Government of **Western Australia**
Department of **Health**

Consultation Report

Amendments to the Medicines and Poisons Regulations 2016 and the Schedule 8 Medicines Prescribing Code

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Executive Summary

The introduction of ScriptCheckWA, Western Australia's Real Time Prescription Monitoring (RTPM) system, means prescribers and dispensers have greater and more timely access to information about their patient's exposure to medicines monitored by the System. This provides an opportunity to reduce the regulatory burden for prescribers, without diminishing the public health protections afforded by the Medicines and Poisons legislation.

Between 12 August and 7 October 2022, the Department undertook public consultation on proposed changes to the Western Australian Medicines and Poisons Regulations 2016 (the Regulations) and the Schedule 8 (S8) Medicines Prescribing Code (the Prescribing Code).

The online consultation survey was accompanied by a Discussion Paper[1] which outlined options for updates to the regulation of:

- Medicines to be monitored by ScriptCheckWA.
- Registration for and use of ScriptCheckWA by prescribers and pharmacists.
- Prescribing of stimulant medicines in Schedule 8 (S8).
- Prescribing of medicinal cannabis in S8.

The Discussion Paper also included potential amendments to a number of other regulations. These proposed changes are not directly related to real-time prescription monitoring but rather relate to regulations assessed as not operating as effectively or efficiently as possible.

There were 39 submissions to the consultation. Eighteen were from organisations and 21 were from individuals. Responses were received from key stakeholders representing the medical profession, the nursing profession and the pharmacy profession as well as from patients and consumers more generally.

Schedule 4 reportable medicines

These are Schedule 4 (S4) prescription-only medicines considered to pose a higher-risk for dependency and diversion. The proposed list for monitoring via ScriptCheckWA was all benzodiazepines in S4, pregabalin and gabapentin, tramadol, quetiapine, codeine-based preparations in S4, zolpidem and zopiclone.

Overall, 77.8% of respondents either supported or partially supported the proposed list.

It was recommended that the proposed list be included in the Regulations, as the S4 reportable medicines defined in Section 77 of the *Medicines and Poisons Act 2014.* The list is very similar to the S4 medicines monitored in other States and Territories.

There was little support for including requirements for prescribers to be authorised before they could prescribe these higher-risk S4 medicines. Other States and Territories have not introduced authorisation requirements for these S4 medicines.

It was recommended that, in high-risk clinical scenarios, such as where the patient is recorded as a Drug Dependent Person (DDP), the prescriber would be required to document risk mitigation steps associated with prescribing monitored S4 medicines in the patient's clinical notes.

[1] https://consultation.health.wa.gov.au/medicines-and-poisons-regulation-branch/consultation-amendments-to-the-medicines-and-poiso/user_uploads/discussion-paper-amendments-medicines---poisons-regulations-2016-and-prescribing-code-august-2022.pdf (accessed 19 December 2022).

To facilitate patient identification, when prescribing and dispensing events involving monitored S4 medicines are captured by ScriptCheckWA, it is recommended that the patient's date of birth be required on all S4 prescriptions. The widespread use of computer systems for prescribing will limit the regulatory burden for prescribers, and this requirement would mean all prescriptions would need to be issued with the patient's name, address and date of birth as identifiers.

Repeat intervals on prescriptions for monitored S4 medicines, were also considered. Consultation feedback supported the proposal that no repeat intervals be mandated, which is consistent with other States and Territories.

Mandates associated with Real Time Prescription Monitoring

Requirements written into law can relate to whether a prescriber or dispenser must register to use the RTPM system or must query the system, in particular circumstances. Reduction in risky prescribing of monitored medicines is generally higher when there are mandates for registration for access or use of RTPM systems.

The majority of respondents (63%) supported mandatory registration for access to ScriptCheckWA. There was also a reasonable level of support (59.3%) for mandating use of ScriptCheckWA, in some or all circumstances, where prescribing and dispensing of monitored medicines was being considered. The Department continues to support making it compulsory for prescribers and pharmacists to register to use ScriptCheckWA but allowing the individual practitioner to make the decision as to whether they will view their patient's record within ScriptCheckWA.

Regulation of stimulant medicines in Schedule 8

The current stimulants regulatory scheme commenced in August 2003.

The majority of prescriptions for stimulant medicines in S8 are issued to treat Attention Deficit Hyperactivity Disorder (ADHD). Only 0.3 percent of children and 5.1 percent of adults are treated with stimulant medicines for other medical conditions, such as narcolepsy, depression and brain injury.

Currently, there are detailed requirements in the Regulations controlling the prescribing of stimulants in S8. The constraints of the Regulations mean the controls over prescribing stimulants, have not kept pace with changes in clinical practice and the increased mobility of patients.

Consultation questions about stimulant prescribing resulted in feedback from the largest number of respondents. The majority were involved in managing patients diagnosed with ADHD.

While many of the requirements for stimulant prescribing proposed in the Discussion Paper were well supported, there was concern expressed about:

- expanding initiation of stimulant medicines to general practitioners;
- increased length of mandatory specialist review periods (12 months to 3 years), particularly in relation to paediatric and adolescent patients;
- patient age restrictions for treatment initiation by paediatric versus adult specialists;
- dose adjustment by non-specialist prescribers; and
- continued recommendations for use of urine drug screening.

A new stimulant regulatory scheme is proposed, which will be similar to the scheme used for other S8 medicines, where the detail of the prescribing controls is included in the Prescribing Code rather than the Regulations themselves.

Elements of the new scheme are as follows:

- Support specialist input for diagnosis of ADHD and other medical conditions for which stimulant medicines are a recognised therapeutic intervention and, consequently, limit initiation and stabilisation of treatment with stimulant medicines to these same clinicians.
- Include provisions within the Regulations for 'case-by-case' approval of prescribers to initiate stimulant treatment, to accommodate future development of training and credentialing programs for other prescribers, such as general practitioners.
- Support shared care between the patient's specialist medical practitioner and their usual treating health practitioner, but not require formal notification to the Department.
- Retain the 12 month specialist review for children but increase the mandatory time between review for adults being prescribed stable stimulant regimens.
- Remove restrictions on the upper patient age at which a paediatric specialist can initiate stimulant treatment, and similarly, remove the lower patient age at which adult specialists can initiate stimulant treatment.
- Allow prescriptions for stimulant medicines, written in other States and Territories to be dispensed in Western Australia (WA).
- Include a series of parameters relating to the drug, the prescriber and the patient within the Prescribing Code, and allow prescribing without authorisation or notification where all these parameters are met.
- Only require authorisation to prescribe stimulants where high-risk parameters are met and ensure there is ongoing specialist input on prescribing stimulants for these patients.
- Only require notification of cessation of prescribing stimulant medicines, where the stimulant medicines are ceased due to high-risk circumstances existing.
- Continue to include special arrangements for patients, who are admitted to hospital or whose ongoing treatment is within a custodial setting.

It was also determined that further targeted consultation was required to:

- better define substance abuse/misuse for the purposes of the Prescribing Code; and
- develop an evidence-based approach to the requirement for prescribing authorisation for stimulant medicines, where the patient has significant psychiatric co-morbidities.

Regulation of cannabis-based products in Schedule 8

The current regulatory scheme for cannabis-based products in S8 was developed soon after cannabis had been included in S8 and before product availability in Australia. The scheme was modelled on the current Stimulant Regulatory Scheme, and requires either notification of prescribing or authorisation to prescribe, in all cases, where cannabis-based products in S8 are being prescribed.

Five years after cannabis was re-scheduled to allow therapeutic use, most notifications and applications for prescribing authorisation for these products fit within what could be considered lower-risk parameters.

During 2022, over a total of over 11,000 applications for authorisation and notification of treatment with medicinal cannabis were received, with only 1.2% of the total applications/notifications declined because prescribing met high-risk criteria, and there was no support from a relevant specialist medical practitioner.

The above experience, combined with the increased information visibility afforded by ScriptCheckWA, provides an opportunity to reduce the regulatory burden associated with prescribing medicinal cannabis in S8.

A similar regulatory scheme to that used for opioids is proposed, where a number of parameters are used to divide prescribing into high-risk and lower-risk, where the prescriber only requires a patient and regimen specific authorisation to prescribe in high-risk circumstances.

The consultation survey sought feedback on specific parameters to be included in the Prescribing Code. Following analysis of the feedback, it is proposed that, if any of the following parameters are met, the prescriber would be required to seek authorisation prior to prescribing cannabis-based products in S8 for their patient:

- Total daily dose of tetrahydrocannabinol (THC) greater than 40mg, unless the prescriber is a Therapeutic Goods Administration (TGA) Authorised Prescriber and is approved to prescribe higher doses.
- Product is intended to be used via vaporisation, unless the product is TGA registered, or the prescriber is a TGA Authorised Prescriber for these type of products.
- More than two cannabis-based products in S8 are being prescribed concurrently, unless the prescriber is a TGA Authorised Prescriber for all products being prescribed.
- Patient is under 18 years-of-age.
- Patient is recorded as a DDP or an oversupplied person.
- Patient has a recent significant history of substance misuse.
- Patient has recent, or a history of, a significant psychiatric diagnosis.
- Patient is also being treated with other S8 medicines that themselves require prescribing authorisation, such as high dose opioids or benzodiazepines in S8.

Other miscellaneous regulatory changes

Minor amendments are recommended to a number of regulations, including:

- removal of the requirement for pharmacists to seek approval from the Department before transferring repeats of S8 prescriptions to another pharmacy;
- clarification that repeats of electronic prescriptions are not subject to repeat retention requirements;
- an allowance for the Chief Executive Officer (CEO) of Health to be able to approve a medical practitioner to prescribe a veterinary medicine for a human, in exceptional circumstances;
- clarification of the circumstances, when a ‘wet’ signature is required; and
- re-drafting to support use of electronic medication charts in residential care facilities as prescriptions.

Consultation on adopting Appendix M of the National Poisons Standard, by reference, was also undertaken. Appendix M provides for imposition of additional conditions on Schedule 3 (S3) (pharmacist-only) substances to support their down-scheduling from Schedule 4 (prescription-only). The concept of Appendix M is that there may be prescription-only medicines, where a case can be made for the substance meeting the S3 factors but where there are some specific additional public health risks that are above those normally considered acceptable for S3 substances.

The majority of respondents supported adoption of this Appendix M, by reference. In addition to adopting this Appendix, it is proposed that a pharmacist must make a record and add a patient label each time they supply a S3 Appendix M medicine.

List of Recommendations

Recommendation 1: The list of S4 medicines designated as 'reportable' should be all benzodiazepines in S4, pregabalin and gabapentin, tramadol, quetiapine, opioid-based preparations in S4 (which includes codeine-based preparations), zolpidem and zopiclone.

Recommendation 2: There is no delay between including a list of S4 reportable medicines in the Regulations and inclusion of prescribing and dispensing data for these medicines in ScriptCheckWA.

Recommendation 3:

- The Regulations be amended to require prescribing of S4 reportable medicines to be in accordance with the 'Prescribing Code'.
- Include any prescribing requirements for S4 reportable medicines in the same 'prescribing code' as the prescribing restrictions for S8 medicines.
- Suitably amend the definition of the 'Prescribing Code' in Regulation 114.

Recommendation 4: Amend the Prescribing Code to require prescribers make a record of risk mitigation steps in the patient's clinical notes, including communication with other relevant prescribers, when prescribing S4 reportable medicines for patients recorded as a Drug Dependent Person or an Oversupplied Person.

Recommendation 5: When prescribing S4 reportable medicines, documentation of risk mitigation steps are not mandated through the Prescribing Code when doses are (1) being administered to the patient (no dispensing or other supply), (2) when the patient is in a custodial or residential care setting or (3) when the S4 reportable medicines are being prescribed as part of 'end of life' care (life expectancy is less than 2 months and therefore prescribing should be for no more than 2 months).

Recommendation 6:

- The Regulations be amended to require all prescriptions for S4 and S8 medicines (to treat humans) be issued with three patient identifiers: their name, address and date of birth.
- The Regulations to also include a clause to allow a pharmacist to dispense a prescription, despite the prescription not being issued with the patient's date of birth provided the pharmacist can adequately verify the patient's date of birth and the Regulations to require a pharmacist to record the patient's date of birth when dispensing a prescription.

Recommendation 7: That there be no requirement to include a repeat interval, where repeats are prescribed for monitored S4 medicines (status quo, no regulatory amendment required).

Recommendation 8: The Regulations be amended to require medical practitioners, nurse practitioners, dentists and pharmacists to register to use ScriptCheckWA, provided the practitioner practices in WA ,or routinely prescribes or dispenses for patients who ordinarily reside in WA (accommodates telehealth providers and online pharmacies with an address outside WA).

Recommendation 9: No delay in commencement of the regulatory requirement for practitioners to register to use ScriptCheckWA.

Recommendation 10: The Regulations to include a defence for prescribers and pharmacists, who do not complete registration for ScriptCheckWA, where the health practitioner does not prescribe or dispense monitored medicines as part of their practice.

Recommendation 11: Use of ScriptCheckWA by prescribers and pharmacists is not mandated through the Regulations (status quo, no regulatory change required).

Recommendation 12: The Regulations be amended to remove the requirement for a Stimulant Prescriber Number to be issued.

Recommendation 13:

- The Regulations be amended to allow specialist medical practitioners in a class described in the Prescribing Code to initiate treatment with stimulant medicines (also see Recommendation 14).
- The current diagnosis/specialist prescriber matrix for stimulant prescribing within the Prescribing Code, be retained until further consultation with relevant specialist colleges is undertaken.

Recommendation 14: The Regulations be amended to allow the CEO of Health to authorise an individual prescriber or a class of prescriber to initiate treatment with stimulant medicines, and to allow the CEO of Health to include conditions on any such authorisation.

Recommendation 15: The Regulations be amended to remove the requirement for an authorised stimulant prescriber to notify when initiating or changing their patient's treatment with stimulant medicines but, to continue to require notification of treatment termination, but only in circumstances where high-risk criteria, as detailed in the Prescribing Code are met, and where further prescribing of stimulants would require authorisation.

Recommendation 16:

- The requirement for the initiating stimulant prescriber to appoint and notify the Department of a co-prescriber, be removed.
- The Regulations be amended to allow any prescriber to prescribe ongoing stimulant treatment to their patient, provided the prescriber complies with the requirements of the Prescribing Code and provided the patient is currently being treated with the same stimulant medicine, prescribed by a prescriber authorised to initiate stimulant treatment.

Recommendation 17:

- The requirement for regular specialist review be retained within the Prescribing Code as follows:
  a) A requirement for an annual specialist review for patients until they reach 18 years-of-age.

  b) For adult patients, where no high-risk criteria within the Prescribing Code are met, the requirement for specialist review be extended to a maximum of 3 years between reviews.

- Include a restriction within the Prescribing Code to limit any prescriber, who is continuing treatment with stimulants under a shared care arrangement with a specialist prescriber to only continue the same stimulant medicine(s) at the same dose(s) and frequency as documented by the specialist prescriber.

Recommendation 18: The current list of specialist medical practitioners and the medical conditions for which they can initiate stimulant medicines (without requiring a patient-specific prescribing authorisation), be retained within the Prescribing Code. Further consultation be undertaken with relevant specialist colleges in relation to adding other specialist types to the list.

Recommendation 19: Amend the Prescribing Code to remove the lower age limit for initiation of treatment with stimulant medicines by specialist medical practitioners, who treat adults. In other words, cease restricting initiation of stimulants to treat adolescents to specialist medical practitioners registered in the specialty of paediatrics and child health and psychiatrists practising in the subspecialty of child and adolescent psychiatry.

Recommendation 20:
Within the Prescribing Code:

- Retain the current requirements for prescribers to be authorised to prescribe a specific stimulant regime for each patient, if the patient is less than 4 years-of-age.
- Continue to limit all prescribing of lisdexamfetamine to patients aged 6 years or older.
- Remove the upper age limit for paediatric specialist prescribers commencing treating a patient with stimulant medicines for the first time.

Recommendation 21: Remove the current upper age limit, within the Prescribing Code, for continuation of treatment by paediatric specialists.

Recommendation 22:

- Maintain the current requirements for maximum doses without authorisation within the Prescribing Code.
- Continue to require prescribers, who are not medical specialists, to only prescribe the drug and dose previously documented by the patient's treating medical specialist.

Recommendation 23: Continue to reference the use of urine drug screens within the Prescribing Code, with the following changes:

- include an explanation of the utility of these tests;
- increase the age at which such tests are encouraged, to 16 years-of-age;
- continue to require the results of a urine drug screen to be included with any application for authorisation to prescribe stimulant medicines for a patient, who is recorded as a Drug Dependent Person, recorded as an oversupplied person or, who has a current, or recent history of, substance use disorder.

Recommendation 24: Further targeted consultation be undertaken to better define substance abuse/misuse for the purposes of the Prescribing Code and develop an evidence-based approach to the requirement for prescribing authorisation for stimulant medicines, where the patient has significant psychiatric co-morbidities.

Recommendation 25: The Regulations be amended to regulate the prescribing of medicinal cannabis in the same manner as other S8 medicines (other than stimulant medicines).

Recommendation 26: The Prescribing Code to provide for a maximum dose of 40mg/day of THC without authorisation, unless the prescriber is a TGA Approved Prescriber and is approved to prescribe higher doses. Higher daily doses of THC would require the prescriber to apply to the Department for authorisation to prescribe a particular medicinal cannabis regimen to their patient.

Recommendation 27: That the Prescribing Code requires a prescriber to be issued a patient and regimen specific authorisation before prescribing medicinal cannabis products intended for vaporisation, unless the prescriber has TGA Authorised Prescriber status for medicinal cannabis products or the medicinal cannabis product is a product for vaporisation with full marketing approval from the TGA.

