January 2025

FAMILY FIRST SUBMISSION

IN RESPONSE TO CONSULTATION BY THE MINISTRY OF HEALTH ON SAFETY MEASURES FOR THE USE OF PUBERTY BLOCKERS IN YOUNG PEOPLE WITH GENDER-RELATED HEALTH NEEDS

1 Family First submits that urgent action needs to be taken by the Minister of Health and his Associates and the Ministry of Health to stop the prescription of puberty blockers (**PBs**), even off label, under section 25 of the Medicines Act 1981 (the **Medicines Act**) until there is sufficient quality evidence that the prescribing of PBs is safe and reversible and efficacious in the treatment of Gender Dysphoria (**GD**). The status quo is not sustainable given the Evidence Brief as summarised by the Ministry of Health's Position Statement on the Use of Puberty Blockers in Gender-Affirming Care issued on 21 November 2024 (**PS**) found that:

> Overall, the evidence brief found significant limitations in the quality of evidence for either the benefits or risks (or lack thereof) of the use of puberty blockers. This means there is insufficient basis to say that puberty blockers are safe or reversible (or not) for use as an intervention for gender dysphoria in adolescents.

2 Given this finding, it is critical that the Ministry makes regulations under the Medicines Act to stop the prescribing of puberty blockers for delaying puberty in gender incongruent or gender dysphoric young people until there is sufficient quality evidence that puberty blockers are both safe and reversible and efficacious in the treatment of gender dysphoria.

Summary of reasons for prescribing of PBs to stop

3 First, allowing the prescribing of puberty blockers off label given the lack of this probative evidential basis may breach sections 8-11 of the New Zealand Bill of Rights Act 1990 (**BORA**), as set out in the **attached** letter to the Ministry dated 13 December 2024 (**Letter**). It also may breach the United Nations Convention on the Rights of the Child (**UNCROC**) also as set out in the Letter.

4 Secondly, there is insufficient quality evidence to ensure that clinicians advising on puberty blockers can meet their professional practice and ethical standards such that their patients can give properly informed consent to the use of puberty blockers. The Position Statement states:

> Clinicians 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.
>
> 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 Services Consumer Rights.

5 Despite saying this, the Position Statement then refers to the PATHA guidelines:

> Guidelines for gender-affirming care have been independently published in New Zealand. These guidelines set out the key considerations for health teams, including the prescribing of puberty blockers. There are also local clinical pathways within primary care and specialist services across New Zealand, but there is not currently a nationally consistent approach.

6 The fundamental mistakes of fact in the *Guidelines for Gender Affirming Health care for Gender Diverse and Transgender Adults in Aotearoa New Zealand* by Oliphant J, Veale J, Macdonald J et al (Transgender research lab: University of Waikato, URL) 2018 (**PATHA Guidelines**)[1] are set out in the Letter along with those same mistakes being replicated in the consent forms in the appendices to the PATHA guidelines which state: *"Blockers are a reversible medication used to stop the physical changes of puberty. It can be started in early puberty (Tanner stage 2–3)."*

7 The PS says that Health New Zealand (**HNZ**) is currently developing an updated set of guidance and the Ministry of Health will work closely with HNZ. But no timeframes have been given. Given the current lack of quality research and clinical guidance (which is not based on mistakes of fact but quality evidence), Family First submits that the Ministry should make regulations to prohibit the use of puberty blockers.

Medicines Act

8 Section 25(1)(b) of the Medicines Act allows an authorised prescriber to *"procure the sale or supply of any medicine"* for a patient in their care. This means that prescribers may prescribe any medicine to a patient (within their scope of practice), regardless of whether it is approved or unapproved in New Zealand.

9 An unapproved medicine is a medicine for which consent, or provisional consent, has not been given by the Minister of Health for sale, distribution, or marketing in New Zealand, i.e. it has not been through the Medsafe regulatory process, approval has lapsed, the application was withdrawn or the product available is different in some way to the product that was approved. Unapproved medicines may still be prescribed to patients.

