Criteria for inclusion of additional medicines in SafeScript

Framework for Schedule 4 medicines

Introduction

Schedule 4 medicines that are being monitored in SafeScript from the onset of implementation have been included based on the findings from a literature review that was conducted in 2017 and recommendations from the SafeScript External Advisory Group. Membership of the advisory group included key medical and pharmacy organisations, including the Australian Medical Association, Pharmacy Guild of Australia, Royal Australian College of General Practitioners and Pharmaceutical Society of Australia, as well as alcohol and other drug organisations and consumers.

A framework has been developed to guide future recommendations on the inclusion of additional Schedule 4 medicines in SafeScript. Importantly, this will enable a consistent and evidence-based approach to be applied. Recommendations on the removal of any Schedule 4 medicine monitored in SafeScript will also be assessed against this framework.

The framework has adopted the main determinants of the literature review. Given the use of SafeScript will become mandatory, the framework also includes consideration of the overall regulatory impact.

For noting, given the existing additional regulatory controls in place on the supply and use of Schedule 8 medicines, any new Schedule 8 medicine will always be monitored in SafeScript. This framework refers to additional Schedule 4 medicines being considered for monitoring.

Process for review of medicines

The review of medicines monitored in SafeScript will be undertaken by the department in consultation with the Expert Advisory Committee on Potential Misuse of Drugs of Dependence. The interval between each review will be no longer than every five years, or when there is compelling new evidence of harm for particular medicines.

Including new medicines in SafeScript will require an amendment to Schedules 5 – Monitored poisons and 6 – Monitored supply poisons of the Drugs, Poisons and Controlled Substances Regulations 2017.

This will require a submission to the Governor-in-Council and approval by the Minister for Health. The Minister will need to be assured that a thorough consultation process has been undertaken, and any recommended changes are based on best evidence and expert advice. A Regulatory Impact Statement and wider public consultation may also be necessary.

Criteria for inclusion of additional Schedule 4 medicines

1. Evidence of harms

Medicines included in SafeScript should demonstrate evidence of harms, which include misuse, abuse, addiction and fatal and non-fatal overdoses. The evidence of harms should be at least the same extent to that of medicines currently monitored in SafeScript. As an indicative measure, medicines recommended for inclusion by the advisory group had a fatality toxicity index (number of deaths per million prescriptions) of over 100.

When assessing evidence of harms, the following should be considered:

- the severity of harm
- the total burden of harm relative to the total volume of the medicine prescribed
- whether harm results from use of a substance on its own or in combination with other high-risk substances (and the extent of the extra harm from the combination).

For example, pregabalin was considered for inclusion as part of the updated literature review conducted in 2019. Based on the findings in the literature review, pregabalin was not recommended for inclusion. While pregabalin had the greatest number of deaths from the medicines analysed in the literature review, its fatality toxicity index (harm relative to number of prescriptions supplied) was below the 100 threshold. Further, harms were not observed when pregabalin was prescribed own its own, but it potentiated the harms from opioids and benzodiazepines.

Sources for evidence of harms may include locally or internationally peer-reviewed journals and datasets. Specific datasets may include:

- Drug-related deaths reported to the Coroners Court of Victoria
- Data from the National Coronial Information System
- Ambulance attendances data from Ambulance Victoria
- Poisonings reported to the Victorian Poisons Information Centre.

For noting, none of these datasets are more important than one another. Ambulance attendances and Poisons Information Centre data may be used to provide earlier signals of evidence of harm, that is, as a predictor of increased deaths before they are observed.

2. Trends in prescribing, misuse and abuse

Prescribing trends influence consumption rates, which in turn can influence aberrant use, dependence, overdoses, hospitalisations and deaths. Prescribing rates and trends can be influenced by a number of factors, including the introduction of new drugs and formulations; prescriber education; changes in marketing approaches, regulations and Pharmaceutical Benefits Scheme subsidies; and changes in population life expectancy and burden of disease.

Medicines considered for inclusion in SafeScript should demonstrate increasing trends in misuse and abuse in a global and/or Australian context, as these can help predict emerging threats of harm locally. Trends should reflect a consistent increase over time.

Sources of data for trends in prescribing include datasets such as supply data from the Pharmaceutical Benefits Scheme.

3. ‘Substitution effect’

Consideration should be given to the potential for the ‘squeezed balloon’ or ‘substitution’ effect, whereby uncoordinated and/or increased regulation of a medicine or medicine class may result in misuse and harm being displaced to other medicines or illicit substances.

For example, the recommendation to monitor all benzodiazepines, not just diazepam, which is involved in the greatest number of pharmaceutical drug-related deaths, was based on the likely potential for the ‘substitution’ effect to occur.

4. ‘Chilling effect’

Increased regulation or monitoring of specific medicines or medicine classes may result in the ‘chilling effect’, whereby prescribers may become reluctant to prescribe monitored medicines. The chilling effect may result in patients receiving suboptimal care, reduced access to treatment and/or poorer health outcomes. Consideration should be given to the potential for these unintended consequences and their likely impact.

For example, olanzapine was not recommended for monitoring in 2019 as there were concerns that clinicians would be discouraged from prescribing atypical antipsychotics to patients which could have a negative impact on their therapeutic outcomes (given that quetiapine was already monitored in SafeScript).

5. Regulatory burden and cost-benefit

The addition of a monitored medicine in SafeScript, while intended to provide benefits through more informed clinical decisions and safer patient care, should not add unnecessary or unreasonable regulatory burden on health practitioners. Overly burdensome programs can threaten their success and result in poor outcomes.

The social and economic benefits of including a medicine in SafeScript may include (but are not limited to):

- reduction in deaths
- reduction in emergency department presentations
- reduction in hospital admissions
- reduction in supply of high-risk medicines.

Given the use of SafeScript will become mandatory, the marginal benefits of monitoring an additional medicine should be considered alongside the marginal costs imposed on prescribers and pharmacists to check SafeScript each time the medicine is prescribed or dispensed. Depending on the volume of prescriptions, these marginal costs may be significant.

The Regulatory Impact Statement for SafeScript noted that it was unlikely that the Benefit Cost Ratio would increase by monitoring additional Schedule 4 medicines to those already included in SafeScript.

For noting, as of 2019, any proposed regulatory change that is estimated to increase regulatory burden by over $2 million each year requires a Regulatory Impact Statement and wider public consultation. Note: this amount is subject to change over time.

6. Inter-jurisdictional approaches

Consideration should be given on whether additional medicines that are being considered for monitoring in SafeScript have been included in prescription monitoring systems implemented overseas or in other Australian jurisdictions. Consideration should also be given on how decisions in other jurisdictions were reached and what the level of evidence base was to support this.

It is important to note that the inclusion of a medicine in another jurisdiction does not necessarily mean it is suitable for monitoring in Victoria. The medicines monitored in Victoria must reflect the requirements and circumstances specific to Victoria, in particular, consideration that the use of SafeScript will be mandatory.