Recommendation 28: The Prescribing Code to require a prescriber to be issued a patient and regimen specific authorisation before prescribing more than two medicinal cannabis products concurrently, unless the prescriber is a TGA Authorised Prescriber for all types of products being prescribed.

Recommendation 29: Prescribing authorisation be required, through the Prescribing Code, to prescribe medicinal cannabis in S8 to a person aged less than 18 years-of-age.

Recommendation 30: No change to the regulatory requirement for a prescriber to be authorised to prescribe medicinal cannabis in S8 for a person recorded as a Drug Dependent Person or oversupplied person.

Recommendation 31: Further targeted consultation be undertaken to better define substance misuse, for the purposes of the Prescribing Code, in relation to the risk of adverse outcomes when medicinal cannabis in S8 is prescribed.

Recommendation 32: The Prescribing Code to include a requirement for authorisation to prescribe medicinal cannabis in S8 to a patient with current, or a history of, a significant psychiatric diagnosis.

Recommendation 33: The Prescribing Code to include a requirement for authorisation to prescribe medicinal cannabis in S8 for a patient concurrently being treated with other S8 medicines that themselves require prescribing authorisation.

Recommendation 34:

- Retain the requirement for a pharmacist to keep the remaining repeats of paper-based prescriptions at the pharmacy at which the original prescription was dispensed.
- The Regulations to continue to allow a pharmacist to transfer the remaining repeats to another pharmacy.
- The Regulations be amended to remove the requirement for a pharmacist to seek authorisation from the Department before transferring repeats for paper-based S8 prescriptions (handwritten or computer generated prescriptions) to another pharmacy.
- The Regulations to clarify that repeat retention for S8 prescriptions does not apply to fully electronic prescriptions.

Recommendation 35: Continue to prohibit the prescribing of veterinary medicines for human use but amend the Regulations to allow a medical practitioner to be authorised, in writing, by the CEO of Health, to prescribe a named veterinary medicine product (registered by the Australian Pesticides and Veterinary Medicines Authority), which contains a named S4 medicine to treat a named human patient and to also allow the CEO of Health to add other conditions to any such authorisation. These regulations should restrict the CEO of Health to only issuing an authorisation, where the health of the person would be significantly compromised if the veterinary medicine was not used and where no equivalent or suitable human medicine product is available to treat the patient's health condition.

Recommendation 36:

- The Regulations be amended to adopt the requirements of Appendix M of the current Poisons Standard, by reference.
- The Regulations be amended to require details of every supply of a S3 medicine which is also listed in Appendix M to be recorded by the pharmacist in the patient's clinical record.
- The Regulations be amended to require the pharmacist to add a patient-specific label with details as described above.

Recommendation 37: The Regulations be amended to make it clear that only a handwritten signature (also known as a 'wet' signature) can be used to sign a paper-based prescription.

Recommendation 38: The Regulations be amended to more clearly support the use of Electronic National Residential Medication Chart (eNRMC), provided the system used to create the chart for each resident is an approved electronic prescribing system.

1 Introduction

Between 12 August and 7 October 2022, the Department undertook public consultation on proposed changes to the Western Australian Medicines and Poisons Regulations 2016 (the Regulations). Questions were also asked about consequential changes to the Schedule 8 Medicines Prescribing Code (the Prescribing Code), which is referenced by the Regulations and therefore mandatory for prescribers.

An online survey on the Department's Citizen Space consultation website was used to gather responses. A written submission could also be made. Key stakeholders were contacted by email to advise them of the consultation and offered a meeting to discuss the proposed changes.

The online consultation survey was accompanied by a Discussion Paper[2] which outlined options for updates to the regulation of:

- Medicines to be monitored by ScriptCheckWA, the WA Real-Time Prescription Monitoring (RTPM) system.
- Registration for, and use of, ScriptCheckWA by prescribers and pharmacists.
- Prescribing of stimulant medicines in S8.
- Prescribing of medicinal cannabis in S8.

The Discussion Paper also described a number of potential amendments to other regulations. These proposed changes are not directly related to RTPM but rather relate to regulations assessed as not operating as effectively or efficiently as possible.

The introduction of ScriptCheckWA means prescribers and dispensers have greater and more timely access to information about their patient's exposure to medicines monitored by the system. This provides an opportunity to consider reducing the regulatory burden for prescribers, without diminishing the public health protections afforded by the Medicines and Poisons legislation.

The consultation covered options aimed at continuing to protect public health while:

- reducing regulatory burden for health professionals;
- improving efficiency for the Department of Health (DOH), as the agency administering the Medicines and Poisons legislation; and
- updating some regulations to reference current standards and legislation.

As there is an integral connection between the Regulations and the Prescribing Code, some survey questions canvassed opinion about changes to this Code. The proposed changes to the Prescribing Code were consequential to the proposed changes to the Regulations.

2 Respondent demographics

There were 39 submissions to the consultation. Eighteen were from organisations and 21 were from individuals. Thirteen respondents provided their submission in written form with the remainder using the Citizen Space survey. The majority of written submissions were from organisations.

[2] https://consultation.health.wa.gov.au/medicines-and-poisons-regulation-branch/consultation-amendments-to-the-medicines-and-poiso/user_uploads/discussion-paper-amendments-medicines---poisons-regulations-2016-and-prescribing-code-august-2022.pdf (accessed 19 December 2022).

Responses were received from key stakeholders representing the medical profession, the nursing profession and the pharmacy profession as well as from patients and consumers more generally.

The survey was constructed so respondents could choose to only answer sections of interest to them. A significant number of respondents only answered the section about regulation of the prescribing of stimulant medicines or the section about regulation of the prescribing of medicinal cannabis. With the exception of the compulsory demographic questions, the number of respondents per question varied from 8 to 30, with a median of 24 respondents per question.

3 Schedule 4 reportable medicines

3.1 Legislative context

Section 77 of the *Medicines and Poisons Act 2014* (the Act) defines a 'Schedule 4 reportable medicine' as a drug of addiction for the purposes of Part 6 of the Act. Part 6 is about reporting and recording people as a 'drug dependent person' or an 'oversupplied person'.

This means a person can be reported to the Department by their treating medical practitioner as a 'drug dependent person' if the medical practitioner believes a S4 reportable medicine is the cause of that drug dependence. Similarly, a person could be reported as an 'oversupplied person' if they were being prescribed and dispensed quantities of a S4 reportable medicine in excess of therapeutic need. In other words, a person can be recorded as an oversupplied person if they 'doctor shop' for one or more S4 reportable medicines.

The provisions of Part 6 of the Act also mean prescriptions for S4 reportable medicines will form part of the data within the RTPM system. The Act also includes protections over the information relating to S4 reportable medicines such that identifiable information can only be disclosed to health practitioners, who will be prescribing for the patient or dispensing prescriptions for the patient.

Monitoring certain S4 medicines through ScriptCheckWA can help prescribers make informed clinical decisions by:

1. Ensuring a prescriber is aware if another prescriber is already treating their patient with a S4 medicine with a higher-risk of misuse, diversion and associated health harms; and
2. Ensuring prescribers have information about S4 medicines being prescribed and dispensed for their patient that may increase the risk of harm from concurrent use of S8 medicines.

3.2 Determining which Schedule 4 medicines are reportable

3.2.1 Background

Over recent years, all States and Territories in Australia have implemented RTPM systems. All these systems monitor all S8 medicines. Other States and Territories also monitor a list of higher-risk S4 medicines via their RTPM systems.

Other States and Territories use the term 'monitored medicines', 'monitored drugs' or 'monitored substances' in their equivalent legislation, to describe medicines that are subject to RTPM. The term used in the Act is 'drug of addiction' which is defined as a poison[3] in S8 or a S4 reportable poison[2]. While the Regulations will continue to use the term 'drug of addiction' and the term

[3] The term 'poison' is defined as a substance included in the Poisons Schedules. Medicines are a subset of poisons and the term medicines encompasses a substance in Schedule 2, 3, 4 or 8.

‘Schedule 4 reportable poison’, the term ‘monitored medicine’ is preferred for use in correspondence and within the Prescribing Code. In other words, the term ‘monitored medicine’ would be routinely used to describe all medicines subject to monitoring through ScriptCheckWA.

The term ‘monitored medicine’ would also better differentiate S4 reportable medicines from other S4 medicines referred to as ‘S4R’ (Schedule 4 *restricted*), which are restricted through state-wide policy within public hospitals. S4R medicines within public hospitals have additional storage and record keeping requirements due to their risk of diversion in the hospital setting. There is some overlap with the proposed ‘S4 reportable’ list; however, the S4R list is for a different purpose and is subject to a different suite of risk mitigation measures.

3.2.2 Selection criteria

As the designation of a S4 medicine as ‘reportable’, has significant regulatory impact, it is important only those S4 medicines posing the greatest risk of harm are included. Harms may result from misuse, abuse, diversion, substance use disorder and/or overdose. While S4 reportable medicines do not meet the factors associated with inclusion in S8, this is a group of medicines that can still lead to significant harm.

Details of criteria for determining which S4 medicines should be designated as ‘Schedule 4 reportable’ medicines and the results of stakeholder consultation conducted during 2019 are available in the Discussion Paper.

In summary, the criteria, which are also used by other States and Territories are:

1. *Evidence of harms* (misuse, abuse, addiction, fatal/non-fatal overdose): consideration of the severity of harm, total burden of harm relative to the amount of prescribing, whether the harm is associated with the medicine alone or in combination with other high-risk medicines.
2. *Trends in prescribing, misuse and abuse*: increasing trend in misuse and abuse in the jurisdiction, consideration of interstate and international evidence to predict locally emerging trends.
3. *Potential for the ‘substitution effect’*: where monitoring a particular medicine may result in misuse or harm being displaced to other medicines or illicit drugs.
4. *Potential for the ‘chilling effect’*: where monitoring a particular medicine could result in prescribers being reluctant to prescribe the medicine, resulting in patients receiving sub-therapeutic treatment and poorer health outcomes.
5. *Regulatory burden*, *including cost-benefit*: the regulatory burden for prescribers, dispensers and the regulator must be balanced with the benefits of more informed decision making and safer patient care.
6. *Inter-jurisdictional approaches*: consideration of which medicines are monitored in other Australian jurisdictions and in comparable overseas countries.

A question was included in the survey which asked respondents whether there were other criteria that should be used for determining which medicines should be monitored through ScriptCheckWA. Of the 24 organisations and individuals, who answered this question, 10 (41.7%) considered there were other criteria that could be used.

A number of the suggestions were essentially a subset of the proposed criteria, for example, the risk of dependence was mentioned by a number of respondents and this would be captured by the *Evidence of harms* criterion. Others suggested whether prescribing was by a specialist doctor and characteristics of the patient themselves, were also important. These criteria are important when selecting a particular medicine to treat an individual patient but are not applicable to determining whether a S4 medicine should be monitored through ScriptCheckWA or not.

3.2.3 Proposed list

For the current consultation, respondents were asked for their opinion on the following list of S4 medicines to be monitored, via ScriptCheckWA:

- All benzodiazepines in Schedule 4
- Tramadol
- Opioid-based preparations in Schedule 4 (currently codeine-based only)
- Pregabalin and gabapentin
- Quetiapine
- Zolpidem and zopiclone.

This list is very similar to the medicines monitored by other States and Territories. The only variations (as at December 2022) are:

- Gabapentin is not monitored in New South Wales[4] (NSW).
- Gabapentin, pregabalin and tramadol are not currently monitored in Victoria but are under consideration[5].
- Tasmania has also included olanzapine and dextropropoxyphene on their list of monitored medicines[6].

Twenty seven respondents answered this question and 14 (51.9%) supported the proposed list. Another 7 respondents (25.9%) partially supported the proposed list. Reasons given for partially supporting or not supporting the proposed list were concerns that monitoring may reduce access for legitimate patients and be a barrier to appropriate treatment.

There was greater support for the proposed list of monitored S4 medicines from organisations compared to individual respondents. Of the 13 organisations that responded to this question, 9 (69.2%) agreed with the proposed list.

Other issues raised included concerns about regulatory burden for clinicians and concerns that the list could be later expanded without appropriately balancing the risk to patients against tighter regulatory restrictions. While the list could be amended at a future date, this would require changes to the Regulations, which means the usual public consultation process would be followed.

Recommendation 1: The list of S4 medicines designated as 'reportable' should be all benzodiazepines in S4, pregabalin and gabapentin, tramadol, quetiapine, opioid-based preparations in S4 (which includes codeine-based preparations), zolpidem and zopiclone.

3.2.4 Commencement of monitoring via ScriptCheckWA

At the time the consultation took place, it was unclear when ScriptCheckWA would be fully implemented and accessible by prescribers and pharmacists. As ScriptCheckWA will be available months ahead of any changes to the Regulations to list any S4 reportable medicines, it is no longer considered necessary to build in a delay between implementation and commencement of monitoring of S4 reportable medicines.

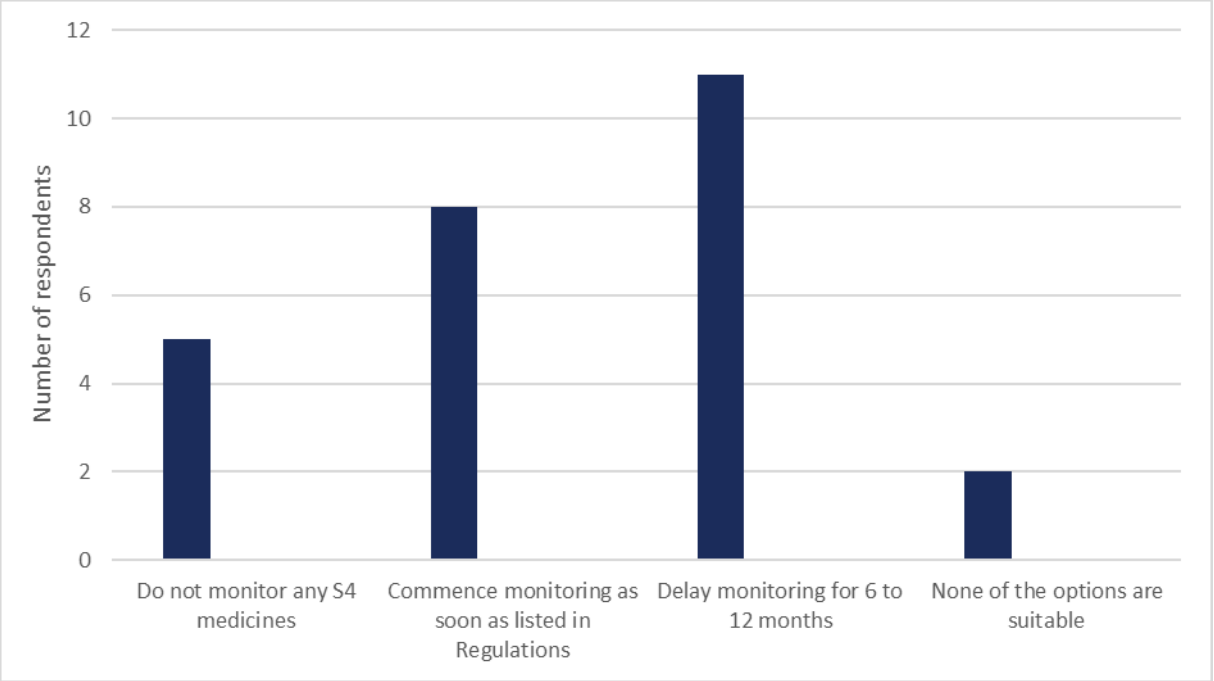
A question in the survey sought to determine the level of support for delaying inclusion of S4 reportable medicines in ScriptCheckWA. Although there was more support for a 6 to 12 month

[4] https://www.safescript.health.nsw.gov.au/__data/assets/pdf_file/0005/751298/Monitored-medicines-QRG.pdf (accessed 20 December 2022).
[5] https://www.health.vic.gov.au/drugs-and-poisons/medicines-monitored-in-safescript (accessed 20 December 2022).
[6] https://www.legislation.tas.gov.au/view/whole/pdf/asmade/sr-2022-028 (accessed 20 December 2022).

delay, a reasonable number of respondents supported monitoring commencing as soon as the list of S4 medicines was included in the Regulations.

An advantage of immediate commencement of data flow into ScriptCheckWA is that this information is then available to support prescribing and dispensing decisions. This inclusion of this data will also mean there is an expectation that clinicians will use ScriptCheckWA when they are notified there is relevant information about their patient, when they are considering prescribing or dispensing monitored medicines for their patient.

Figure 1: Commencement of monitoring of S4 reportable medicines via ScriptCheckWA



Recommendation 2: There is no delay between including a list of S4 reportable medicines in the Regulations and inclusion of prescribing and dispensing data for these medicines in ScriptCheckWA.

3.3 Restrictions on prescribing Schedule 4 reportable medicines

3.3.1 Background

Designating a S4 medicine as 'reportable' does not automatically mean there will be restrictions on the prescribing of these medicines, over and above the regulatory requirements applicable to all prescription-only medicines.

Currently, the Regulations only require a prescriber to be authorised to prescribe for people, who are recorded as drug dependent or oversupplied[7], if they are prescribing S8 medicines. There are no equivalent provisions in place in relation to the prescribing of any S4 medicines designated as 'reportable' for people recorded as drug dependent or oversupplied.

In other States and Territories, where RTPM has been implemented, no additional restrictions over the prescribing of monitored S4 medicines have been introduced. In Queensland, there are mandatory documentation and communication requirements for prescribers. For example, before prescribing any monitored medicine (S4 or S8) for a person currently registered on Queensland's Opioid Substitution Treatment (OST) program, the prescriber must document a

[7] Administration by a health professional does not require authorisation.

