Appendix Three: Comparison of policy options

Policy option	Description	Effects - stand alone	Effects - additive	Implementation	Implementation risks	Impact risks	International comparison
A Current baseline of close monitoring and adjustment • Monitor prescribing, services, new information, evidence • Report six-monthly • Prescribing led by expectations of Position Statement • Develop observational NZ research or longitudinal study	Keeps abreast of trends in NZ and internationally. Observational research on NZ patient experiences and outcomes – this is not a clinical trial but may still produce information that adds to understanding of benefits and risks	Firm basis for Medical Council to investigate/ prosecute complaints. Tracks prescribing trends Adjusts Position Statement or settings in response to new information	Base for all other options which can be added if and when needed	Already underway Ministry lead Health NZ important contributor Medical Council and Health & Disability Commissioner	Resource constraints may limit research funding.	More cautious prescribing that is not accompanied by improved service access may already be leading to negative patient outcomes 9(2)(h)	More cautious than but otherwise similar to Australia (outside Queensland), Canada, Japan In time, will contribute to international knowledge through observational research
B Baseline plus pre-planned trigger points for further action if required • Monitoring and research development as in Option A • Pre-plan trigger points for further action – changes to prescribing practices can result in rapid adjustments to address concerns	Maintains safety measures of the Position Statement as in Option A Plan and monitor for trigger points at which further action will be taken to respond to any new evidence of risk	Proactive planning to adjust settings in response to new information if required	Builds on from Option A Strategic approach to other options and when to use them	Ministry lead Health NZ important contributor Medical Council and Health & Disability Commissioner	Resource constraints may limit research funding.	Similar level of risk as Option A	Similar to cautious approach taken in countries mentioned in Option A
C Regulations to prohibit new prescribing while making youth gender services more accessible • Option has 2 parts: a) regulatory prescribing restriction b) increasing accessibility of holistic gender services for young people (including medical, psychological and social services) • Formally prohibit new prescribing • Develop alternative gender services for young people • Director-General of Health would provide updated advice once evidence on safety from the UK's clinical trial **and any other significant new evidence** is available • Regulations could be revoked following a revised safety assessment such as if there is evidence of benefits and an acceptable level of risk for use	<u>Regulations:</u> Regulations under Medicines Act s105(1)(d) to prohibit puberty blocker prescribing to treat gender incongruence or dysphoria in new patients <u>Services:</u> Youth gender services will follow a structured service delivery model incorporating medical, psychological and social support for gender incongruent young people. Accessibility will be improved to be more consistent across New Zealand.	Regulations will immediately stop all new puberty blocker prescribing for gender incongruence/dysphoria in young people. Whilst the regulations are to prevent new initiation of puberty blocker prescribing until further information on benefits or risks is available (such as through the UK's clinical trial), the timeframes of this evidence are unknown and could be many years away.		Ministry lead (regulatory process and enforcement of regulation) Health NZ would lead service provision Involvement of multiple health entities Enforcement will require new resource Development of holistic gender services would require redistribution of Health NZ and Ministry of Health resource	Penalties in the Medicines Act are less significant than existing safeguards (eg through the Medical Council) Establishing new or enhanced gender services will require health system resources to be reallocated, which could affect delivery of wider priorities Without additional resource, patient outcomes could be compromised, while services are consolidated	9(2)(h) Risk of unintended impacts that could include increase in harm to health or exacerbation of the higher victimisation and social isolation rates gender diverse young people experience A novel approach for medicines prescribing regulation in New Zealand that may set a precedent for government intervention in medicines use	Option is similar to the effect of the UK's current prescribing controls and mirrors awaiting the result of clinical trials before reconsidering regulatory restrictions Option differs to the UK in that there will be no provision for limited prescribing as is planned in the UK through clinical trials, once established
D New specific legislation • Prohibit or restrict prescribing, or limit who can receive treatment • Create structures and processes that support restricted prescribing	Bill to amend the Medicines Act specifically designed to limit prescribing of puberty blockers (eg specific assessment criteria, informed consent processes, patient monitoring)	Likely to significantly curtail prescribing Might require indication statements on prescriptions	Could work with Option A if legislation was designed to set requirements that could be met through changes to service provision	Ministry lead (legislative process and enforcement) Involvement of multiple health entities Resource needed to implement and enforce	Resource and opportunity costs for Ministry, PCO, Parliament Penalties would remain minor unless amended through legislation	9(2)(h)	Some states in the United States and planned in Alberta, Canada (though paused by judicial review)

PROACTIVELY RELEASED