COMMISSIONER FOR
BETTER REGULATION

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20 March 2017

Dr Anna Peatt
Chief Officer
Drugs and Poisons Regulation
Department of Health and Human Services
50 Lonsdale St
MELBOURNE VIC 3000

Dear Dr Peatt

I would like to thank the staff of the Department of Health and Human Services for working with our team on the preparation of the Regulatory Impact Statement (RIS) for the proposed *Drugs, Poisons and Controlled Substances Regulations 2017*. These Regulations are proposed due to the sunsetting of current arrangements in May 2017.

Under section 10 of the Subordinate Legislation Act 1994 (the Act), the Commissioner for Better Regulation is required to provide independent advice on the adequacy of all RIS prepared in Victoria. The Commissioner's role is to advise on the adequacy or otherwise of the analysis presented in the RIS, rather than the merits or otherwise of policy or regulatory proposals. A RIS is deemed to be adequate when it contains analysis that is logical, draws on relevant evidence, is transparent about assumptions made, and is proportionate to the proposal's expected effects. The RIS also needs to be clearly written so that it can be a suitable basis for public consultation.

I am pleased to advise that the final version of the RIS received by us on 17 March 2017 meets the adequacy requirements of the Act.

The Regulations include controls to administer, prescribe or supply drugs. Examples of requirements include rules surrounding the writing of prescriptions, pharmacists' supply of drugs to patients and for securely storing and destroying drugs and poisons to prevent theft, diversion or misuse. The proposed Regulations re-make the current Regulations with limited amendments. The proposed Regulations affect a range of stakeholders such as medical professionals, pharmaceutical, chemical and other industries, educational and research bodies, and organisations that provide healthcare services such as hospitals and aged care facilities. The proposed Regulations operate within a broader legislative context which has been in place for many decades, including Federal requirements and Australia's obligations under several international treaties.

To estimate the expected costs of the proposed Regulations, the Department has reviewed its costs in administering and enforcing the current Regulations, and surveyed a sample of regulated parties' costs of compliance. Based on this review, the Department estimates that the costs of the Regulations for all licence and permit holders wishing to manufacture, sell, supply, purchase or use drugs and poisons are $6.44 million per year.

As with the current Regulations, the proposed Regulations aim to fully recover the total costs of administration and enforcement, with the exception of patient-specific treatment warrants and permits — the Department explains in the RIS its choice not to recover these costs on public interest grounds (p.28). The Department's review of its costs has changed its understanding of the nature of the costs of different administrative and enforcement activities, as well as how these costs are distributed across different categories of licence and permit holders. As a result the proposed Regulations make several changes to some of the individual fees paid by licence and permit holders. These include changes to fees for both new applications and for licence/permit renewals and

amendments. The Department expects that the new fee structure outlined in the proposed Regulations will achieve a better match between the costs it incurs, and the fees paid by different categories of licence and permit-holder.

The RIS indicates that the proposed Regulations would be expected to yield net benefits for society if they prove to be effective at reducing the number of overdose deaths due to inappropriate use of drugs by an average 1.5 persons per year (or around one per cent of the current average annual death rate due to pharmaceutical drug overdose). The Department expects that the benefits of the proposed Regulations will be larger than this, and therefore it considers that the proposed Regulations will yield substantial net benefits for the Victorian community.

In identifying the proposed Regulations as the preferred policy option, the Department considered that the range of possible alternative policy approaches available to achieve its regulatory objectives was constrained by the overarching legislative framework mentioned above. The RIS includes a discussion of two other regulatory approaches, as well as a discussion of various options for modifying specific provisions of the current Regulations.

The Department states in the RIS that some policy options may be subject to future consideration as it continues to refine regulatory arrangements in this policy area over time. Once the proposed Regulations are made, the issue most likely to be considered further will be arrangements to support the introduction of real-time prescription monitoring.

It is government practice that this letter be published with the RIS when it is released for public consultation.

Should you wish to discuss any issue raised in this letter, or the implications of new information or policy options identified through the public consultation process for your proposal, please do not hesitate to contact me on (03) 9092 5800.

Yours sincerely

Anna Cronin
Commissioner for Better Regulation