'joint prescribing plan' with the OST prescriber. Similarly, documentation of risk mitigation strategies is mandatory for all monitored medicines, where particular high-risk clinical scenarios apply, such as patients receiving monitored medicines from multiple prescribers or increased overdose risk due to combined opioid and benzodiazepine combination.

It should be noted that prescribing authorisations are separate to any warnings that may be provided to clinicians through a RTPM system. For example, a warning may be used to alert a prescriber that they are about to prescribe a monitored S4 medicine for a person recorded as a DDP, so they can consider the implications of this decision. Similarly, alerts may be triggered when a prescriber is considering prescribing a benzodiazepine for any patient currently being prescribed a S8 or monitored S4 medicine by another prescriber.

3.3.2 Methods for applying prescribing controls

The consultation considered options for how to apply any additional prescribing controls for S4 reportable medicines, including the option of there not being any additional prescribing controls. Although 8 of the 23 respondents (34.8%) chose the option of no extra requirements, over half (12 of 23) supported any criteria being included in a 'prescribing code', like the method currently used for S8 medicines.

The Department favours use of a 'prescribing code' rather than including detailed, prescriptive provisions within the Regulations. This regulatory model provides a balance between flexibility and regulatory transparency.

Requirements within a 'prescribing code' could range from a statement that there are no additional prescribing restrictions, to requirements for documentation of risk mitigation strategies in defined high-risk clinical scenarios or to requirements for authorisation prior to prescribing in specific circumstances.

Recommendation 3:

- The Regulations be amended to require prescribing of S4 reportable medicines to be in accordance with the 'prescribing code'.
- Include any prescribing requirements for S4 reportable medicines in the same 'prescribing code' as the prescribing restrictions for S8 medicines; and
- Suitably amend the definition of the 'prescribing code' in Regulation 114.

In a separate question, the survey sought views on a model similar to that used in Queensland, where there would be a requirement for the prescriber to keep a record of the risk mitigation strategies they will use in defined high-risk clinical scenarios instead of having to actively seek authorisation from the Department. The intent is both high-risk clinical scenarios and specific documentation and communication requirements would be detailed in a 'prescribing code'.

There was limited support for the above described model (4/23 respondents, 17.4%) with the majority either supported there being no authorisation requirements for any S4 medicines (11/23 respondents, 47.8%), or believed there should be authorisation requirements in high-risk clinical scenarios (8/23 respondents, 34.8%).

Concerns were expressed about whether the documentation only option would be used by clinicians and how it would be monitored; however, even those who supported having some authorisation requirements thought the documentation only option had some merit and was a balanced approach which supported safe use of higher-risk S4 medicines without creating unnecessary barriers to appropriate clinical care and increased bureaucracy for prescribers.

Comments by those who preferred there to be no extra requirements to prescribe S4 reportable medicines included:

- Visibility of previous and current prescribing and dispensing via ScriptCheckWA, is considered sufficient protection.
- Authorisation requirements may be a barrier to good clinical care.
- Having authorisation requirements may undermine the prescriber's professional knowledge, skills and experience.
- Increased regulation may negatively impact the clinical relationship.
- Requirements for authorisation to prescribe may be a real or perceived barrier to patients accessing healthcare.
- If additional requirements are believed to be necessary, consideration should be given to whether these S4 medicines should be included in S8.
- Specialists should be excluded from requiring authorisation, in all circumstances.
- No authorisation should be required to prescribe for palliative care patients.

Pharmacists also had concerns they would become the 'gatekeeper', where prescribing without authorisation was detected at the point of dispensing. The Department's policy has always been that the pharmacist is not responsible for monitoring a prescriber's regulatory compliance and this will not change with the implementation of ScriptCheckWA; however, pharmacists must still make a professional assessment about whether it is appropriate to dispense a prescription and whether they should discuss the prescription with the prescriber.

3.3.3 Prescribing criteria

As S4 medicines create less risk than S8 medicines, it is considered appropriate for any additional requirements to be met prior to prescribing these medicines to be limited to situations, where patient and community harm, is significant.

The consultation canvassed opinion on a number of situations, where authorisation to prescribe, could be used to manage risk of patient and community harm:

- Where the patient is recorded as a 'drug dependent person'
- Where the patient is recorded as an 'oversupplied person'
- Where the patient is being treated with opioid substitution therapy[8]
- Where the patient is being treated with doses of the S4 reportable medicine higher than standard recommended doses and is already recorded as either a 'drug dependent person' or an 'oversupplied person'

On the online survey, respondents could select multiple options in answer to the question: If prescribing authorisation was required for S4 monitored medicines, in what circumstances should it be mandatory?

Twenty one responses were received. As shown in Figure 2, opinion was quite divided. A number of respondents made suggestions in relation to potential criteria for high-risk clinical scenarios:

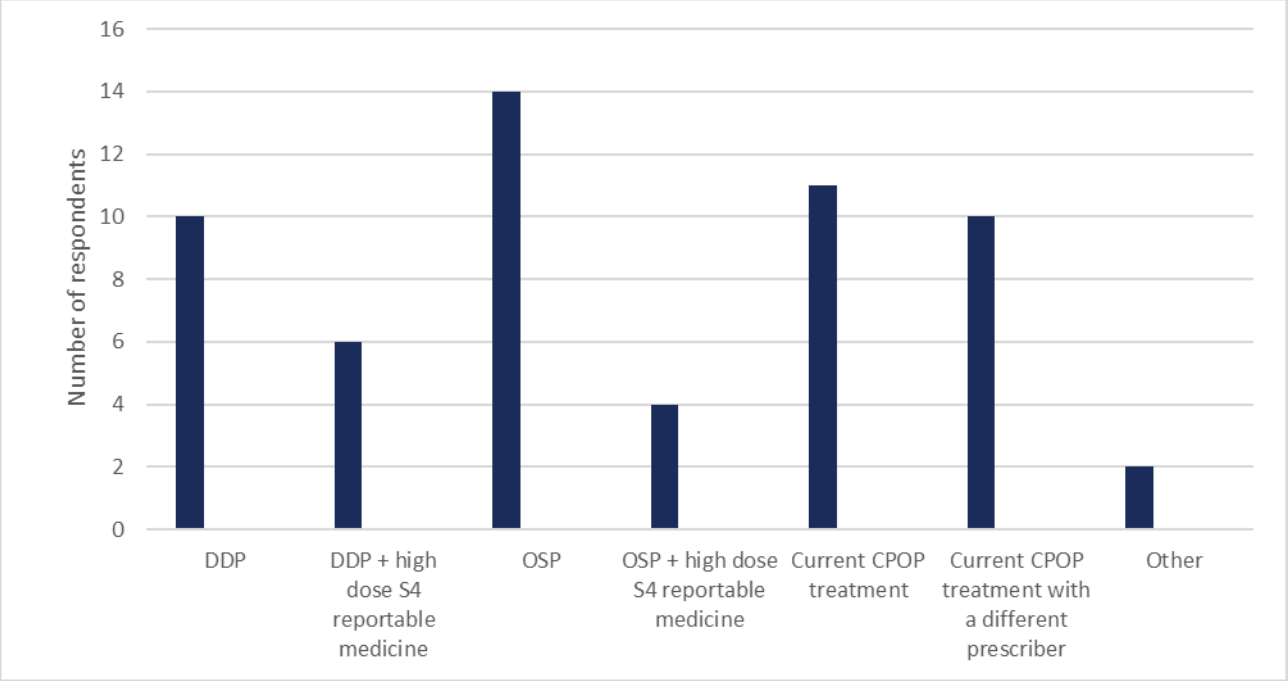
- Authorisation should be required if the patient is attending more than 6 prescribers or pharmacies.
- Authorisation should be required if treatment with unusually high doses will be for more than 1 month.

[8] Also known as the Community Program for Opioid Pharmacotherapy (CPOP) in WA.

- Prescribers writing unusually high doses of S4 reportable medicines for themselves, should require authorisation.

Section 78 of the Act already prohibits a prescriber from self-prescribing both a S8 medicine and a S4 reportable medicine. There is a defence for self-prescription in emergency circumstances. In addition, the Medical Board of Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia[9] expects medical practitioners to be aware of the risks of self-diagnosis and self-treatment and to refrain from prescribing for themselves. Other health practitioner boards similarly counsel against self-diagnosis and self-treatment[10].

Figure 2: Criteria for prescribing authorisation



Legend: DDP = Drug Dependent Person, OSP = Oversupplied Person, CPOP = Community Program for Opioid Pharmacotherapy.

Initially, the Department favoured using limited authorisation requirements in high-risk clinical scenarios, delayed until at least 6 months after prescribing and dispensing data about monitored S4 medicines became available in the RTPM system.

This option was considered most consistent with the principles for prescribing monitored medicines, such as one general practitioner prescribing for the patient at any point in time and shared care arrangements between specialist medical practitioners and the patient's general practitioner.

The proposed delayed implementation of this option was to allow the Department to use data from real world RTPM use in WA to inform any prescribing restrictions imposed through the Prescribing Code, including whether any such prescribing restrictions were necessary.

The significant support for no authorisation requirements, including the concerns raised, combined with the fact that other States and Territories have not introduced prescribing authorisation requirements for monitored S4 medicines, would suggest a model similar to

[9] https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx (accessed 21 December 2022).
[10] https://www.ahpra.gov.au/Resources/Code-of-conduct/Shared-Code-of-conduct.aspx (accessed 21 December 2022).

Queensland is a more suitable regulatory option. Incorporation of documentation and communication requirements for monitored S4 medicines into the Prescribing Code, would be supported by the regulatory amendment proposed in Recommendation 3.

If ongoing monitoring was to find lack of adherence to the documentation requirements and risky prescribing practices, the Prescribing Code could be later amended to include authorisation requirements instead of documentation requirements.

Potential risk mitigation steps when prescribing S4 reportable medicines, particularly in high-risk clinical scenarios, include:

- Taking reasonable steps to confirm the patient's identity, including use of photographic identification documents. This may occur when the patient first registers with the practice.
- Checking ScriptCheckWA as part of the prescribing process.
- Documenting the patient's diagnosis and details of the clinical condition being treated with the monitored medicine.
- Documenting the goals of treatment with the monitored medicine, including any specific dose management plan.
- Documenting both initial and ongoing assessments of the patient's risk profile, such as their risk of overdose, substance use disorder, drug seeking behaviour, age-related risks, medication-related risks and co-morbid health conditions.
- Based on the patient's risk profile, considering supply controls, such as a treatment contract, dispensing from a single pharmacy, staged supply, such as weekly dispensing, and defining how soon a repeat supply can be dispensed or re-prescribed.
- Documenting the use of validated clinical tools to establish baseline levels of function and/or to monitor effectiveness of the monitored medicine.
- Documenting when the patient will be reviewed and any triggers that would warrant review at a different frequency.
- Participating in an active shared care arrangement with other prescribers, who are caring for the patient, including:
    - recording details of recommendations for treatment with S4 reportable medicines made by specialist medical practitioners; and
    - documenting communication with other prescribers.

These risk mitigation steps are all elements of good clinical care and even in settings where the patient does not have direct control of their medicines, such as custodial settings or residential care settings, documenting the above described information promotes quality use of medicines.

The above described risk mitigation measures are considered appropriate to mandate, where the patient is currently on the Drugs of Addiction Record as a DDP or an Oversupplied Person, noting that all patients enrolled in the Community Program for Opioid Pharmacotherapy are recorded as a DDP.

Recommendation 4: Amend the Prescribing Code to require prescribers make a record of risk mitigation steps in the patient's clinical notes, including communication with other relevant prescribers, when prescribing S4 reportable medicines for patients recorded as a Drug Dependent Person or an Oversupplied Person.

3.3.4 Exemptions from additional prescribing criteria

It was proposed that the revised Prescribing Code include a list of exemptions from needing to adhere to any additional prescribing criteria for S4 reportable medicines. It should be noted that exemptions from adherence to prescribing criteria are not necessarily the same as exemptions from needing to check the RTPM system prior to prescribing (see Section 4.2).

The current Prescribing Code, which is limited to S8 medicines, does not apply to situations where an authorised health professional is administering the medicine to the patient. In other words, in situations, such as a hospital, surgery or other clinic or during pre-hospital emergency care, where a health professional administers doses and there is no prescription for the patient to have dispensed at a pharmacy, there are no authorisation requirements through the Prescribing Code. In addition, Regulation 117 allows a health professional to administer S8 medicines to a person recorded as a drug dependent or oversupplied person, without requiring patient-specific authorisation from the CEO of Health.

It would be appropriate to also allow administration of S4 reportable medicines without any authorisation requirements.

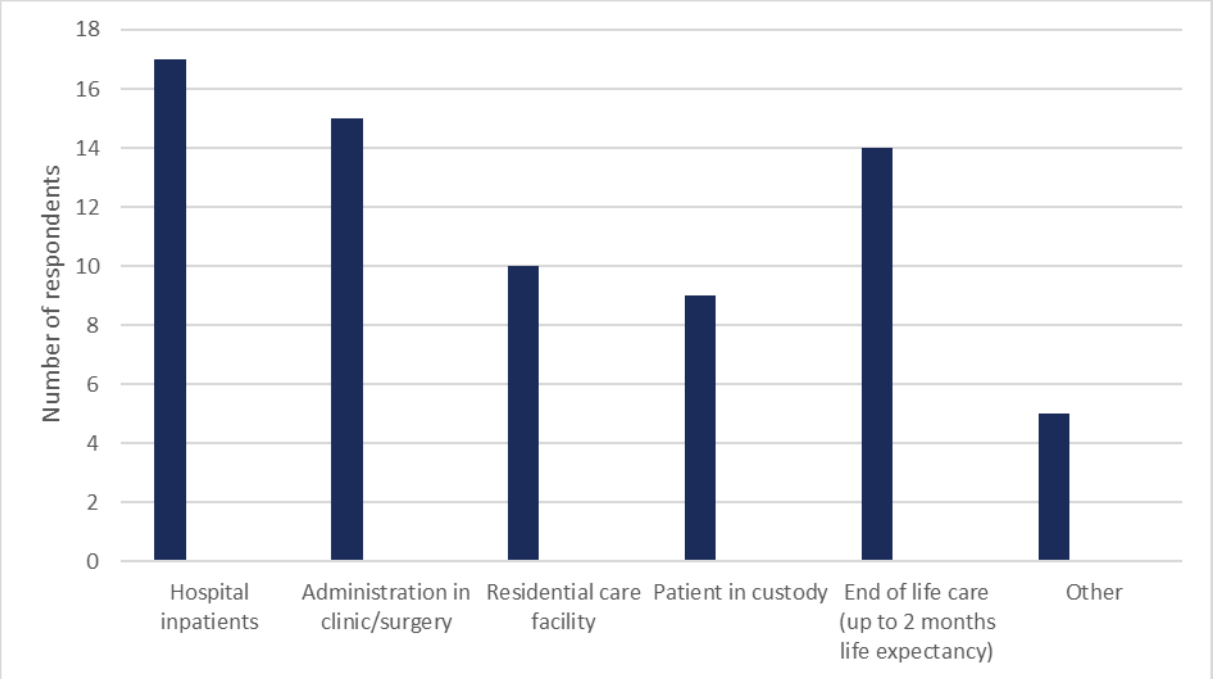
There are other circumstances, where the risk of concurrent prescribing by multiple prescribers and prescription shopping, is significantly reduced, such as in prisons and in residential care facilities. Additionally, in these situations, patients are not personally managing their medicines, which reduces the risk of diversion by the patient. The identity of the patient is also more likely to have been verified as part of their admission to such facilities.

The current Prescribing Code also allows prescribing for 'end of life' care (where the patient's life expectancy is less than 2 months) without authorisation. This waiving of additional requirements recognises the need for flexible dosing and choice of treatment during 'end of life' care and supports accessibility of care.

The online survey included a question which asked respondents to select from a list of situations, where an exemption from any prescribing criteria would be appropriate; however, the question was written in terms of exemption from authorisation requirements rather than exemption from any prescribing criteria. It is acknowledged responses may have been different if the question was related to documentation requirements rather than authorisation requirements.

Twenty responses were received. As well as the proposed exemptions, respondents also suggested an exemption should exist for oncology patients and when the prescriber is a specialist.

Figure 3: Exemptions from additional prescribing criteria



Recommendation 5: When prescribing S4 reportable medicines, documentation of risk mitigation steps are not mandated through the Prescribing Code when doses are (1) being administered to the patient (no dispensing or other supply), (2) when the patient is in a custodial or residential care setting, or (3) when the S4 reportable medicines are being prescribed as part of 'end of life' care (life expectancy is less than 2 months and therefore prescribing should be for no more than 2 months).

3.4 Requirements for prescriptions for Schedule 4 reportable medicines

3.4.1 Inclusion of patient's date of birth

Once a S4 medicine is designated as 'reportable', data about prescribing and dispensing events associated with these medicines will be sent to ScriptCheckWA. This data must be matched with identified patients to be available to clinicians to support decision making when prescribing and dispensing.

Standard primary parameters used for matching data are the patient's name and date of birth. This means prescriptions for monitored S4 medicines will need to include the patient's date of birth. Otherwise, there is significant risk of unmatched, and therefore unusable data being captured by ScriptCheckWA. Unmatched data has the potential to significantly reduce the utility of RTPM systems as a clinical decision tool and as a regulatory tool.

With the almost universal use of computer-generated paper-based prescriptions and electronic prescriptions, practice management software can be developed in a manner that reduces the risk of prescribers not including their patient's date of birth on relevant prescriptions. This is already in place for S8 medicines.

