Fact Sheet

Monitored Drugs: Criteria for the inclusion of a Schedule 4 drug

Prescription drugs that pose the greatest risk of harm to the South Australian community are monitored through **Script**Check**SA** and are referred to as *monitored drugs*[1].

Monitored drugs include:

- any Schedule 8 drug (e.g. dexamfetamine, methadone, morphine, oxycodone)
- any Schedule 4 drug that is a Benzodiazepine (e.g. diazepam, temazepam)
- any Schedule 4 drug that contains Codeine (e.g. codeine with paracetamol, codeine with paracetamol and doxylamine)
- the following Schedule 4 drugs:
    - Gabapentin
    - Pregabalin
    - Quetiapine
    - Tramadol
    - Zolpidem
    - Zopiclone.

The Schedule 4 drugs have been included because evidence demonstrates their potential to increase harms associated with Schedule 8 drugs if co-prescribed. Both national and international evidence was considered, in particular the findings from the Victorian Austin Health literature reviews conducted in 2017 and 2019.

SA's monitored drugs list is consistent with the medicines monitored in other jurisdictions.

Schedule 4 monitored drug inclusion criteria

Following review of the available evidence and criteria used in other jurisdictions, the **Script**Check**SA** Clinical Advice and Pathways Working Group (CAPWG) developed criteria to guide the addition or removal of Schedule 4 drugs from the list of monitored drugs. SA's criteria is consistent with other jurisdictions to ensure a national approach.

A decision to monitor a Schedule 4 drug needs to be carefully considered, strongly justified and supported by clinical evidence to ensure widespread support and to deliver the objective of **Script**Check**SA** – to reduce the potential harms associated with prescribed Schedule 8 drugs. Any recommendation to include (or remove) a Schedule 4 drug from SA's monitored drugs list will be assessed using these criteria.

Noting the greater regulatory controls on the supply and use of Schedule 8 drugs, any new Schedule 8 drug will always be monitored.

[1] Regulation 3 of the Controlled Substances (Poisons) Regulations 2011

1. **Evidence of harms (misuse, abuse, addiction and fatal / non-fatal overdoses)**
   Consideration should be given to the severity of harm, the total burden of harm relative to the total volume of drug prescribed and whether the harm associated was because of a medicine on its own or in combination with other high-risk medicines.

2. **Trends in prescribing, misuse and abuse**
   A demonstrated increasing trend in misuse and abuse of the medicine in SA. Consideration should be given to interstate and international evidence to assist in predicting locally emerging trends of harm.

3. **Potential for the 'substitution effect'**
   Where monitoring a particular medicine or medicine class causes or can cause misuse or harm to be displaced to other medicines or illicit drugs.

4. **Potential for the 'chilling effect'**
   Where monitoring a particular medicine or medicine class results or could result in prescribers becoming reluctant to prescribe the drug, thereby leading to patients receiving sub-therapeutic treatment and poorer health outcomes.

5. **Regulatory burden (including cost-benefit) and clinical utility**
   The addition of a monitored drug in **Script**Check**SA** is intended to provide benefits through more informed clinical decisions and safer patient care. However, monitoring a medicine should not add unnecessary or unreasonable regulatory burden on health practitioners or the Regulator (Drugs of Dependence Unit).
   The benefit of monitoring a medicine should be considered in the context of:

   - the potential increased demand for addiction medicine, pain management, psychiatry and other specialist services
   - the regulatory burden to users of **Script**Check**SA**
   - the social and economic benefits to individuals and the community (reduced deaths, hospital admissions, use of high-risk medicines).

6. **Inter-jurisdictional approaches**
   Where appropriate, inclusion of medicines should align with other jurisdictions.

Review process

SA's monitored drugs list will be periodically reviewed by the Department for Health and Wellbeing in consultation with an Expert Advisory Group. Any changes to the monitored drugs list will require an amendment to the Controlled Substances (Poisons) Regulations 2011 and will undergo public consultation.

For more information

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