10 Section 25(3) provides that: Subsection (1) *"…is subject to the other provisions of this Act and any regulations made under this Act."*

11 The regulation making power in section 105(1) of the Medicines Act is broad and can authorise the making of a regulation prohibiting the prescribing of puberty blockers in the context of gender-affirming care (to treat gender dysphoria), without affecting prescribing for other conditions. It provides:

> The Governor-General may from time to time, by Order in Council made on the advice of the Minister tendered after consultation with such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations, make regulations for all or any of the following purposes:
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> …
>
> (d) prohibiting, limiting, restricting, or imposing conditions on, either generally or in relation to particular cases or classes of case, or particular descriptions or classes of medicines, or particular classes of person, the prescribing, manufacture, packing,

[1] https://patha.nz/Guidelines

> labelling, administration, sale, or supply of medicines pursuant to any provision of this Act:
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> ...

12 Law reform through Parliament of the Medicines Act is therefore not required. An Order in Council made by Cabinet after detailed consideration by the Cabinet Legislation Committee, and then a recommendation from the Executive Council to the Governor General could prohibit the use of puberty blockers, until sufficient quality evidence justifies their use.

Consent for under 16 year olds is not possible

13 In New Zealand, consent to medical treatment can be given by legal minors of or over the age of 16 years as set out in section 36 of the Care of Children Act 2004. Under common law, Gillick competence is used to establish if an adolescent under 16 years is capable of giving consent to medical treatment.[2]

14 Gillick competence is about determining when a person under 16 can consent to their own medical treatment without the need for parental permission or knowledge. Lord Scarman's test is generally considered to be the test of 'Gillick competency'. He required that a child could consent if they fully understood the medical treatment that is proposed: "As a matter of law the parental right to determine whether or not their minor child below the age of sixteen will have medical treatment terminates **if and when the child achieves sufficient understanding and intelligence to understand fully what is proposed**."[3]

15 Family First submits that consent is not possible when there is insufficient evidence about the efficacy of the treatment or the resultant complications following use of puberty blockers; put another way, it is impossible for anyone – let alone an under 16 – to consent to a treatment that itself is not understood nor has sufficient evidence to support it.

Prohibitions and restrictions on PBs in comparable countries to NZ

16 There are precedents overseas for such a prohibition or greater prescribing restrictions/informed consent requirements given the lack of quality evidence of safety, reversibility or efficacy for PBs. As the media release of the brief and the Position Statement stated:

> The Government has now tasked the Ministry with consulting on whether the new precautions should be backed by additional safeguards, such as regulations under the Medicines Act 1981 to strengthen changes in prescribing expectations.
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> These tighter controls reflect a level of concern both here and overseas about the increasing use of these medicines for the treatment of gender identity issues without sufficient evidence to support their safety and effectiveness both now and in the longer-term. The appropriate and safe care for this group of young people is critically important. Any additional safeguards in the form of regulations would be to protect against the risk of future harm to vulnerable individuals.

17 As the Position Statement states:

> The UK, Finland, Norway, and Sweden have recently decided to limit the initiation of new prescriptions of puberty blockers for young people seeking gender-affirming care

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[2] Evidence Brief at [130].

[3] *Gillick v West Norfolk and Wisbech AHA* [1985] UKHL 7, at [188-189], emphasis added.

> to clinical trials. Young people already initiated on puberty blockers will continue to have access to these medications.
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> … the Canadian province of Alberta is currently considering banning the use of puberty blockers for young people aged under 16 years, referencing the recent decision made by NHS England.

[We note that on the 11 December 2024 it was announced that puberty blockers for under-18s with gender dysphoria will be banned indefinitely across the UK except for use in clinical trials.[4]]

18 Alberta has now introduced a bill titled the Health Statutes Amendments Act 2024 which will prohibit prescription of puberty blockers to minors, with some exceptions.[5] Health-care professionals, including but not limited to doctors, nurses, nurse practitioners and pharmacists, would be prohibited from prescribing hormone therapy drugs such as puberty blockers and hormone replacement therapies to treat gender dysphoria or incongruence for those 15 or under. The amendment would not ban specific drugs. Exceptions to the rules apply to minors aged 16 and 17 who are currently taking formal therapy or have parental, physician and psychologist approval to treat gender dysphoria or gender incongruence. Further amendments would enable the health minister to clarify procedures and add drugs that are in the scope of the legislation in the future.

19 The Evidence Brief states that except in South Australia (where the legal age of adulthood is 16 years), in all Australian states the prescription of puberty blockers for GD in people under 18 years requires **consent from all parties** who have parental responsibility for the young person.[6] In South Australia. This ruling has been applied even when a young person is deemed Gillick competent and consents to their own treatment. If there is any dispute between treating medical practitioners and parents regarding a young person's Gillick competence or diagnosis or treatment, a court application is required.