The widespread use of computer systems to generate prescriptions, whether fully electronic or paper-based, will limit the regulatory burden for prescribers. These computer systems can be set up to automatically populate the date of birth on a prescription for S4 reportable medicines, in the same way this already occurs for prescriptions for S8 medicines.

It is also standard practice for medical practices to collect a patient's date of birth, when the patient first attends the practice and saves this information for future visits meaning, it is then available to be entered onto a prescription.

Similarly, date of birth is a standard field in pharmacy dispensing software and is saved between visits, thereby limiting the regulatory burden on pharmacists.

A consultation question was included asking for any reasons the patient's date of birth should not be included on a prescription for a S4 reportable medicine.

Sixteen responses were received. One response did not support inclusion of the patient's date of birth and suggested the name, address and Medicare number should be sufficient. As not all patients have a Medicare card, their date of birth is considered a primary parameter for ensuring all relevant data in ScriptCheckWA is visible to prescribers and dispensers when caring for their patient.

In New South Wales (NSW), from 1 November 2022, all prescriptions for S4 and S8 medicines must be issued with the patient's date of birth, as well as their name and address. NSW has stated that the date of birth strengthens identification of the patient and improves the quality of information held in their RTPM system[11]. Through the Australian Digital Health Agency

[11] https://www.health.nsw.gov.au/pharmaceutical/Pages/prescribers-dob-factsheet.aspx (accessed 22 December 2022).

conformance requirements, the patient's date of birth is already required on fully electronic prescriptions.

In NSW, the date of birth requirement is applicable to all prescriptions for S4 medicines, not only monitored S4 medicines. Advice to NSW Health was that making the requirement applicable to all prescriptions was simpler for prescribers than having different rules for different types of prescriptions.

To ensure patient care is not adversely affected by the new date of birth requirements in NSW, a clause has been included which allows a pharmacist to dispense the prescription, even if it has been issued without the patient's date of birth, provided the pharmacist obtains the patient's date of birth from the patient or their agent and records the patient's date of birth in their dispensing system.

Recommendation 6:

- The Regulations be amended to require all prescriptions for S4 and S8 medicines (to treat humans) be issued with three patient identifiers: their name, address and date of birth.
- The Regulations to also include a clause to allow a pharmacist to dispense a prescription, despite the prescription not being issued with the patient's date of birth, provided the pharmacist can adequately verify the patient's date of birth and the Regulations to require a pharmacist to record the patient's date of birth when dispensing a prescription.

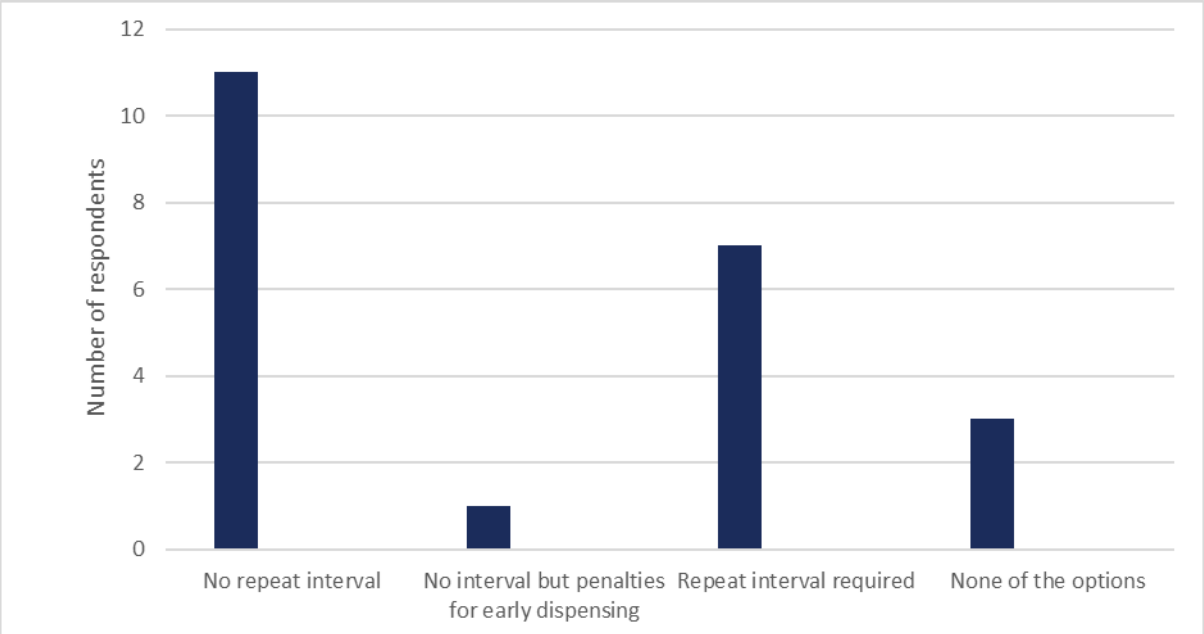
3.4.2 Repeat intervals

For S8 prescriptions with repeats, the prescriber must include the interval at which the repeats can be dispensed. This is a mechanism to reduce the risk of oversupply to the patient and the risk of diversion. Endorsing S8 prescriptions with repeat intervals, has been a requirement for prescriptions for S8 medicines across Australia for at least the last forty years.

The Act has provisions for the recording of a patient as an 'oversupplied person' for both S8 and S4 reportable medicines, if the patient is obtaining quantities of the medicine in excess of therapeutic need.

A consultation question was asked about whether prescriptions for monitored S4 medicines should also include a repeat interval. Twenty-two respondents answered the question.

Figure 4: Options for repeat intervals on prescriptions for monitored S4 medicines



Those who supported no repeat intervals on prescriptions for monitored S4 medicines gave the following reasons for this choice:

- When prescribed as Pharmaceutical Benefit Scheme (PBS) items, repeats for these medicines are usually not allowable.
- The risk of not being able to maintain continuity of dosing is not worth potentially preventing some diversion.
- Repeat intervals can be a problem when the prescriber changes the dose but does not write a new prescription.
- The visibility within ScriptCheckWA means repeat intervals, should not be needed.
- There is a need for flexibility, including for particular patient groups, such as Fly-in Fly-out workers.
- Repeat intervals waste a lot of time for both pharmacists and prescribers.

The Department's preferred option was that repeat intervals should not be mandated on prescriptions for monitored S4 medicines and consultation feedback supported this. Given their lower-risk profile compared to S8 medicines, a mandatory requirement for repeat intervals on prescriptions for S4 reportable medicines, is not considered necessary, provided both prescribers and dispensers can view evidence of recent prescribing and supply in real-time, via a RTPM system.

Penalties for supply, when a patient has sufficient medication available for at least another week, would be difficult to administer, where the S4 reportable medicine is used on a 'when required' basis. Such penalties may also undermine patient-centred care for medicines that have been nationally assessed as meeting the criteria for 'prescription-only' rather than 'controlled drug'.

Other States and Territories that have implemented RTPM systems have not amended their regulations to include a requirement for prescriptions for S4 medicines that are designated as monitored medicines to be endorsed with a repeat interval.

Recommendation 7: That there be no requirement to include a repeat interval, where repeats are prescribed for monitored S4 medicines (status quo, no regulatory amendment required).

4 Mandates associated with Real Time Prescription Monitoring

4.1 Background

Requirements written into law can relate to whether a prescriber or dispenser must register to use the RTPM system or must query the system, in particular circumstances. When prescription monitoring systems were first developed in North America, the systems were not particularly 'user-friendly' and user mandates were considered necessary for clinicians to engage with the system.[12]

The effectiveness of current RTPM systems in reducing overdose and death associated with monitored medicines, is variable;[13] however, mandates requiring either health practitioner registration for access or health practitioner use of the system, when prescribing, generally results in improvements in indicators of risky prescribing of S8 and other monitored medicines, such as total number of opioid prescriptions, reductions in the 'oral morphine equivalent daily dose' and reductions in hospital admissions and emergency presentations for adverse medication-related outcomes.[14, 15]

4.2 Requirement for practitioner registration to use ScriptCheckWA

Reduction in requirements for notification and authorisation when prescribing S8 medicines are predicated on prescribers being able to view details of their patients in the RTPM system and, similarly, for dispensers to be able to view this information. Prescribers and dispensers will need to complete a simple one-time registration process to be able to access ScriptCheckWA.

Evidence from overseas indicates access mandates for RTPM systems increases both the number of practitioners with access to the program and the number of active users of the program.[16]

In the consultation, respondents were asked whether registration should be voluntary or mandatory. Twenty-seven respondents answered the question. The majority (17/27, 63%) supported mandatory registration for access to ScriptCheckWA with 7 (25.9%) supporting registration for access remaining voluntary.

Reasons for supporting voluntary registration for access to ScriptCheckWA included:

- Making registration mandatory could be seen as a barrier by some prescribers.
- Concern that having a separate registration process will reduce the benefits of ScriptCheckWA and RTPM must be fully incorporated into all clinical software systems used in medical practices and all dispensing software used in pharmacies to maximise success.

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[12] Gontaszewski, S (2018). Churchill Fellowship Report: Investigating the implementation of online prescription monitoring programs in the United States and Canada. Winston Churchill Memorial Trust. Available at: https://www.churchilltrust.com.au/project/to-investigate-the-implementation-of-online-prescription-monitoring-programs/

[13] Fink D, Schleimer J, Sarvet A et al. Association between prescription drug monitoring programs and nonfatal and fatal drug overdoses: a systematic review. Ann Int Med 2018;168:783-790.

[14] Wen H, Hockenberry JM, Jeng PJ, Bao Y. Prescription drug monitoring program mandates: impact on opioid prescribing and related hospital use. Health Affairs 2019:38:1550-1556.

[15] Castillo-Carniglia A, Gonzalez-Santa Crus A, Cerda M et al. Changes in opioid prescribing after implementation of mandatory registration and proactive reports within California's prescription monitoring program. Drug Alcohol Depend 2021;218:108405, 2021 01 01.

[16] Shev AB, Wintemute GJ, Cerda M et al. Prescription drug monitoring program: registration and use by prescribers and pharmacists before and after legal mandatory registration, California, 2010 – 2017. Am J Pub Health 2018;108:1669-1674.

As the Act only authorises prescribers and pharmacists to access the information within ScriptCheckWA, and only when prescribing or dispensing monitored medicines for their patient, this RTPM system cannot be fully embedded within clinical or dispensing software; however, the majority of such software products will have integrated links to ScriptCheckWA, thereby allowing practitioners to seamlessly access the RTPM system.

Where clinical or dispensing software is integrated with ScriptCheckWA, prescribers and dispensers will receive a pop-up notification within the software whenever an alert is triggered within ScriptCheckWA. Clicking on the notification will then open the patient's ScriptCheckWA profile in a web browser.

For prescribers, who write handwritten prescriptions, or in other circumstances where the health practitioner does not have access to fully integrated clinical or dispensing software, a standalone version of ScriptCheckWA will be available. In addition, where partially integrated clinical or dispensing software is in use, an RTPM notification app will allow receipt of alert notifications immediately after finalising prescribing or dispensing of a prescription for a monitored medicine.

Recommendation 8: The Regulations be amended to require medical practitioners, nurse practitioners, dentists and pharmacists to register to use ScriptCheckWA, provided the practitioner practices in WA, or routinely prescribes or dispenses for patients who ordinarily reside in WA (accommodates telehealth providers and online pharmacies with an address outside WA).

4.2.1 Period for completion of registration for ScriptCheckWA

The Discussion Paper proposed a minimum six month period from official launch of ScriptCheckWA for health practitioners to complete their registration to access the system. It is now known that ScriptCheckWA will be fully implemented prior to any amendment of the Regulations. This means there is less need to provide practitioners with a period of time to commence using ScriptCheckWA, especially if the Department clearly communicates to practitioners that registration will become mandatory later in 2023.

There was significant support for a period of 6 months for practitioners to complete the registration process, with 15 of the 23 respondents who answered this question choosing this option.

One respondent suggested there should be a 12 month delay to account for practitioners working in settings where prescribing or dispensing software was not integrated with ScriptCheckWA. As ScriptCheckWA will be available as a standalone system, there should be no need to delay completion of registration until all clinical and dispensing software is integrated with the RTPM system.

Recommendation 9: No delay in commencement of the regulatory requirement for practitioners to register to use ScriptCheckWA.

4.2.2 Defences for not completing registration for ScriptCheckWA

There will be some health practitioners who have prescribing or dispensing rights under the Regulations but who do not practice in a setting where they will be writing prescriptions or supplying medicines. The intent is that the Regulations will provide a defence for these health practitioners if they do not complete registration for ScriptCheckWA, unless their status changes. Backend compliance checking of ScriptCheckWA can be used to determine whether a practitioner is prescribing or dispensing monitored medicines but has not completed the registration process.

Recommendation 10: The Regulations to include a defence for prescribers and pharmacists who do not complete registration for ScriptCheckWA, where the health practitioner does not prescribe or dispense monitored medicines as part of their practise.

4.3 Requirements for practitioners to use Real Time Prescription Monitoring

Use of mandates by prescribers and dispensers are commonly implemented, when prescription monitoring systems are available and have been shown to increase use of these systems by practitioners.[17] Mandates can range from requiring practitioners to check the prescription monitoring system only where deceptive or illegal behaviour is suspected, through to requiring a check every time the practitioner is prescribing or dispensing a medicine monitored by the system. A list of exceptions to mandated use is common.

In North American jurisdictions, regulators do not necessarily undertake proactive monitoring against use of mandates. Rather, where prescribing is under review, information about a prescriber's use history of the prescription monitoring system would form part of the investigation.[16]

There is some variation across Australia with respect to whether use of the local RTPM system by prescribers and pharmacists is mandated; however, in States and Territories where use remains voluntary, health practitioners are still strongly encouraged to use the RTPM system to support clinical decision making when prescribing and dispensing monitored medicines.

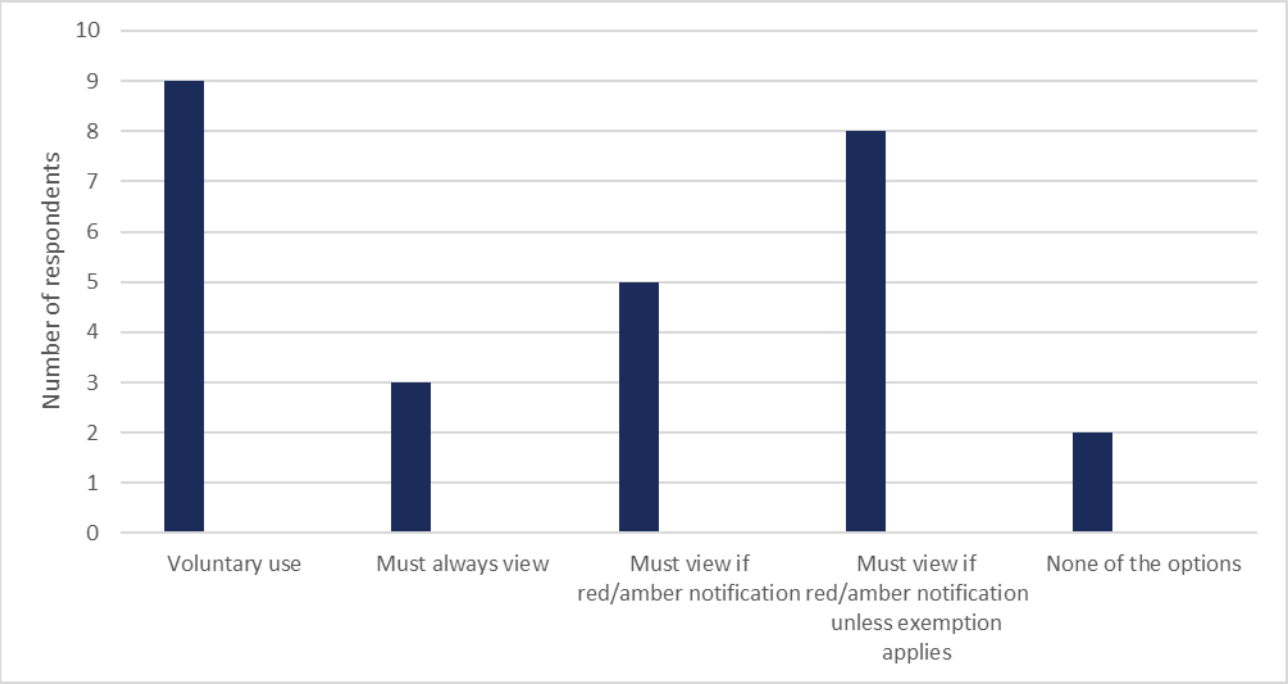
A consultation question sought view on whether use of ScriptCheckWA should be mandatory, with a number of options relating to different circumstances.

In ScriptCheckWA, there are a number of alert levels in relation to information available about a patient and the consequential risk associated with prescribing monitored medicines for the patient. Medium risk information will trigger an amber alert and high-risk information will trigger a red alert. Where the prescriber or pharmacist is using prescribing or dispensing software that integrates with ScriptCheckWA, a corresponding amber or red notification will pop-up on their screen when they are prescribing or dispensing a monitored medicine for their patient, indicating that there is relevant information to look at in ScriptCheckWA.

Twenty-seven responses were received to this consultation question with 16 of these (59.3%) supporting some level of mandatory use.

[17] Gontaszewski, S (2018). Churchill Fellowship Report: Investigating the implementation of online prescription monitoring programs in the United States and Canada. Winston Churchill Memorial Trust. Available at: https://www.churchilltrust.com.au/project/to-investigate-the-implementation-of-online-prescription-monitoring-programs/

Figure 5: Use mandates for ScriptCheckWA



Notes:

1. Red or amber notification indicates a red (high-risk) or amber (medium-risk) alert has been triggered within ScriptCheckWA.
2. Exemptions are detailed further in section 4.3.1.

