Sensitive

Office of the Minister of Health

Cabinet

Refining regulations to clarify the restriction of medicines for puberty suppression

Proposal

1 This paper seeks agreement from Cabinet to refine the recently approved Medicines (Restriction on prescribing gonadotropin releasing hormone analogues) Amendment Regulations 2025 on prescribing medicines for puberty suppression.

2 The refinement will ensure the regulations apply only to the use of these medicines for puberty suppression, consistent with Cabinet's original intent [SOU-25-MIN-0160], and do not inadvertently capture adult treatment contexts.

Relation to government priorities

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

Executive Summary

4 Cabinet previously agreed to regulate to restrict puberty blocker prescribing to treat gender incongruence or dysphoria in new patients, reflecting concerns about the limited evidence base and potential risks [SOU-25-MIN-0104].

5 While the Medicines (Restriction on prescribing gonadotropin releasing hormone analogues) Amendment Regulations 2025 were drafted to give effect to this decision, feedback from clinicians indicates that the current wording may unintentionally apply to adults seeking treatment.

6 This paper proposes a targeted amendment to clarify the scope of the regulations.

Policy

7 In November 2024, Cabinet considered advice on the use of medicines for puberty suppression in young people experiencing gender dysphoria [CAB-24-MIN-0455]. Ministers noted the lack of robust evidence on long-term outcomes for young people and agreed that a precautionary approach was warranted. Cabinet directed officials to consult on options to restrict prescribing for new patients while maintaining access for those already in treatment.

8 Following consultation, Cabinet agreed in September 2025 [SOU-25-MIN-0104] to proceed with regulations under section 105 of the Medicines Act 1981. These

regulations, the Medicines (Restriction on prescribing gonadotropin releasing hormone analogues) Amendment Regulations 2025, prohibit the prescribing of medicines for puberty suppression for new patients with gender dysphoria or incongruence.

9 The intent was clear: to limit use for puberty suppression, while preserving clinical discretion for other therapeutic uses and ensuring continuity of care for existing patients.

Proposed amendment to the Medicines (Restriction on prescribing gonadotropin releasing hormone analogues) Amendment Regulations 2025

10 The drafting of the regulations did not explicitly refer to "puberty suppression". This is because, at the time of drafting, it was not known these medicines were prescribed to adults as part of gender affirming care when other medicines are not tolerated. The use in adults is not for puberty suppression. This ambiguity has created uncertainty among clinicians and raised concerns that the prohibition could extend to other clinical contexts or adult treatment, contrary to Cabinet's intent.

11 The absence of a reference to "puberty suppression" in the regulations means that the prohibition applies more broadly. Adults seeking treatment for gender dysphoria or incongruence may be denied access.

12 s 9(2)(h)

13

14 The original Cabinet decision was grounded in the principle of minimising possible harm associated with puberty suppression in young people, given the uncertainty about long-term benefits and risks. That rationale does not apply in the same way to other clinical uses or to adults, and for whom the clinical risk profile differs.

15 Refining the regulations to specify that the restriction applies only to the use of medicines for puberty suppression will align the regulations with Cabinet's policy intent and reduce the risk of unintended consequences.

16 It is proposed that the regulations be amended to specify that the prohibition applies only to the prescribing of medicines for the purpose of puberty suppression in new patients who are children or adolescents with gender dysphoria or incongruence.

Timing and 28-day rule

17 I am seeking a waiver of the 28-day rule to ensure the change comes into force on the same day as the original regulations of 19 December 2025, avoiding confusion with commencement dates of the regulation.

Compliance

18 The compliance of the amended regulation is consistent with the compliance of the regulation approved by Cabinet under submission SOU-25-SUB-160.

9(2)(h)

Impact Analysis

21 A Regulatory Impact Assessment was prepared in accordance with the necessary requirements and was submitted at the time that Cabinet approval was sought of the policy relating to the regulations [SOU-25-MIN-0104].

Publicity

22 Any announcements will be decided on in discussion with the Prime Minister's Office.

Proactive Release

23 The release of any reports will be decided on in discussion with the Prime Minister's Office.

s 9(2)(h)

Consultation

25 I am satisfied that the statutory prerequisites for consultation on amendments to the Medicines Regulations have been met under section 105 of the Medicines Act 1981.

26 The Ministry of Health, Crown Law Office, and the Parliamentary Counsel Office have been consulted on the proposed amendment.

Communications

27 Communications will be updated to reflect the amended regulations, providing clarity regarding the regulations.

Recommendations

The Minister of Health recommends that Cabinet:

1 **agree** to amend the Medicines (Restriction on prescribing gonadotropin releasing hormone analogues) Amendment Regulations 2025 to specify that the prohibition on prescribing applies only to medicines for puberty suppression in new patients with gender dysphoria or incongruence.

2 s 9(2)(h)

3 **agree** to a waiver of the 28-day rule to ensure the amendment comes into force at the same time as the Medicines (Restriction on prescribing gonadotropin releasing hormone analogues) Amendment Regulations 2025 on 19 December 2025.

4 **note** the Parliamentary Counsel Office has drafted the amendment to the Medicines (Restriction on prescribing gonadotropin releasing hormone analogues) Amendment Regulations 2025 under section 105 of the Medicines Act 1981, giving effect to the regulation amendment agreed by Cabinet in recommendation 1.

5 **authorise** the submission to the Executive Council of the Medicines (Restriction on prescribing gonadotropin releasing hormone analogues) Amendment Regulations 2025.

Authorised for lodgement.

Hon Simeon Brown

Minister of Health