

In Confidence

Office of the Minister of Health
Chair, Cabinet Legislation Committee

MEDICINES (ASSISTED DYING MEDICATIONS) AMENDMENT REGULATIONS 2021

Proposal

- 1 I seek authorisation to submit to the Executive Council the Medicines (Assisted Dying Medications) Amendment Regulations 2021.

Policy

- 2 The End of Life Choice Act 2019 (the Act) received Royal assent in November 2019. Assisted dying will become lawful on 7 November 2021. The Act is new for the health and disability sector and it is likely there will be some uncertainty from the health and disability sector about how it will operate.
- 3 The Medicines Act 1981 defines medicines as substances used for a therapeutic purpose, which include influencing a physiological process. Although I agree that medicines used in connection with an assisted dying service satisfies this definition, some health practitioners may not feel that it is clear whether medications for assisted dying are medicines under the Medicines Act 1981.
- 4 When the End of Life Choice Bill was being considered by Parliament, officials' advice to Select Committee was that regulations could be made under the Medicines Act during implementation to clarify that medications used for assisted dying are medicines as defined by the Medicines Act 1981.
- 5 The End of Life Choice Act intends to enable the provision of medicines for assisted dying to alleviate unbearable suffering that an eligible person does not find tolerable.
- 6 Section 19(2) of the Act enables assisted dying by specifying four methods for medicines to be administered or provided to an eligible person. Although the Act does not specify anything about the supply or regulation of those medicines, it:
 - 6.1 uses terminology consistent with the medicines regulatory regime in New Zealand;
 - 6.2 amends other legislation to position the assisted dying service within the health and disability system; and

- 6.3 appoints suitable professionals to roles where providing and prescribing medicines will be a required part of the assisted dying process.
- 7 Section 105(1)(i) of the Medicines Act 1981 enables regulations to be made to specify “substances or articles that are, or are not, medicines or medical devices” for the purposes of the Medicines Act. This regulation-making power has been used to provide clarification for health practitioners where appropriate – for example, this power has been used to clarify that substances used for abortion are medicines.
- 8 Consistent with this precedent, I propose that this regulation-making power be used to clarify the status of medications used for assisted dying under the Act, and that these are medicines that can be prescribed lawfully.
- 9 It is important to clarify that the medicines used for assisted dying are subject to the same conditions and requirements that apply to other medicines under the Medicines Act. Improving clarity would provide more certainty for prescribers and reduce the risk that some may choose not to be involved due to legal uncertainties.

Timing and 28-day rule

- 10 It is proposed that the Regulation come into force on 7 November 2021. This complies with the 28-day rule.

Compliance

- 11 The Regulation complies with:
- 11.1 the principles of the Treaty of Waitangi
 - 11.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993
 - 11.3 the principles and guidelines set out in the Privacy Act 1993
 - 11.4 relevant international standards and obligations
 - 11.5 the Legislation Guidelines (2018 edition), which are maintained by the Legislation Design and Advisory Committee.
- 12 Under section 105(1) of the Medicines Act 1981, before regulations are made, I am required to consult with such organisations or bodies that appear to be representative of persons likely to be substantially affected by the Regulation.
- 13 As this is a minor and technical amendment, there are no persons likely to be substantially affected by this Regulation so the statutory prerequisite is met.

Regulations Review Committee

- 14 There are no grounds for the Regulations Review Committee to draw the Regulation to the attention of the House of Representatives under Standing Order 327.

Certification by Parliamentary Counsel

- 15 The Regulation is certified by the Parliamentary Counsel Office as being in order for submission to the Executive Council.

Impact Analysis

- 16 The Regulation makes only a very minor change to the Medicines Regulations 1984 for the purposes of clarity, and therefore does not require an impact analysis.

Publicity

- 17 The Ministry of Health will communicate these changes directly to stakeholders.

Proactive release

- 18 This paper will be proactively released within 30 business days of a final decision by the Executive Council.

Consultation

- 19 As this Regulation makes only a minor and technical amendment, I do not consider it necessary for this to be consulted with any other organisations or entities beyond the Ministry of Health, as there are unlikely to be persons substantially affected by a clarificatory amendment.

Recommendations

I recommend that the Cabinet Legislation Committee:

- 1 **note** that there may be some doubt about whether medications which are prescribed for an assisted dying service are “medications” for the purposes of the Medicines Act 1981.
- 2 **agree** that the Medicines Regulations 1984 be amended to clarify that medicines which are used for assisted dying are subject to the same conditions and requirements that apply to other medicines under the Medicines Act 1981.
- 3 **note** that under section 105 of the Medicines Act 1981, I am required to consult with such organisations that are likely to be substantially affected by the Regulation before it is made.

- 4 **note** that the minor and technical nature of this amendment means that there are no persons or organisations likely to be substantially affected by this Regulation.
- 5 **authorise** the submission to the Executive Council of the Medicines (Assisted Dying Medications) Amendment Regulations 2021.

Authorised for lodgement

Hon Andrew Little

Minister of Health

PROACTIVELY RELEASED