Those who supported the use of ScriptCheckWA remaining voluntary provided the following reasons for their responses:

- Making use mandatory may undermine the professional knowledge of prescribers.
- There will be many circumstances where it is not practical to check ScriptCheckWA before prescribing, such as during home visits or in remote areas where internet access is limited.
- Concern that prescribers will be in breach of the regulations if they cannot access ScriptCheckWA for some reason.
- An opinion that health practitioners would be more willing to use ScriptCheckWA if it remains voluntary.

Of the nine respondents who supported voluntary use, five also supported voluntary registration for ScriptCheckWA.

The Department remains supportive of only mandating registration to access ScriptCheckWA. Obviously, mandating registration alone does not mean a prescriber or pharmacist will necessarily review the information in ScriptCheckWA about their patient, every time a red or amber alert is triggered; however, it does make it difficult for a prescriber to claim they did not know their patient was being treated with S8 or S4 reportable medicines by other prescribers or was on the record as drug dependent or oversupplied. A similar argument would apply to pharmacists, who should have no reason to claim they did not know the patient had the same monitored medicine recently dispensed at another pharmacy.

Recommendation 11: Use of ScriptCheckWA by prescribers and pharmacists is not mandated through the Regulations (status quo, no regulatory change required).

5 Regulation of stimulant medicines in Schedule 8

5.1 Background

The current Stimulant Regulatory Scheme (the Scheme) commenced in August 2003, following community concerns about stimulant prescribing in WA, including perceptions of a high level of prescribing. The Scheme regulates the prescribing of dexamfetamine, lisdexamfetamine and methylphenidate. In addition to regulating prescribing, the Scheme was intended to allow collection of comprehensive data to enable a better understanding of stimulant use in this State. This data has been published in annual reports since the Scheme commenced.

The majority of prescriptions for stimulant medicines in S8 are issued to treat ADHD. Only 0.3 percent of children and 5.1 percent of adults[18] are treated with stimulant medicines for other medical conditions, such as narcolepsy, depression and brain injury. This means, most commonly, patients are under the care of either a paediatrician or a psychiatrist. A small number of patients are treated by other specialist medical practitioners, such as neurologists, respiratory and sleep physicians and rehabilitation physicians.

Currently, there are detailed requirements in the Regulations controlling the prescribing of stimulants in S8. This is unlike other S8 medicines, such as opioids, where the detailed requirements are included in the Prescribing Code rather than the Regulations. An exception is where the patient is recorded as a DDP or an oversupplied person, in which case, the Regulations require a prescriber to be authorised before prescribing a S8 medicine for them.

The constraints of the Regulations mean the controls over prescribing stimulants have not kept pace with changes in clinical practice, such as increased use of telehealth including with specialists located in other States and Territories, and the increased mobility of patients.

Under the current Scheme, only certain specialist medical practitioners can initiate treatment with stimulant medicines. This restriction recognises that the conditions stimulant medicines are used to treat require specialist diagnosis and monitoring, at least until the patient is taking a stable and effective dose of stimulant medicines.

Other States and Territories also limit initiation of stimulant prescribing to appropriate medical specialists, although the specific regulatory mechanisms by which this is achieved varies.

In summary, under the current Scheme:

- Only medical practitioners are eligible to prescribe stimulants in S8.
- Only certain types of specialist medical practitioners are eligible to initiate treatment with stimulants and alter the patient's treatment regime.
- In addition, eligible specialist medical practitioners must be individually designated as a 'stimulant prescriber' before they can commence prescribing stimulants in S8.
- The stimulant prescriber must notify the Department whenever they initiate or change their patient's stimulant treatment.
- In most cases, a stimulant prescriber can appoint another medical practitioner, such as the patient's usual general practitioner, as a 'co-prescriber'.
- A co-prescriber can prescribe stimulant medicines but cannot make changes to the treatment regimen determined by the stimulant prescriber.
- There are provisions for the Department to authorise a general practitioner or other medical practitioner to prescribe stimulants for their patient for a short period, in

[18] Department of Health (WA). Western Australian Stimulant Regulatory Scheme 2015 Annual Report. Available at: http://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/medicines%20and%20poisons/PDF/Stimulant%20Annual%20Report%202015.ashx

circumstances where the patient's specialist prescriber is unavailable to prescribe (known as interim authorisation).
- There are specific provisions for prescribing at clinics operated by WA Health and continuing treatment of patients in hospitals and custodial facilities.
- There are additional prescribing restrictions through the Prescribing Code including: dose limits, age limits, annual specialist review and use of urine drug screens.
- In high-risk situations, such as where the patient has a history of drug dependence or prior stimulant induced psychosis, there are requirements for specialist stimulant prescribers to apply for authorisation to prescribe for the individual patient. These applications are routinely referred to the Stimulant Assessment Panel. The Panel is an advisory group of expert clinicians and relevant staff from the DOH, appointed by the Minister for Health.
- In high-risk situations, only the patient's specialist prescriber with be authorised to prescribe stimulants for the patient.

The current scheme is workload intensive for both clinicians and regulators. The increased information visibility achieved by implementation of ScriptCheckWA paves the way for modification of the Scheme to 'reduce red tape', without compromising the public health benefits of regulating stimulant prescribing.

5.2 Consultation response

As the majority of patients treated with stimulants are taking these medicines for the management of ADHD, the consultation questions were generally asked in terms of ADHD treatment rather than treatment of other conditions for which stimulants are considered therapeutically appropriate.

This part of the consultation resulted in feedback from the largest number of respondents. The majority of respondents were involved in managing patients diagnosed with ADHD. Thirty of the 39 respondents (77%) answered one or more questions in this section. In many cases, considerable written detail was also provided.

The level of interest may have been influenced by a number of external factors, including the current WA Parliamentary Inquiry into child development services[19], a National shortage of paediatricians[20], an ongoing skills shortage in the mental health area, including psychiatrists[21] and the launch of a new Australian evidence-based guideline for ADHD in October 2022[22].

5.3 Overview of proposed new Stimulant Regulatory Scheme

The availability of ScriptCheckWA to all prescribers and pharmacists in WA will mean clinicians have access to information about:
- what monitored medicine(s) their patient is being prescribed and dispensed;
- when monitored medicine(s) were prescribed and dispensed for their patient;
- who prescribed and dispensed monitored medicine(s) for their patient; and

[19] https://www.parliament.wa.gov.au/Parliament/commit.nsf/(EvidenceOnly)/4F80772DF02D4AE6482588B0000A7782 (accessed 17 January 2023)
[20] Cathy O'Leary. Paediatrician shortage is biting. Medical Forum 3 May 2022. Available at: https://mforum.com.au/paediatrician-shortage-is-biting/ (accessed 17 January 2023)
[21] https://www.health.gov.au/sites/default/files/documents/2021/09/national-medical-workforce-strategy-scoping-framework.pdf (accessed 17 January 2023)
[22] https://aadpa.com.au/guideline/ (accessed 17 January 2023)

- whether their patient is recorded as a DDP or an oversupplied person or whether their patient has been previously diagnosed as experiencing stimulant induced psychosis.[23]

This increased information access presents an opportunity to regulate stimulant medicines in a similar manner to other S8 medicines, such as opioids, where detailed prescribing parameters are included in the Prescribing Code, which is referenced by the Regulations.

Elements of the proposed new stimulants regulatory scheme are as follows:

- Support specialist input for diagnosis of ADHD and other medical conditions for which stimulant medicines are a recognised therapeutic intervention and, consequently, limit initiation and stabilisation of treatment with stimulant medicines to these same clinicians.
- Include provisions within the Regulations for 'case-by-case' approval of prescribers to initiate stimulant treatment, to accommodate future development of training and credentialing programs for other prescribers, such as general practitioners.
- Support shared care between the patient's specialist medical practitioner and their usual treating health practitioner, such as their general practitioner.
- Acknowledge that, in general, ongoing treatment of children requires greater specialist input than adults, due to ongoing child growth and development.
- Allow prescriptions for stimulant medicines, written in other States and Territories to be dispensed in WA, in recognition of patient mobility and use of telehealth consultation to facilitate access to specialist medical practitioners.
- Include a series of parameters relating to the drug, the prescriber and the patient within the Prescribing Code, and allow prescribing without authorisation or notification where all these parameters are met.
- Only require authorisation to prescribe stimulants where high-risk parameters are met and ensure there is ongoing specialist input with respect to treatment with stimulants for these patients.
- Continue to retain access to a group with clinical expertise in the management of ADHD, so advice can be provided to decision makers within the Department, where prescribing authorisation is required.
- Require notification of cessation of prescribing stimulant medicines, where the stimulant medicines are ceased due to high-risk circumstances existing.
- Continue to include special arrangements for patients, who are admitted to hospital, or whose ongoing treatment is within a custodial setting.

The expert advisory group, known as the Stimulant Assessment Panel, is considered an important resource to provide advice to the CEO delegates within the Department, in circumstances where the patient, if treated with stimulants, is at increased risk of adverse outcomes. The Panel is established as a Ministerial advisory board under the *Health Legislation Administration Act 1984,* and changes to the Regulations and the Prescribing Code will not affect the continuation of the Panel.

Changes to the detail of the regulatory controls over prescribing of stimulant medicines will make it appropriate to review the protocols used by the Stimulant Assessment Panel in making their recommendations.

[23] The Health (Notification of Stimulant Induced Psychosis) Regulations 2010 require psychiatrists to notify the Department of Health within 72 hours of making a diagnosis of stimulant induced psychosis. The Regulations do not differentiate between prescribed stimulants and illicitly sourced stimulants.

5.4 Prescriber eligibility to initiate treatment with stimulants

5.4.1 Guideline recommendations

In October 2022, the Australian Evidence-Based Clinical Practice Guideline for Attention Deficit Hyperactivity Disorder, 1st edition – 2022 was published by the Australian ADHD Professionals Association. The Australian Guideline recommendations were approved by the National Health and Medical Research Council, in July 2022.

This new Australian Guideline emphasises the importance of health professionals, who are diagnosing ADHD being adequately trained in diagnostic assessment using the Diagnostic and Statistical Manual of Mental Disorders and/or International Classification of Diseases, and also being experienced in ADHD diagnostic assessment. Furthermore, Recommendation 5.1.2 of the Guideline states that before starting medication for ADHD, a comprehensive assessment should be undertaken which includes confirmation that ADHD diagnostic criteria are met, evaluation of current educational or employment circumstances, risk assessment for substance misuse and drug diversion and assessment of physical health.

The Royal Australian and New Zealand College of Psychiatrists (RANZCP)recommends a number of guidelines published overseas as suitable for use by Australian and New Zealand psychiatrists when treating both adults and children experiencing ADHD. These include the Canadian ADHD Resource Alliance Practice Guidelines and the UK National Institute for Health and Care Excellence (NICE) Diagnosis and Management of ADHD in children, young people and adults. These guidelines also recommend that a diagnosis of ADHD be made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with specific training and expertise in the diagnosis of this health condition. Similarly, these guidelines recommend all medication for ADHD be initiated by healthcare professionals with training and expertise in diagnosing and managing ADHD.

The above-described recommendations mean that, at present, those with the appropriate training and expertise will most likely be particular classes of medical specialist, such as paediatricians and psychiatrists.

It is acknowledged that general practitioners and other primary care health practitioners have a vital role in identifying people who may have undiagnosed ADHD. In addition, a person's usual healthcare provider in the community has a role in working with their patient, the patient's family and the patient's treating specialist to monitor responses to medication.

The NICE guidelines recommend shared care protocols for medication monitoring between primary and secondary health care professionals and the new Australian Guideline supports the development of collaborative models of care, particularly shared care, within the Australian context. The RANZCP has published a professional practice guideline which details what the College considers to be best practice, in terms of managing shared care arrangements for patients experiencing mental health disorders more generally (i.e. not limited to care for patients experiencing ADHD),[24] however, the Australian Guideline also recommends research prioritisation should consider cost-effectiveness and new models of shared care, as there is a research gap in this area within the Australian context.

In particular, Recommendation 7.1.2 of the new Australian Guideline states: Laws and regulations for stimulant prescribing and shared care should be uniform between the States and

[24] RANZCP Professional Practice Guideline: Best practice referral, communication and shared care arrangements between psychiatrists, general practitioners and psychologists. Available at: https://www.ranzcp.org/files/resources/college_statements/practice_guidelines/ps-referral-between-psychiatrist-and-gp.aspx (accessed 25 January 2023).

Territories in Australia and allow for cross-border dispensing. They should reflect best practice and evidence of safety and effectiveness.

5.4.2 Designation of individual prescribers as 'stimulant prescribers'

Regulation 128 requires the Department designate each individual specialist medical practitioner who wishes to prescribe stimulant medicines for their patients as a 'stimulant prescriber' and issue them with a Stimulant Prescriber Number (SPN).

Although the Prescribing Code describes the classes of specialist medical practitioner who can be considered for designation, the current Regulations require each such specialist to apply and be individually designated as a 'stimulant prescriber'.

The designation process for medical specialists was reasonable at the time the Scheme was set up, as details of a medical practitioner's specialist registration were not publicly available. Since the introduction of the National registration scheme for health practitioners, details of whether a medical practitioner is registered in a relevant specialty are publicly available from the Australian Health Practitioner Regulation Agency (AHPRA) Register of Practitioners.

Through the public consultation, only 8 of 29 respondents (27.6%) supported continuation of the requirement for each stimulant prescriber to be individually designated. Comments from those who supported the status quo suggested that active approval as a 'stimulant prescriber' was consistent with ensuring those initiating stimulants had the appropriate specialist skills in diagnosing and monitoring conditions requiring treatment with stimulant medicines.

While the need to apply to be designated as a 'stimulant prescriber' may be a disincentive to those prescribers without a special interest in medical conditions for which stimulant medicines are appropriate treatment, the 'value add' from the regulator's perspective is now very limited. The Department's policy is that provided the applicant can be confirmed as holding registration as a medical specialist and is a member of a specialist class listed in the Prescribing Code, they will be designated as a 'stimulant prescriber'. No additional checks of their training or expertise are made.

Another advantage of moving from an individual designation to a system based on the specialist status of the prescriber is that this would then mean the majority of prescriptions for stimulant medicines written in another State or Territory would be valid for dispensing within WA.

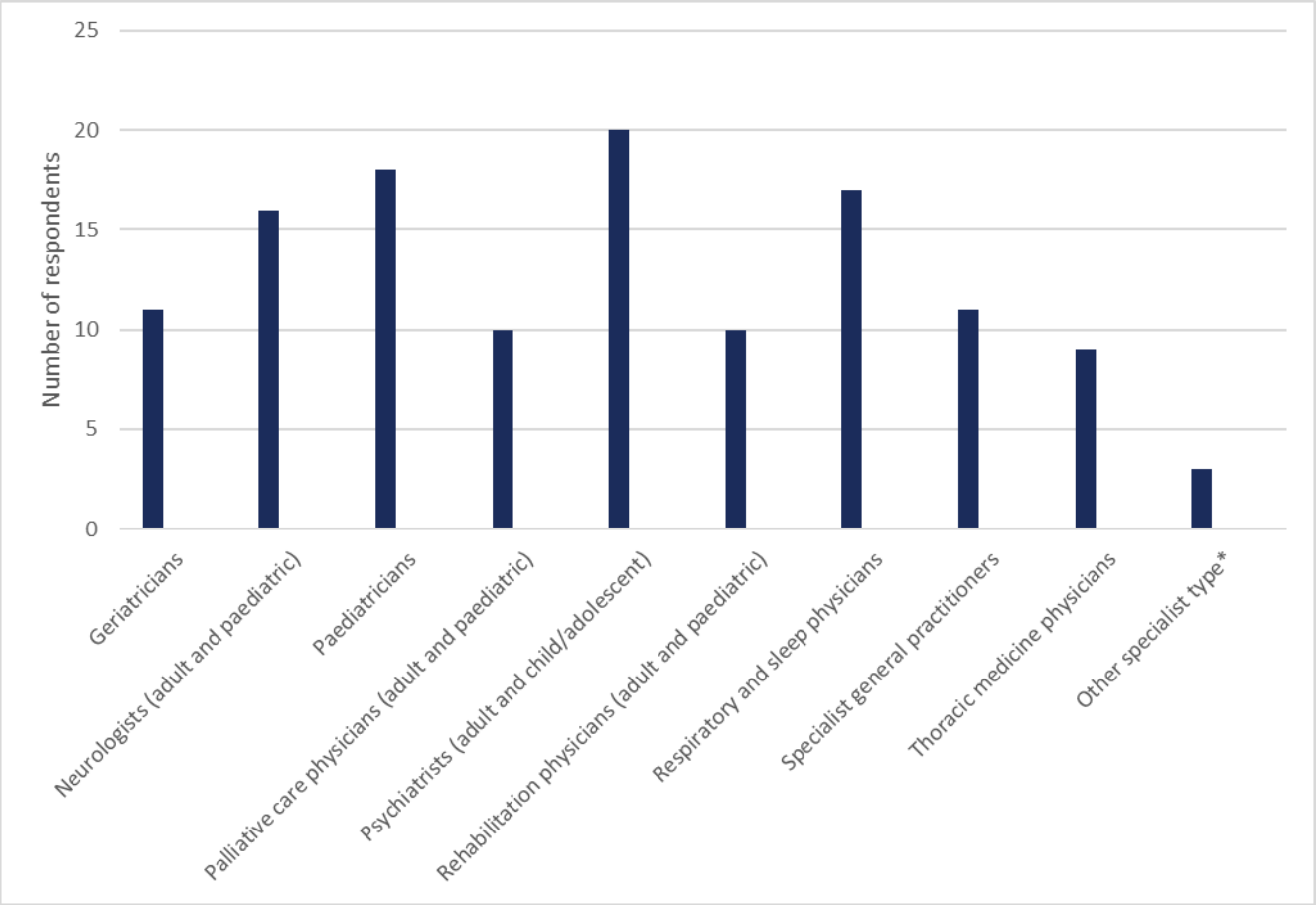
Recommendation 12: The Regulations be amended to remove the requirement for a Stimulant Prescriber Number to be issued. (See also Recommendation 13)

5.4.3 Initiation of stimulant treatment by specialist medical practitioners

Seventeen of 29 respondents (58.6%) supported either initiation of stimulant treatment by any specialist in defined groups or specialists plus other prescribers approved by the CEO of Health.

