2024043566 refers).
2. Further information relates to regulatory changes recently taken under urgency in the United Kingdom (UK) to impose further regulation on the prescribing, supply and use of medicines used as puberty blockers in gender-affirming healthcare.

Summary

3. The Ministry of Health | Manatū Hauora (the Ministry) has been leading work relating to the use of puberty blockers in gender-affirming care.
4. The advice detailed:
    a. work to date
    b. the Ministry's intention to publish an evidence brief and addendum (setting out the evidence available) and a position statement (setting out expectations for the use of puberty blockers as part of gender-affirming care)
    c. information about options considered to provide tighter control of the prescribing environment for puberty blockers.
5. Since the Ministry provided the advice, the United Kingdom has taken emergency regulatory action, in the form of:
    a. The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (England, Wales and Scotland) Order 2024; and
    b. The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2024.
6. The Ministry has reviewed these changes in comparison to the advice previously considered relating to regulatory settings in New Zealand.
7. Whilst there are options for New Zealand to introduce additional regulatory controls, these options should be balanced by considering the additional value such controls would add further to the position statement, against potential risks s 9(2)(g)(i)
8. The Ministry's recommended approach remains the same as the advice previously provided. The position statement and work underway to strengthen monitoring and governance of gender-affirming care are effective, immediate actions to influence

clinician prescribing practices and provide assurance on the safety of gender-affirming care.

9. This does not preclude taking additional regulatory actions in the future, should evidence indicate that greater control is required.

Recommendations

We recommend you:

a)	**Note** that this briefing provides further information to previous advice provided on 11 June 2024 to Ministers Reti and Doocey (Puberty Blockers in gender-affirming care - H2024043566 refers).	**Yes/No**
b)	**Note** that the Ministry's position statement and broader work underway to strengthen monitoring and governance of gender-affirming care are sufficiently effective immediate actions.	**Yes/No**
c)	**Note** This does not preclude taking additional regulatory actions in the future should evidence indicate that greater control is required.	**Yes/No**

Dr Diana Sarfati

Director-General of Health
Te Tumu Whakarae mō te Hauora
Date:

Hon Matt Doocey

Associate Minister of Health

Date:

Puberty Blockers: Regulatory Controls in the UK and New Zealand

Background

10. In New Zealand, the current use of Gonadotrophin Releasing Hormone analogues (GnRHa) is by 'off label' prescription. The onus sits with the prescribing clinician to ensure that the person receiving the medication 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.

11. In recent years the use of GnRHa in young people in New Zealand has increased significantly, though numbers started on treatment annually remain small. This trend is consistent with international experience.

12. Recently, there have been changing positions internationally on the use of puberty blockers in young people with gender incongruence or gender dysphoria.

13. NHS England published a clinical policy in March 2024. This policy took the position that new prescriptions of puberty blockers would only be accessible for young people with gender incongruence or gender dysphoria when used as part of a clinical trial.

Regulatory settings in the UK

14. The United Kingdom has introduced two pieces of secondary legislation to prohibit the use of puberty blockers for the purposes of treating gender dysphoria, gender incongruence or a combination or both in the UK. These are:

    a. The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (England, Wales and Scotland) Order 2024.

       This Order prohibits, subject to exceptions, the supply of medicinal products that consist of or contain one of a list of gonadotrophin-releasing hormone ("GnRH") analogues. This Order was made without the statutorily required consultation pursuant to a power of Ministers to make an Order with immediate effect "to avoid serious danger to health"; and

    b. The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2024.

       These regulations amended the Schedule "Drugs, Medicines and other substances that may be ordered only in certain circumstances". These Regulations set out the drugs, medicines or other substances that may be ordered for patients in the provision of medical services under a general medical services contract by the National Health Service. This amendment prohibits the ordering of GnRH analogues for the purpose of puberty suppression in the treatment of gender dysphoria, gender incongruence or a combination of both.

Comparisons with New Zealand Regulatory Environment

15. The Medicines Order was made under the UK equivalent of the New Zealand Medicines Act 1981. Under the Medicines Act 1981, there are a range of legislative tools available. s 9(2)(h)

16. We do not have an equivalent control mechanism to the NHS Regulations for the contracts of Heath New Zealand | Te Whatu Ora. s 9(2)(h)

Regulatory options available through the Medicines Act (1981)

Previous advice

17. 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).

18. A summary of options explored for further regulation of puberty blockers was provided within the advice. In summary:

    a. 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.

    b. 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.

19. Regulation of this type is unprecedented and has a risk of creating a precedent for this approach being advocated for other medicines.

Additional provision under Section 37

20. There is a provision available under Section 37 of the Medicines Act which enables the Minister of Health to, by notice, prohibit the import, manufacture, packing, sale, possession, supply, administration, or other use of medicines of any specified description either absolutely or subject to such conditions as the Minister thinks fit, for any specified period not exceeding 1 year; but the Minister shall not exercise this power more than once in respect of medicines or medical devices so specified.

[1] **https://www.legislation.govt.nz/act/public/2004/0115/latest/DLM330361.html**

21. This provision would enable the total prohibition on the supply or administration of the medicines for a particular use. The Minister is required to provide reasons for the prohibition in giving the notice on the written request of any person.

22. s 9(2)(h)

23. s 9(2)(h)

Controls available through Manatū Hauora Position Statement

24. 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.

25. Setting expectations through a position statement allows us to swiftly tighten the prescribing environment whilst the broader work programme, including the establishment of an External Advisory Group will increase our monitoring of implementation of the position statement and next steps. It does not preclude taking additional steps in the future, should evidence indicate that greater control is required.

26. 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.

Next steps

27. Ministry officials will liaise with your office regarding publication date and planning for publishing the evidence brief and position statement.

ENDS.

Minister's Notes