20 The Evidence Brief states that in Canada, the only federal legislation or governance related to use of puberty blockers to manage GD in Canada relates to the regulation of pharmaceuticals. Health Canada, through the Food and Drugs Act 1985, approves pharmaceuticals and audits and monitors their safety, efficacy and quality (126). The Canada Health Act legislates for the provinces and territories to administer and deliver most of Canada's health care services; all provincial and territorial health insurance plans are expected to meet national principles set out under the Act (127). Further detail related to minors, medical consent and assessing competence, and on how decisions are made related to puberty blockers, was not available.

21 The Evidence Brief states that in the United Kingdom, new legislative requirements were introduced in 2020 requiring a multi-professional review group to review all cases being referred by GISs to endocrine services, and all cases to follow an interim clinical guidance specification. The interim specification for children and young people with gender incongruence was published by NHS England in June 2023 (119). It requires the ICD-11 diagnostic criteria to be followed, and states that administration of puberty blockers is not to be commenced before Tanner stage 226 (119). When considering the validity of consent for medical treatment in the United Kingdom, practitioners are directed to the General Medical Council guidance for decision-making and

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[4] https://www.theguardian.com/society/2024/dec/11/puberty-blockers-to-be-banned-indefinitely-for-under-18s-across-uk

[5] https://edmontonjournal.com/news/local-news/alberta-ban-gender-surgery-puberty-blockers

[6] Evidence Brief, 117.

consent (121). That guidance sets out people's rights to make health care decisions for themselves when their consent is affected by the law ('mental health or other legislation and by common law powers of the courts' (such as the power to assess Gillick competence)) and advises medical practitioners to 'be aware of what treatment is, and is not, legally permissible'.[7]

[Again - we note that on the 11 December 2024 it was announced that puberty blockers for under-18s with gender dysphoria will be banned indefinitely across the UK except for use in clinical trials.[8]]

Inconsistency in Ministry of Health approach

22 The Position Statement for Progesterone says:

"The Ministry of Health does not support or recognise the practice of 'abortion reversal' and is concerned about reports that this may be offered in New Zealand.

'Abortion reversal' is not established by clinical research trials and could lead to severe side effects and adverse outcomes.

Heath professionals should not be providing or offering 'abortion reversal. Those who promote the use of medicines for this purpose are breaching section 20 (2) of the Medicines Act 1981.

23 Family First submits that there should be a similar Position Statement in substance and tone for puberty blockers given that the Evidence Brief is summarised in the Position Statement that it is "*not established by clinical research trials and could lead to severe side effects and adverse outcomes"* for the treatment of gender dysphoria. This is important given that puberty blockers can continue to be prescribed by clinicians off label under s 25 of the Medicines Act, as Progesterone can be for abortion reversal. If the Ministry is stating no evidence for progesterone and bans its use, how can they then say there is no good evidence for puberty blockers but still allow usage? A Position Statement consistent with the Evidence Brief must be urgently issued until the greater regulation on prescribing puberty blockers is in place.

Conclusion

24 Finally, Family First submits that NZ must stop the prescription of puberty blockers given the convergence of four factors along with the lack of quality research on the safety, reversibility and efficacy of puberty blockers. We also note:

(a) The Court of Appeal in the UK has found regarding puberty blockers: *"the clinical interventions involve significant, long-term and, in part, potentially irreversible long-term physical, and psychological consequences for young persons. The treatment involved is truly life changing, going as it does to the very heart of an individual's identity."*[9] As Dr Whitehall says, it is a *"massive intervention into the minds and bodies of children."*[10] Young or very young children/adults - those under 16 are most vulnerable and unable to give consent, and there is a lack of quality data for their parents/guardians to make decisions on informed consent.

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[7] Evidence Brief, 27

[8] https://www.theguardian.com/society/2024/dec/11/puberty-blockers-to-be-banned-indefinitely-for-under-18s-across-uk

[9] *R v Tavistock*, above n 9 at [148].

[10] *Children transitioning*, above n 10, on page 3.

(b) Highly vulnerable group of people – suicide rates in transgendering adults are reported to be at least 20 times that of the general population.[11] Mental illness is strikingly associated with gender dysphoria.[12]

(c) Avoiding harm is a fundamental ethical consideration for clinicians who are being asked to prescribe puberty blockers for gender dysphoria.

[11] Whitehall, pages 3-4.

[12] Whitehall - page 8.