Another consultation question asked respondents to indicate which types of specialist should be allowed to initiate stimulant treatment. Respondents could choose as many options as they wished. The list included in this question in the Citizen Space survey included all specialist types currently named in the Prescribing Code, additional specialist types approved to initiate stimulant treatment in other States and Territories and general practitioners. An option for other prescriber groups was also included.

Figure 6: Type of prescriber eligible to initiate stimulant medicines



*Other prescriber types named by respondents were nurse practitioners and any medical practitioner provided they have completed appropriate training.

As can be seen in Figure 6, there was some support for every class of specialist medical practitioner included in the consultation question.

The current Prescribing Code (page 28) includes a matrix of the diagnoses for which each class of specialist medical practitioner may prescribe. Before amending this matrix, it would be appropriate to undertake further consultation with the relevant specialist colleges to determine their appetite for their fellows being authorised to prescribe stimulants.

Recommendation 13:

- The Regulations be amended to allow specialist medical practitioners in a class described in the Prescribing Code to initiate treatment with stimulant medicines (see also Recommendation 14).

- The current diagnosis/specialist prescriber matrix for stimulant prescribing, within the Prescribing Code, be retained until further consultation with relevant specialist colleges is undertaken.

5.4.4 Initiation of stimulant treatment by other prescribers

Ten of the 29 respondents (34.5%) supported inclusion of a clause in the Regulations that would allow the CEO of Health to authorise prescribers to initiate stimulant treatment on a ‘case-by-case’ basis.

Respondents raised a number of concerns in relation to prescribers other than specific classes of medical specialists being authorised to initiate stimulant treatment. Most concerns related to

the risk of undermining quality use of medicines, including through initial assessment being undertaken by prescribers with less training and experience in the diagnosis of conditions appropriate for treatment with stimulant medicines, particularly ADHD. Responses included:

- Despite issues with the current shortage of paediatricians and psychiatrists, it would be counterproductive to expand access to high-risk medications to more prescribers with less training in this therapeutic area. Such expansion creates a risk of reduced quality of care for an already vulnerable population.
- There is a risk of reduced level of psychiatric care if less qualified practitioners are treating the patient, without the support of a psychiatrist. A figure of up to 70% of adults diagnosed with ADHD having psychiatric co-morbidities was provided and there was concern that if the initiating prescriber had not undertaken comprehensive specialist training in psychiatry, these co-morbidities may be missed.
- It is important that stimulant medicines are not “over-prescribed” and specific training and experience is needed to achieve this.

Some respondents focused more on the issue of access to practitioners than the risks and benefits of allowing prescribers other than specialist medical practitioners to initiate treatment with stimulants. For example, there were calls to improve access to diagnosis and comprehensive treatment of ADHD through public sector clinics, including for adults. It was also stated that general practitioners are time poor and consultation length is limited. Conversely, it was noted that regional and remote access to specialist care has been improved through telehealth options, which have increased during the COVID era.

A number of consumers stated that prescribing by their general practitioner was preferable due to cost issues; however, it was not clear whether this was referring to initiation of treatment or continuation of treatment commenced by a specialist. Another response suggested that nurse practitioners should be able to prescribe stimulants; however, it was again unclear whether this was referring to initiation of therapy or continuation of prescribing in a shared care arrangement with a specialist medical practitioner.

One response summarised the critical issues for expanding who can initiate stimulant treatment as follows: “There is a need to balance access, flexibility and potential risk of inconsistent treatment against the current guidelines. Before the option of expansion of access can be fully supported, there needs to be additional clarification of what constitutes appropriate training and how monitoring will be conducted to minimise risk”.

Although a Regulation to allow the CEO of Health to actively authorise an individual or class of prescriber to prescribe stimulants may not be widely used immediately, it would have the benefit of providing regulatory flexibility into the future. Provided accompanying policy was publicly available, there may even be some incentive for appropriate training and credentialing to be developed for new groups of prescribers. For example, any authorisation could specify that it was only applicable to a certain patient group, such as adults, and could specify the training and experience that had to be completed.

While much of the focus of the consultation respondents was on the use of such a clause to authorise appropriately trained and experienced general practitioners, a ‘case-by-case’ authorisation could also include other individual practitioners, such as a psychiatry registrar in their final years of training.

Recommendation 14: The Regulations be amended to allow the CEO of Health to authorise an individual prescriber or a class of prescriber to initiate treatment with stimulant medicines and to allow the CEO of Health to include conditions on any such authorisation.

5.5 Notification of stimulant prescribing

Currently, specialist prescribers must notify the Department at the time they first prescribe stimulant medicines for each of their patient, whenever they alter the stimulant used to treat their patient and when they cease prescribing stimulant medicines for the patient.

The primary intent of the notification process is to limit a patient to one active stimulant prescriber at any time. This limitation aims to reduce the risk of patients accessing quantities of stimulant medicines in excess of therapeutic need (oversupply).

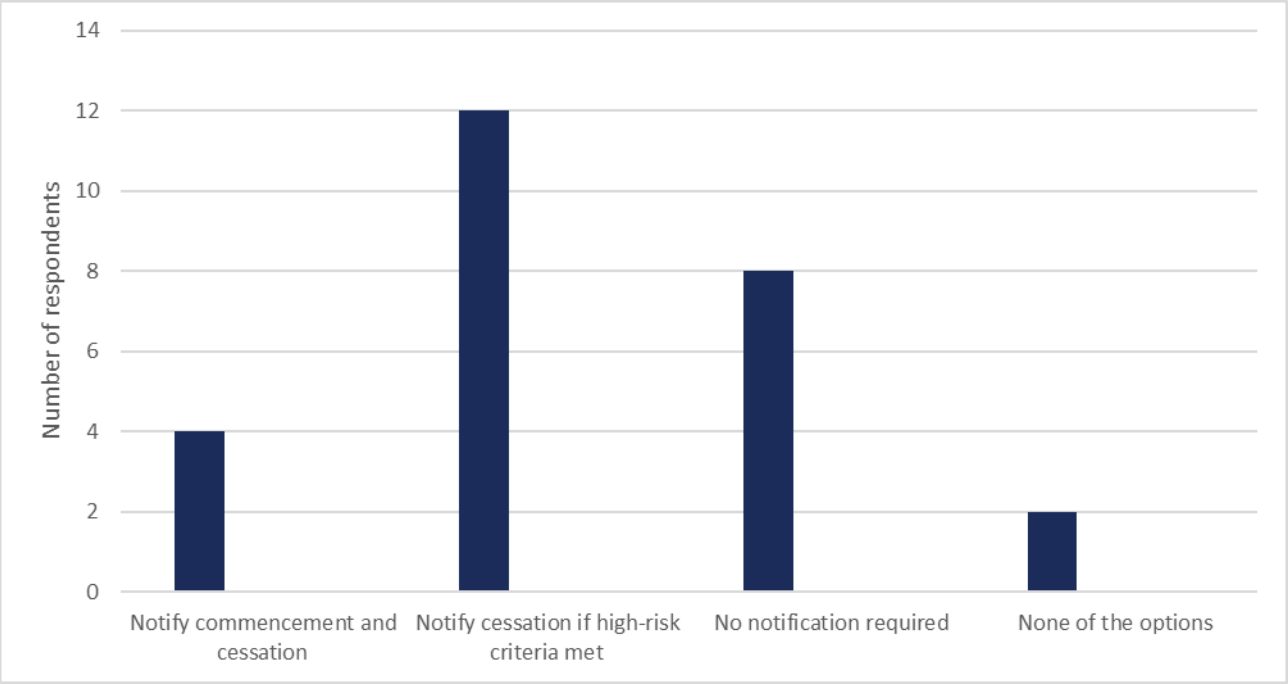
When notifying cessation of prescribing, stimulant prescribers must indicate the reason for termination of treatment. While this is often simply because the patient has moved to a different prescriber, including transitioning from adolescent to adult care, for a small group of patients, cessation of stimulant therapy is due to other reasons, such as serious stimulant-related adverse effects or other events which increase the risk of re-prescribing, such as diversion of stimulants by the patient. In other words, some of the reasons a prescriber ceases treating a patient with stimulant medicines will result in further prescribing of stimulant medicines meeting the high-risk criteria under the Prescribing Code. When high-risk criteria are met, further prescribing requires all subsequent prescribers to obtain a patient-specific prescribing authorisation from the Department.

With the introduction of ScriptCheckWA, dispensing data from community pharmacies will be immediately available to both the regulator and treating practitioners. Where the prescriber uses prescribing software to generate either a paper-based prescription or a fully electronic prescription, the prescribing event will also be immediately visible within ScriptCheckWA. Review of this information will allow prescribers to determine whether their patient has current prescriptions for stimulant medicines from another prescriber and then use this information in their clinical decision making in relation to prescribing for the patient. The Department will also be able to determine whether the patient has moved from one prescriber to another or obtained excess stimulant medicines.

In summary, the advent of RTPM makes the notification process redundant with respect to determining which prescriber is the patient's current stimulant prescriber; however, prescribing and dispensing data within ScriptCheckWA will not provide information about why a prescriber ceased treating a patient with stimulant medicines. This information would only be available via ScriptCheckWA if the Department is notified by the prescriber and the information is loaded into the database.

Twenty-six respondents answered the consultation question about requirements for specialist prescribers to notify commencement or cessation of stimulant prescribing for a patient. Twelve (46.2%) supported there only being a requirement for notification where the reason for ceasing treatment would mean further prescribing of stimulant medicines would require authorisation.

Figure 7: Options for notification of stimulant prescribing



An issue raised by respondents was the implications of cessation notification by a prescriber, who is a different prescriber to the prescriber who initiated the stimulant, particularly in the context of diagnosing stimulant induced psychosis.

To clarify, for patients who have been reported to the Department by a psychiatrist as being diagnosed with stimulant induced psychosis, an alert will be triggered in ScriptCheckWA regardless of whether a notification in relation to cessation of stimulant treatment has been made. Notification of cessation of stimulant prescribing and reporting of stimulant induced psychosis are two separate processes. The intent is for notification of cessation of prescribing to only be required from the initiating prescriber and only in circumstances where that prescriber has ceased stimulant treatment because they have assessed that the patient now meets high-risk criteria.

Recommendation 15: The Regulations be amended to remove the requirement for an authorised stimulant prescriber to notify when initiating or changing their patient's treatment with stimulant medicines but to continue to require notification of treatment termination, but only in circumstances where high-risk criteria, as detailed in the Prescribing Code, are met and where further prescribing of stimulants would require authorisation.

5.6 Appointment of co-prescribers

Under the current Scheme, the initiating specialist prescriber needs to notify the Department of the details of any other prescriber they have appointed to write ongoing prescriptions for stimulant medicines for their patient. Usually, the appointed co-prescriber will be the patient's general practitioner. In the public clinic setting, the co-prescriber may be a registrar.

The notification process ensures the regulator knows which other medical practitioners are authorised to prescribe for the patient. This means, where concurrent prescribing by multiple medical practitioners is detected, the Department knows which prescribers to contact about unauthorised prescribing.

As with all S8 medicines, a fundamental principle to reduce risk is to limit the number of prescribers writing prescriptions for the patient at any point in time. For stimulants, patients

would be expected to have one specialist prescriber and one other prescriber at any point in time.

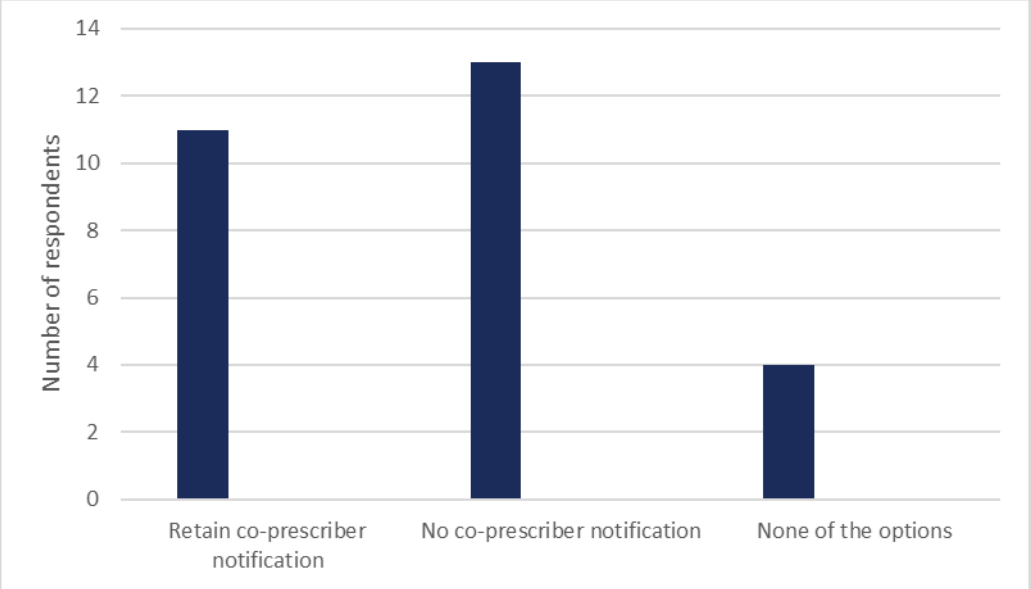
The improved information visibility via ScriptCheckWA will mean prescribers, pharmacists and the regulator will all be able to immediately identify other prescribers who have written prescriptions for stimulant medicines for the patient, when those prescriptions were written, when the prescriptions were dispensed and how many repeats remain on each prescription. In addition, clinicians will be alerted, in real-time, to the patient having multiple prescribers of S8 medicines.

As it is proposed, any specialist within certain classes will be able to initiate stimulant treatment, provided they abide by the criteria within the Prescribing Code, the immediacy of the data available through ScriptCheckWA will allow the Department to identify potential unauthorised prescribing of stimulants. For example, a prescription issued by a general practitioner, where there is no evidence of prior prescribing by a medical specialist, would be of concern. Similarly, a general practitioner writing a prescription, when there are multiple repeats remaining on the previous prescription, would also be of concern, especially if that prescriber had not previously written stimulant prescriptions for the person.

Currently, where there are very strict rules about who can prescribe stimulant medicines, the co-prescriber concept provides regulatory support for models of care, where the patient is jointly managed by their specialist and their general practitioner. In the proposed new scheme, where initiation of stimulant treatment will be linked to a practitioner's recognition as a specialist via their health practitioner registration and, if co-prescriber appointment is no longer required, there will be no regulatory impediment to shared care models from the perspective of writing prescriptions for stimulant medicines.

There were 28 responses to the question about notification of co-prescribing. Those favouring retention of the current co-prescriber appointment requirement were primarily current specialist stimulant prescribers. A concern was raised about multiple general practitioners within a practice prescribing ongoing stimulant treatment due to concerns about skillset variation across the general practitioner cohort. Similar sentiments were expressed by other specialists, who considered their medicolegal risk, level of patient care and monitoring, can be compromised by general practitioner prescribing.

Figure 8: Co-prescriber notification and specialist review periods



Recommendation 16:

• The requirement for the initiating stimulant prescriber to appoint and notify the Department of a co-prescriber be removed.

• The Regulations be amended to allow any prescriber to prescribe ongoing stimulant treatment to their patient, provided the prescriber complies with the requirements of the Prescribing Code and provided the patient is currently being treated with the same stimulant medicine, prescribed by a prescriber authorised to initiate stimulant treatment.

5.7 Specialist review period

The consultation question about the need for co-prescriber appointment was linked to the maximum time between review of the patient by a specialist. The question was asked in this way because the current 12 month review period detailed in the Prescribing Code had been flagged as a disincentive to specialists appointing a co-prescriber.

Other States and Territories also use general practitioner co-prescriber models; however, the required specialist review periods are inconsistent across Australia: periods of 12 months, 24 months, 3 years or even up to 5 years are used.

It should be noted that the writing of a prescription for a stimulant medicine is only a surrogate marker that specialist review has occurred. The Department does not have any other mechanism to determine whether the patient has had an annual consultation with their medical specialist.

A number of concerns were raised in relation to extending the period between specialist review from 12 months to the proposed 3 year period, particularly in relation to the treatment of children and adolescents with stimulant medicines.

The predominant view from those with significant clinical expertise in the treatment of children and adolescents with stimulant medicines was that the regulatory requirements should differentiate these patients from adults being treated with stimulant medicines. There were multiple reasons provided to support retaining a 12 month specialist review period for younger people including:

- greater likelihood of other factors complicating management, including the patient's family situation;
- the need for optimisation of dose as the patient grows and develops;
- the need for adequate monitoring (especially during developmental transitions); and
- treatment considerations in relation to co-morbid conditions.

