COMMISSIONER FOR
BETTER REGULATION

GPO Box 4379
Melbourne Victoria 3001
Telephone: 03 9092 5800

29 January 2018

Ms Melissa Skilbeck
Deputy Secretary
Regulation, Health Protection and Emergency Management Division
Department of Health and Human Services
Level 16, 50 Lonsdale Street
MELBOURNE VIC 3000

Dear Ms ~~Skilbeck~~ Melissa

I would like to thank the staff of Real-Time Prescription Monitoring (RTPM) Implementation team in the Department of Health and Human Services (DHHS) for working with the staff at the OCBR on the preparation of the Regulatory Impact Statement (RIS) for the proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018.

Under section 10 of the *Subordinate Legislation Act 1994*, the Commissioner for Better Regulation is required to provide independent advice on the adequacy of all RIS prepared in Victoria. As you know, the Commissioner's role is to advise on the adequacy 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 29 January 2018 meets the adequacy requirements of the *Subordinate Legislation Act 1994*.

In the 2016-17 State Budget, the Victorian Government announced a $29.5 million commitment to implement SafeScript, Victoria's RTPM system. SafeScript will use computer software to allow prescription and dispensing records for certain medicines to be transmitted in real-time to a centralised database which can then be accessed by doctors and pharmacists during a consultation. The main aim of this initiative is to identify potential misuse of prescription medicines, thereby reducing associated harm and deaths.

Changes to the *Drugs, Poisons and Controlled Substances Act 1981* (the Act) establishing the legislative framework (and the monitored poisons database) to implement SafeScript passed Victoria's Legislative Assembly and Legislative Council in September and October 2017 respectively.

The Act establishes two categories of poisons — 'monitored poisons' and 'monitored supply poisons'. Monitored poisons are those for which supply records will be included in SafeScript. Monitored poisons in the Act include all S8 poisons (such as morphine and pethidine). Monitored supply poisons are those for which all medical practitioners, nurse practitioners and pharmacists will need to check SafeScript prior to their prescribing or supply.

The Act provides for Regulations to be made to specify matters including:

- which medicines are 'monitored poisons' (in addition to those specified in the Act) and 'monitored supply poisons'; and
- exceptions which specify the settings and/or circumstances in which health professionals do not need to check the database before prescribing or supplying a monitored medicine.

The proposed Regulations:

- prescribe 12 S4 medicines (prescription-only medications) as monitored poisons (in addition to the monitored poisons specified in the Act);
- exempt registered medical practitioners, nurse practitioners or pharmacists from the requirement to check the database where the patient is:
    - an in-patient being treated in a hospital (except on discharge); or
    - being treated in an emergency department of a hospital (except on discharge); or
    - a prisoner being treated in a prison; or
    - a person being treated in a police gaol; or
    - a resident being treated in an aged care service;
- specify Prescription Exchange Services (PESs) (electronic systems, connected to medical prescribing and pharmacy dispensing systems, which collect prescription records) as the entities that are required to provide prescription information to SafeScript.

The RIS uses a mix of qualitative and quantitative evidence to explain the effects of options, and outlines the assumptions underlying, and uncertainties associated with, the analysis.

The proposed list of prescribed medicines is based on the recommendations of the External Advisory Group (EAG). These recommendations draw on the findings of an extensive review of medical research conducted by Austin Health that the Victorian Government commissioned in 2017 to develop an evidence base into which medicines should be monitored in Victoria's RTPM system. The proposed Regulations adopt these recommendations in full, and the RIS:

- explains the reasons for the recommendations (based on factors such as the risk of harm associated with individual medicines and classes of medicines; potential drug trends; and drugs included in prescription monitoring systems in the United States, where the systems are well-established); and
- estimates the net benefits of including the selected additional medicines, in addition to those specified in the Act.

The RIS estimates the possible costs of prescribing these medicines to be around $189 million over ten years, but with net benefits of around $2 billion over that time (due largely to reduced deaths and harm associated with medicine misuse). It also presents a range of 'sensitivity analyses' that vary assumptions about costs (such as how long it takes to check the database) and benefits (how much it will reduce harms and deaths). It concludes that, even if costs were at the upper end and benefits at the lower end of the estimated ranges, there would be net benefits of around $500 million dollars.

With the proposed exceptions, DHHS has aimed to balance patient safety with prescriber and pharmacist regulatory burden. Thus, the proposed exceptions are settings and circumstances where patients receive medicines under close supervision and DHHS considers the risk that a patient would be supplied medicines from multiple providers is low. Given a lack of data, this analysis is qualitative.

The RIS includes a detailed implementation plan, which features:

- phased implementation, to allow clinicians to familiarise themselves with the system and incorporate it into their clinical practice, before use becomes mandatory in April 2020;
- DHHS's proposed thorough approach to ongoing monitoring and evaluation; and
- a formal mid-term review in 2023-24 once data for full three full years of RTPM operation are available.

The mid-term review will help DHHS to identify whether RTPM is achieving its intended objectives, and any unintended possible consequences that need to be managed. It will, therefore, provide a basis for reviewing the design of the system, including the scope of medicines monitored and the exceptions.

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