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Ms Lynda Voltz, MP
Chair of the Legislation Review Committee
Parliament of New South Wales
6 Macquarie Street
Sydney NSW 2000

Poisons and Therapeutic Goods Amendment (Voluntary Assisted Dying Substances) Regulation 2023

Dear Chair



I refer to the Legislative Review Committee's comments on the Poisons and Therapeutic Goods Amendment (Voluntary Assisted Dying Substances) Regulation (**Amending Regulation**) in Legislation Review Digest No. 9/58 dated 6 February 2024.

Thank you, and the Committee members, for your consideration of the Amending Regulation. I note that the Committee has raised some issues with the form and/or intention of the Amending Regulation.

Prior to the amendments made by the Amending Regulation, there were some areas in the voluntary assisted dying space that were not properly regulated by either the Voluntary Assisted Dying Act 2022 (**VAD Act**) or the Poisons and Therapeutic Goods Regulation 2008 (**PTG Regulation**). The Amending Regulation was necessary to fill the regulatory gap in this space to ensure the safe handling of voluntary assisted dying substances.

The regulation making power in s 187 of the VAD Act allows regulations to be made about matters that are required or permitted to be prescribed under the Act, or necessary or convenient to be prescribed for the carrying of the Act. However it does not extend to address this regulatory gap. Accordingly, amendments were required to the PTG Regulation.

Voluntary assisted dying substances are certain Schedule 4 and Schedule 8 substances that have been approved by the Health Secretary under the VAD Act. The Schedule 4 and Schedule 8 substances that have been approved as voluntary assisted dying substances are also used for non-voluntary assisted dying purposes. In considering amendments to the PTG Regulation, it was necessary to ensure that the existing provisions about Schedule 4 and Schedule 8 substances in the PTG Regulation would continue to apply where the substance was being used for non-voluntary assisted dying purposes.

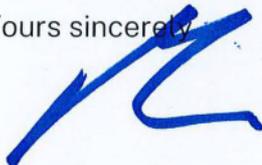
The VAD Act contains requirements with regards to the supply, prescribing, storage, labelling, possession and record-keeping of these substances. The PTG Regulation also contains requirements in relation to Schedule 4 and Schedule 8 substances. As you are aware, the Amending Regulation amends the PTG Regulation to establish a tailored regime to regulate voluntary assisted dying substances. While the VAD Act prevails over the PTG Regulation to the extent of any inconsistency, having two pieces of legislation that cover the same matters but are not aligned, is administratively and operationally problematic, and has the potential to be confusing to persons trying to understand their responsibilities in this space.

The Amending Regulation disapplies, in so far as it relates to voluntary assisted dying substances, most of the provisions in the PTG Regulation relating to Schedule 4 and 8 substances and instead creates a specific tailored regime to regulate voluntary assisted dying substances. The intention behind creating this new Part in the PTG Regulation, rather than amending each provision of the PTG Regulation to create carve outs for special rules relating to voluntary assisted dying substances, was to ease clarity and to ensure the appropriate management of these substances.

The Medicines, Poisons, and Therapeutic Goods Act 2022 will replace the Poisons and Therapeutic Goods Act 1966 on commencement. A draft Medicines, Poisons and Therapeutic Goods Regulation to support the new Act is currently out for public consultation. As part of the Ministry of Health's work in finalising the new regulation, consideration will be given to the Committee's feedback, and whether improvements could be made to further ease understanding of regulation in this space.

Should you have any questions or require any further information, please contact [REDACTED], A/Senior Legal Officer, Legal and Regulatory Services at [REDACTED] or on [REDACTED].

Yours sincerely,



Ryan Park MP
Minister for Health
Minister for Regional Health
Minister for the Illawarra and the South Coast