Other comments included:

- An extended specialist review period, while it may be intended as a regulatory measure to protect public health, is likely to be interpreted by some practitioners as the appropriate review period from a clinical perspective.
- A 3 year review is essentially the equivalent of a new assessment of the patient each time they are seen by their specialist.
- A 3 year review period may be acceptable provided co-prescriber appointment is retained and the co-prescriber is only allowed to continue the same medicine at the same dose as the specialist prescriber.

- A 12 month specialist review period should be retained in all situations where authorisation to prescribe stimulant medicines is required because when authorisation is required, this indicates high-risk criteria are met.

A number of consumers who supported the proposed 3 year specialist review period felt it would reduce 'out-of-pocket' medical costs for patients and make it easier for patients to obtain stimulant prescriptions for ongoing treatment.

It should be noted that having a regulatory requirement for the patient to be reviewed by their specialist at least every three years in no way restricts the specialist from reviewing the patient more regularly. In particular, it would be expected that, if a patient was not fully stabilised on a stimulant dosing regime, they would continue to be reviewed by their specialist within a shorter period of time. Similarly, if the patient was experiencing unacceptable adverse effects a specialist review would also be appropriate. This is consistent with clinical practice guidelines for ADHD which state one of the roles of clinicians with expertise in treating this condition is responsibility for dose titration and stabilisation, before sharing care with primary care providers, such as general practitioners[25].

Recommendation 17:

• The requirement for regular specialist review be retained within the Prescribing Code as follows:

a) A requirement for an annual specialist review for patients until they reach 18 years-of-age.

b) For adult patients, where no high-risk criteria within the Prescribing Code are met, the requirement for specialist review be extended to a maximum of 3 years between reviews.

• Include a restriction within the Prescribing Code to limit any prescriber who is continuing treatment with stimulants under a shared care arrangement with a specialist prescriber to only continue the same stimulant medicine(s) at the same dose(s) and frequency as documented by the specialist prescriber.

5.8 Other Prescribing Code criteria for stimulant medicines

The Prescribing Code operates on an 'in the box/out of the box' model, where a prescriber does not need to be authorised to prescribe a particular regimen for each patient provided all criteria ('in the box') are met. Where at least one criterion is not met ('out of the box'), authorisation to prescribe will be required. Criteria can relate to the prescriber, the medicine, the patient or the condition being treated.

5.8.1 Matrix of specialist type and medical condition

Sixteen responses were received for the consultation question about which type of medical specialist should be allowed to initiate treatment for particular medical conditions.

Responses from organisations representing medical practitioners and individual medical practitioners essentially aligned with the current listing within the Prescribing Code.

However, in another question which simply asked which types of medical specialist should be allowed to initiate stimulant treatment (see Section 5.4.3), there was some support for stimulant initiation by other specialists not included in the current specialist/medical condition matrix, therefore, despite there being no strong signals that the current listing in the Prescribing Code

[25] NICE guidelines, recommendation 1.7.29 https://www.nice.org.uk/guidance/ng87/chapter/Recommendations#managing-adhd (accessed 20 January 2023).

needed to be changed, it would be appropriate to consult further with relevant specialist colleges (see Recommendation 13).

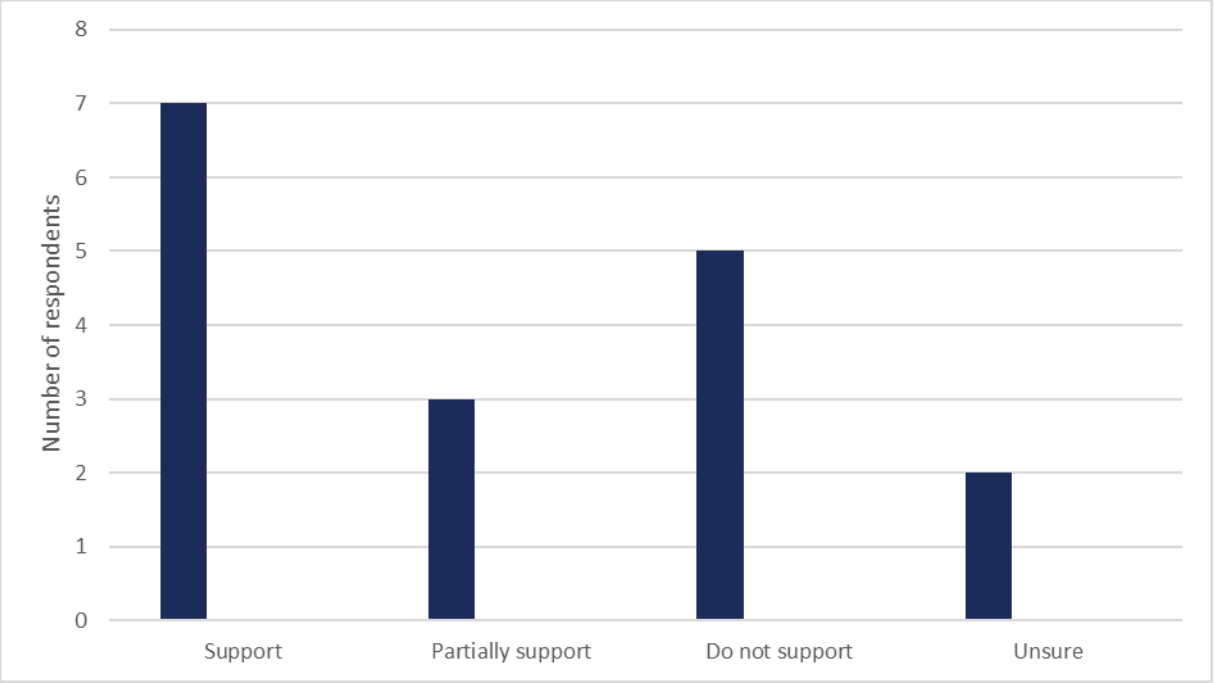
Recommendation 18: The current list of specialist medical practitioners and the medical conditions for which they can initiate stimulant medicines (without requiring a patient-specific prescribing authorisation) be retained within the Prescribing Code. Further consultation be undertaken with relevant specialist colleges in relation to adding other specialist types to the list.

5.8.2 Age limits for stimulant initiation by adult specialists

The consultation question asked whether the current restriction of only allowing non-paediatric specialists to prescribe stimulant medicines for their patient, where the patient has not previously been treated with stimulants, if the patient is 17 years-of-age or older. This restriction within the Prescribing Code means that, if an adult specialist wishes to commence treating a patient, who is under 17 years-of-age with a stimulant medicine, when the patient has never previously been treated with stimulant medicines, they must apply for a patient-specific prescribing authorisation.

Seventeen responses were received for this question.

Figure 9: Patient age 17 years and over for stimulant initiation by non-paediatric/adolescent specialist



Some of those who did not support retaining the current age at which a specialist trained to treat adults can initiate stimulant treatment for a patient (where the patient has not previously been treated with these medicines), cited the current shortage of specialist medical practitioners with specific training in the treatment of children and adolescents as a reason to allow adult specialists to treat people at a younger age. Some respondents thought people as young as 15 years-of-age should be able to commence treatment with an adult specialist.

The current 17 year-old cut-off within the Prescribing Code is consistent with the age at which the number of diagnostic criteria to be met for a diagnosis of ADHD change within the DSM-5[26]

[26] DSM-5: The fifth edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. See https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/DSM/APA_DSM-5-ADHD.pdf

criteria. For patients up to the age of 16 years, the DSM-5 requires 6 or more symptoms for a conclusive diagnosis, while only 5 or more symptoms are required for adolescents aged 17 years and older and adults.

While the age restriction in the Prescribing Code is about the age at which a prescription for a stimulant medicine can be written by particular types of medical specialist, this restriction essentially results in all adolescents, who have not previously been diagnosed with ADHD, having to see a paediatrician or child and adolescent psychiatrist. For patients who are 15 to 16 years-of-age, this restriction may result in transition of care to an adult specialist being required soon after commencing care with a particular paediatric specialist; however, it is also noted that around one third of psychiatrists, for whom child and adolescent psychiatry is a primary area of practice, report working across child and adolescent psychiatry and adult psychiatry.[27]

It is recognised that the minimum age at which a person is able to manage their own health and be responsible for their own healthcare is variable. For a young person, their chronological age is only one of multiple factors influencing their competency to independently manage their healthcare. Information about transitioning from paediatric to adult care, for people with chronic health conditions, usually describes age ranges rather than a single defined age for each part of the transition process.[28, 29]

However, a person can obtain their own Medicare card, independent of the rest of their family, from age 15 years or older and, in some circumstances, people are eligible for a Health Care Card once they turn 16. Within WA Health, the Child and Adolescent Health Service's Child Development Service (CDS) has recently stated that children are eligible for this service if they are under the age of 16 years at the time of referral[30]. If they are first referred when they are older, they will be encouraged to go to an adult service; however, CDS does provide services to adolescents until they turn eighteen.

It could be argued that the current restriction on adult specialists prescribing stimulant medicines is primarily restricting professional practice rather than directly managing a public health risk associated with the prescribing of stimulant medicines.

Recommendation 19: Amend the Prescribing Code to remove the lower age limit for initiation of treatment with stimulant medicines by specialist medical practitioners who treat adults. In other words, cease restricting initiation of stimulants to treat adolescents to specialist medical practitioners registered in the specialty of paediatrics and child health and psychiatrists practising in the subspecialty of child and adolescent psychiatry.

5.8.3 Age limits for stimulant initiation by paediatric and adolescent specialists

Currently, the Prescribing Code limits medical specialists who are registered in the specialty of paediatrics and child health or who are psychiatrists practising in the subspecialty of child and adolescent psychiatry, to only initiate treatment with dexamfetamine or methylphenidate when

(Accessed 23 January 2023). The latest revision of DSM-5, the DRM-5-TR (text revision, June 2022) does not make any changes to the diagnostic criteria for ADHD.

[27] Royal Australian and New Zealand College of Psychiatrists. Discussion paper prescribed by the Faculty of Child and Adolescent Psychiatry. Child and adolescent psychiatry: meeting future workforce needs. June 2019. Available at: https://www.ranzcp.org/files/resources/reports/fcap-workforce-discussion-paper-board-approved-may.aspx

[28] https://pch.health.wa.gov.au/~/media/Files/Hospitals/PCH/General-documents/Patients-and-Families/Health-facts/Transition---Resource-for-parents-and-carers.pdf (Accessed 23 January 2023)

[29] https://raisingchildren.net.au/teens/mental-health-physical-health/chronic-conditions/teens-with-chronic-conditions-adult-care (accessed 23 January 2023).

[30] Submission to the Select Committee into Child Development Services from the Child and Adolescent Health Service. Submission received 9 November 2022. Available at: https://www.parliament.wa.gov.au/Parliament/commit.nsf/luInquiryPublicSubmissions/A4DC2A68A89CA0C64825890900117696/$file/00077NoCover.pdf (accessed 23 January 2023).

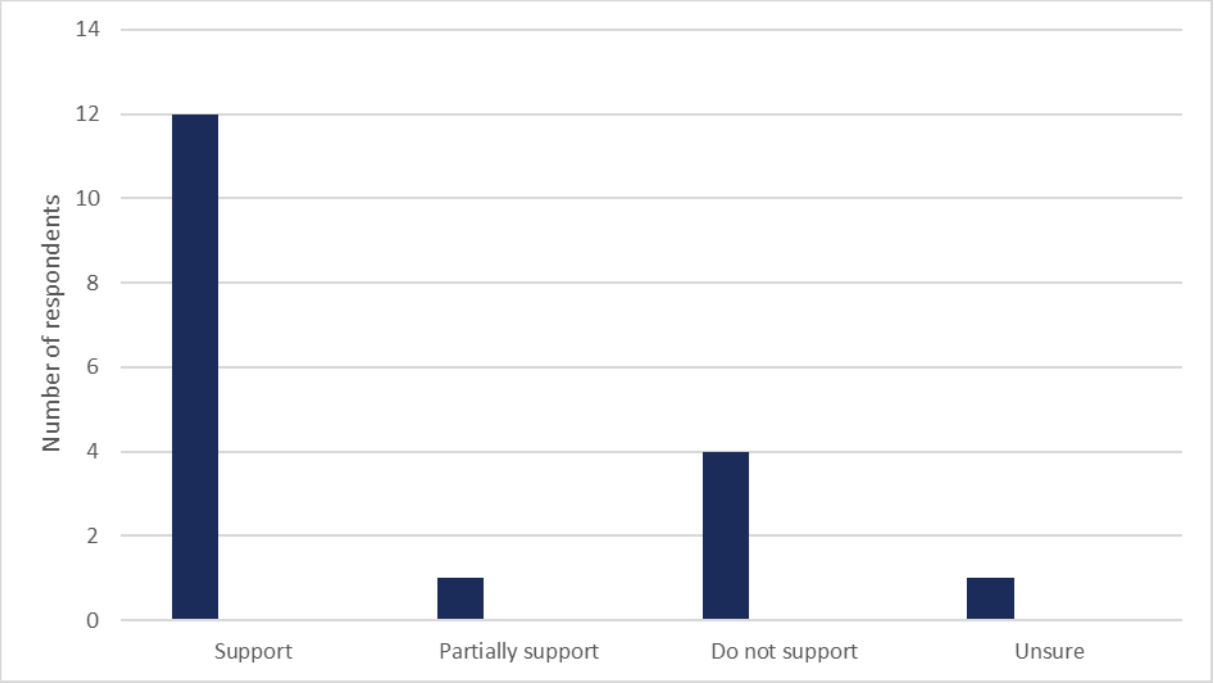
their patient is aged between 4 and 18 years inclusive, unless the specialist has been granted a patient-specific prescribing authorisation. Treatment of a child less than 6 years-of-age with lisdexamfetamine, is not permitted.

For example, if a specialist wanted to prescribe dexamfetamine for a patient under 4 years-of-age, they would need to apply for authorisation to do so.

The consultation question asked respondents about their level of support for the current 4 to 18 years-of-age range. The question did not ask about the lower and upper cut-off ages separately and had this been asked, different responses may have been provided. The question also did not differentiate the different lower age limit for the different stimulant medicines.

There were eighteen responses to this question.

Figure 10: Age range for stimulant initiation by paediatric specialists: Patient age 4 to 18 years inclusive.



The lower age limit of 4 years is consistent with the recommended lower age at which dexamfetamine should be prescribed, as detailed within Australian approved product information. The Australian product information documents for both lisdexamfetamine products state that this medicine has not been studied in children under 6 years-of-age. For methylphenidate products, the Australian product information states methylphenidate should not be used in children under 6 years-of-age, since safety and efficacy in this age group have not been established.

For treatment of ADHD, the Australian Therapeutic Guidelines[31] recommend stimulants should only be used in children aged younger than 6 years, in exceptional circumstances, and only under the close supervision of a specialist.

For lisdexamfetamine and methylphenidate, the PBS Authority requirements also limit use in children under 6 years-of-age.

[31] Attention Deficit Hyperactivity Disorder [published March 2021]. In: Therapeutic Guidelines. Melbourne: Therapeutic Guidelines Limited; accessed 25 January 2023. https://www.tg.org.au

Even though age cut-offs vary between stimulants from a clinical perspective, as a regulatory control, it is considered appropriate to retain the current lower age limits for requiring a patient-specific authorisation to prescribe. This age cut-off has been used in WA for many years without any evidence of increased public health risk. A number of other States and Territories also implement additional regulatory requirements, if a clinician wishes to commence stimulants when their patient is under 4 years-of-age.

The upper age limit of 18 years-of-age for commencement of treatment by specialist practising in the paediatric and adolescent space has similar issues to the current age restriction on initiation of stimulant treatment by adult specialists (see Section 5.8.2). This upper limit is essentially restricting a professional practice decision rather than an inherent risk with the prescribing of stimulant medicines.

Having a hard cut-off age for whether a patient starts their treatment with a paediatric or adult specialist is also inconsistent with adolescent and young adult medicine (usually defined as medical care for people aged 10 to 24 years) being a growing medical specialty area.

Recommendation 20:

Within the Prescribing Code:
• Retain the current requirements for prescribers to be authorised to prescribe a specific stimulant regime for each patient, if the patient is less than 4 years-of-age

• Continue to limit all prescribing of lisdexamfetamine to patients aged 6 years or older.

• Remove the upper age limit for paediatric specialist prescriber commencing treating a patient with stimulant medicines for the first time.

5.8.4 Continuation of treatment to age 25 years by paediatric specialists

This age restriction was intended to support continued treatment by paediatricians or psychiatrists practising only in the child and adolescent psychiatry subspecialty until the patient could be transitioned to adult care. Currently, this restriction operates in conjunction with the restriction that paediatric specialists must have commenced treating their patient with stimulant medicines before the patient turns 19.

This restriction is more about professional practice rather than an issue relating directly to the medicines themselves.

Recommendation 21: Remove the current upper age limit, within the Prescribing Code, for continuation of treatment by paediatric specialists.

5.8.5 Maximum doses and dosage adjustment within shared care arrangements

Currently, the Prescribing Code only allows specialists to change the dose of a stimulant medicine or the stimulant medicines itself. The Code also includes maximum doses that may be prescribed by specialists without needing to apply for authorisation to prescribe the higher dose for their patient. A co-prescriber can only prescribe in accordance with the regimen (drug, dosage form, dose and frequency) prescribed by the patient's medical specialist.

The Discussion Paper proposed a two-tiered approach where:

- specialist prescribers could prescribe up to the current maximum doses within the Prescribing Code without requiring any additional authorisation; and
- other prescribers could adjust the dose during ongoing therapy within the dosing range detailed in the Australian product information, as approved by the TGA.

For example, for dexamfetamine, the current maximum dose in the Code for treatment of all conditions is 1mg/kg/day up to 60mg per day, while the approved product information for dexamfetamine products only recommends a dose of up to 40mg per day for the treatment of ADHD.

There were 18 responses to the questions about the maximum dose that could be prescribed by specialist prescribers, without requiring a patient and regimen specific prescribing authorisation.

There was support for continuing the current maximum doses (without authorisation) for specialist prescribers, with 10 (55.6%) fully supporting a maximum dose of 60mg/day for dexamfetamine, 11 (61.1%) fully supporting a maximum dose of 70mg/day for lisdexamfetamine and 9 (50.0%) fully supporting a maximum dose of 120mg/day for methylphenidate.

There were 20 responses to the questions about dose adjustment by general practitioners.

There was an almost even split between support for the proposal, partial support and not supporting the proposal; however, there was also a considerable amount of comment on the risks of such an approach, primarily from groups representing specialist prescribers and individual specialist prescribers, as follows:

- Qualified support for dosage adjustment by general practitioners provided the specialist has indicated the range to be used.
- Specialist prescribers should be involved in the therapeutic decision-making regarding dose changes to stimulant medication.
- If a dose change is being considered, this should be a trigger for review by a specialist.
- More concern about co-prescribers changing doses for children than adults.
- A belief that the choice of dose is a clinical rather than a regulatory matter, especially as visibility via ScriptCheckWA will provide a lot of information that has previously been ‘invisible’ to prescribers.
- Concern from nurse practitioners that the survey only canvassed opinion about dose adjustment and ongoing prescribing by general practitioners.

There may be circumstances where dose adjustment is time critical, such as a dose reduction in response to intolerable drug side effects. It would therefore be reasonable for the Department to provide guidance about this aspect of care with a recommendation that dose reduction should either be on the advice of the patient’s specialist or, where the specialist is not immediately available, any dose change should trigger referral of the patient back to their specialist for review.

Figure 11: Co-prescriber dose adjustment for dexamfetamine

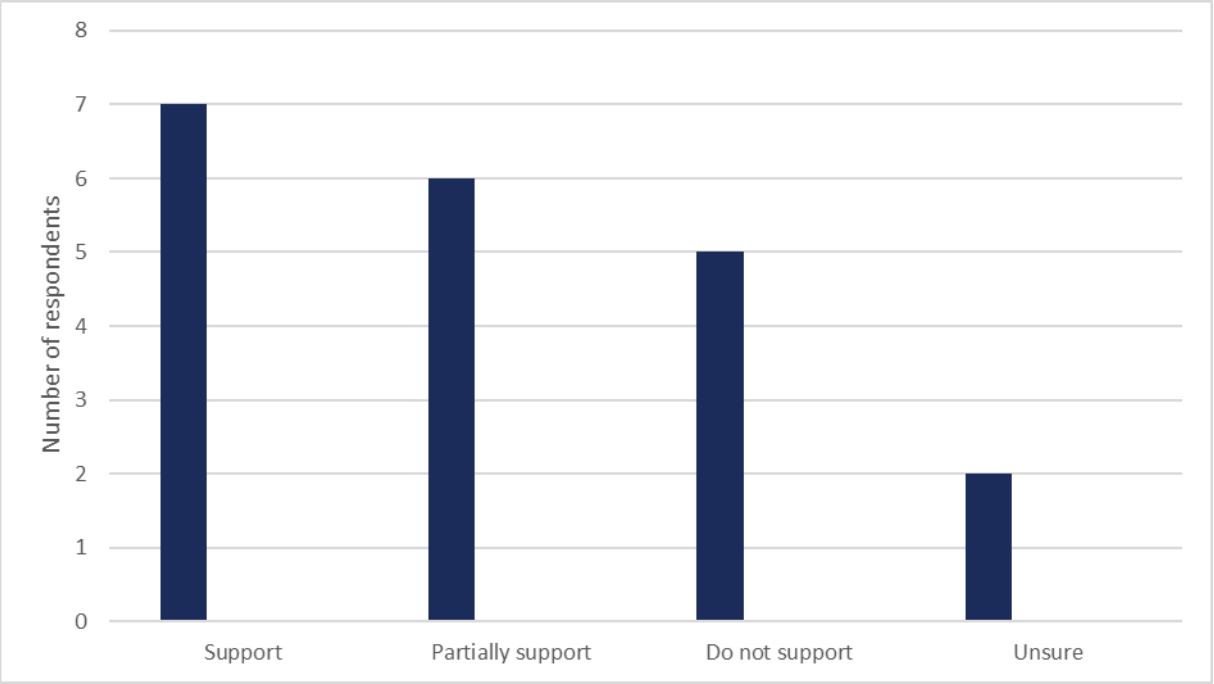
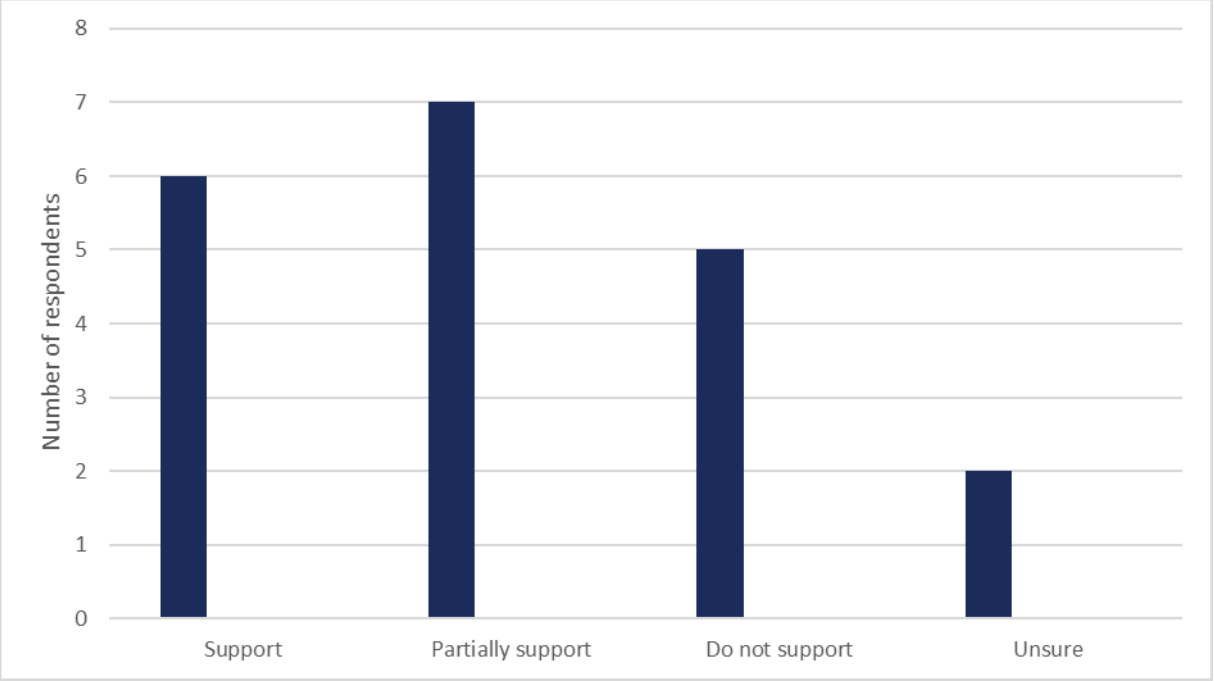


Figure 12: Co-prescriber dose adjustment for lisdexamfetamine



Recommendation 22:

• Maintain the current requirements for maximum doses without authorisation within the Prescribing Code.

• Continue to require prescribers who are not medical specialists to only prescribe the drug and dose previously documented by the patient's treating medical specialist.

5.8.6 Urine drug screening

The Prescribing Code currently includes the following statement: A urine drug screen (in accordance with *Australian/New Zealand Standard 4308*) should be undertaken by all patients

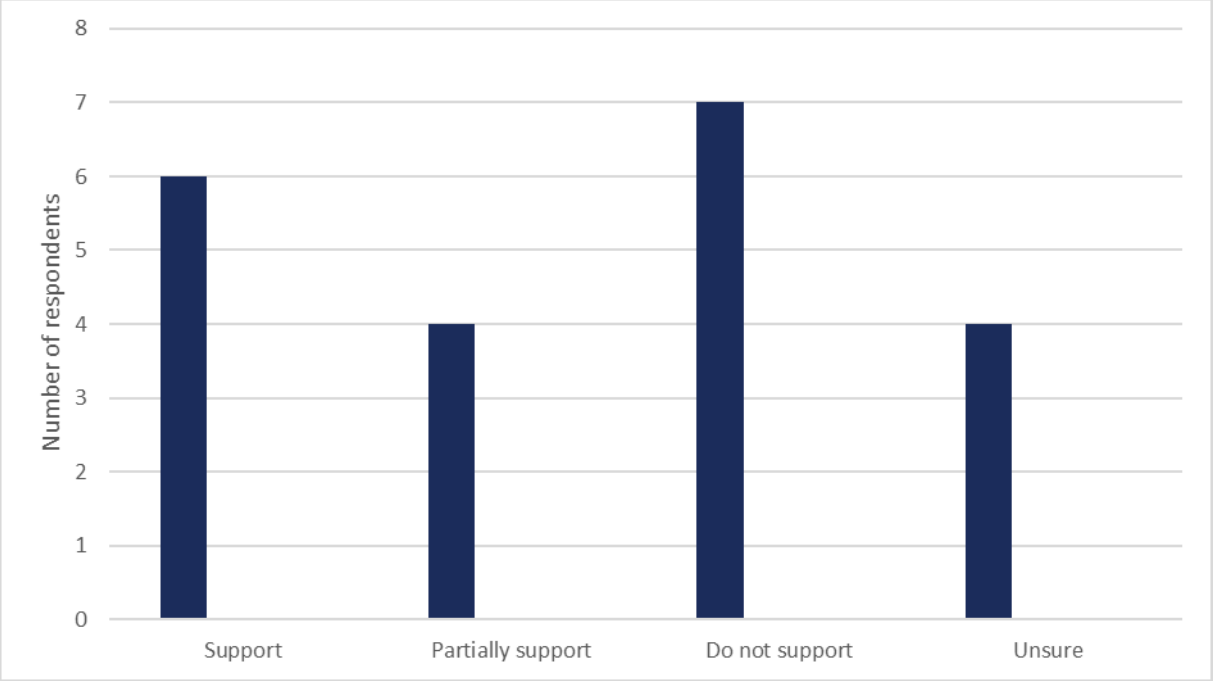
13 years and older before treatment with a stimulant is commenced. Further testing is recommended annually and as indicated.

The Discussion Paper proposed encouraging use of urine drug screens rather than continuing to essentially mandate this requirement. It is noted that other States and Territories do not include statements indicating urine drug screens ‘should’ be taken before commencing treatment with stimulant medicines; however, a number of other States ‘encourage’ the use of these screens, especially in particular circumstances, such as where the patient has a recent history of drug misuse. The purpose of such screens is twofold: to check there is no recent use of other drugs and, once treatment has commenced, to confirm the stimulant medication is being taken by the patient.

This particular prescribing criterion has attracted considerable adverse comment and concern over the years and this was reflected in the consultation responses.

There were 21 responses to the question about the proposal to change the wording around use of urine drug screens.

Figure 13: Encourage, but not mandate, use of urine drug screens prior to starting treatment in adolescents (13 years and older) and adults.



A number of respondents expressed concern that the requirements for urine drug screens present a barrier to care and a disincentive for patients to seek psychiatric support. Other comments included:

- Urine screening does not solve diversion problems.
- Urine screening should not be recommended, it should be discouraged.
- Clinical judgement should be used to manage urine drug screen requirements and these tests should not be mandated.
- The age for which urine drug screening is recommended could be increased to 16 years-of-age.

Recommendation 23: Continue to reference the use of urine drug screens within the Prescribing Code, with the following changes:
• include an explanation of the utility of these tests;

• increase the age at which such tests are encouraged, to 16 years-of-age; and

• continue to require the results of a urine drug screen to be included with any application for authorisation to prescribe stimulant medicines for a patient, who is recorded as a DDP, recorded as an oversupplied person or who has a current, or recent history of, substance use disorder (see also Section 5.8.7).

5.8.7 Other criteria where authorisation to prescribe stimulants is required

All Australian jurisdictions require prescribers to hold a prescribing authorisation (variously called an authority or permit) before they write prescriptions for any S8 medicine for people who have been formally reported as experiencing drug dependency.

In WA, the Act also includes a category of 'oversupplied person' and being recorded in this category results in the same authorisation requirements before prescriptions for S8 medicines can be written.

The current Prescribing Code also requires authorisation where:

- the patient has been reported as experiencing stimulant induced psychosis;
- the patient has a history of psychosis or bipolar disorder; and
- the patient has a history of substance abuse, diversion or misuse of drugs within the previous 5 years.

Although these aspects of the Prescribing Code were not specifically targeted during the consultation, a number of respondents raised concerns as follows:

- For patients with concurrent bipolar disorder (claimed to be approximately 20% of adults diagnosed with ADHD), the current authorisation requirement causes significant delays in commencing therapy with stimulant medicines. The respondent claimed the delay was caused by the time taken for referral of such authorisation applications to the Stimulant Assessment Panel for advice, and that the Panel recommendations often did not allow the prescriber to titrate the dose within standard clinical guidelines.
- There is no definitive information about what constitutes a 'history of substance abuse' within the Prescribing Code, and a recommendation that the criteria within DSM-5 for substance use disorder be used for determining whether a patient is at increased risk due to their use of alcohol and other drugs.

It is noted NSW recently updated their regulatory guidelines for stimulant prescribing for adults with ADHD.[32] This document states "Past history (but not in the last 3 months) of infrequent, non-parenteral illicit substance (including cannabis) abuse, may be considered not significant".

[32] NSW Ministry of Health. TG190/7 Criteria for the management of medication for attention deficit hyperactivity disorder in adults. December 2022. Available at: https://www.health.nsw.gov.au/pharmaceutical/Documents/adhd-criteria-adult.pdf (accessed 25 January 2023).

Recommendation 24: Further targeted consultation be undertaken to better define substance abuse/misuse for the purposes of the Prescribing Code and develop an evidence-based approach to the requirement for prescribing authorisation for stimulant medicines, where the patient has significant psychiatric co-morbidities.

5.8.8 Summary of prescribing criteria recommendations for stimulant medicines

Provided all the following prescribing criteria are met, the prescriber does not require a patient and regimen specific authorisation prior to prescribing a stimulant medicine for their patient. If one or more of the prescribing criteria are *not* met, the prescriber will need to apply for a patient and regimen specific authorisation to prescribe stimulant medicines for their patient.

Table 1: Prescribing criteria for stimulant medicines

Criterion	Current	Change to
Prescriber initiating stimulant treatment	Each prescriber must be appointed as a 'stimulant prescriber', including being issued with a Stimulant Prescriber Number (SPN). Members of certain classes of specialist are able to apply for a SPN, other applications can be considered on a 'case-by-case' basis.	Any specialist in classes of specialist named in the Prescribing Code can prescribe without seeking further authorisation if Prescribing Code criteria relating to patient age, diagnosis, medicine (including dose) and no current/history of substance use are met. Other prescribers can apply to be authorised as a 'stimulant prescriber' on a 'case-by-case' basis.
Medical condition	Matrix within the Prescribing Code which details which type of specialist can prescribe for: ADHD, narcolepsy, binge eating disorder, acquired brain injury and depression.	No changes to current matrix.
Patient age	• Paediatric specialists must only commence treating a patient with stimulants if the patient is aged between 4 and 18 years-of-age inclusive. • Paediatric specialists can continue treating a patient until the patient turns 26, where the specialist was already treating the patient before they reached 19 years-of-age. • Adult specialists can commence prescribing for patients, who are aged 17 years or older.	• Stimulant treatment must only be commenced for patients, who are at least 4 years-of-age. Note (current and future): 1. Lisdexamfetamine cannot be prescribed for anyone under 6 years-of-age. 2. Stimulant medicines cannot be prescribed for patients under 2 years-of-age.

Criterion	Current	Change to
Dexamfetamine	Under 18 years-of-age: 1mg/kg/day to a maximum of 60 mg/day. Adult: maximum 60 mg/day.	No change.
Lisdexamfetamine	Over 6 years-of-age commence at 30mg/day, maximum dose 70 mg/day.	No change.
Methylphenidate	Under 18 years-of-age: 2mg/kg/day to a maximum of 120 mg/day. Adult: maximum 120mg/day.	No change.
Urine drug screen (Australian/New Zealand Standard 4308)	Should be undertaken before commencing treatment with stimulants for all patients 13 years and older. Further testing recommended annually and as indicated.	The decision to undertake a urine drug test is a clinical decision but is encouraged prior to commencing stimulant treatment for all patients aged 16 years and above, except in the following circumstances: Applications, including renewal applications to prescribe stimulant medicines, must be accompanied by the results of a recent urine drug screen, where the patient is recorded as a Drug Dependent Person, is recorded as an oversupplied person or has current, or a recent history of, substance misuse.#

#wording to be finalised following consultation as detailed in Recommendation 24.

6 Regulation of cannabis-based products in Schedule 8

6.1 Background and current regulatory scheme

When the Regulations were first being developed, the decision to move cannabis, for therapeutic use, to S8 (controlled drugs) was awaiting implementation. Prior to this change, cannabis was classified only as a prohibited substance (Schedule 9), with the exception of nabiximols (S8) and two individual cannabinoid substances, dronabinol (S8) and cannabidiol (S4).

At the time, there was limited information about the type of products that may become available and the projected uptake by prescribers. It was anticipated that, because medicinal cannabis is not a first-line treatment for any indication, specialist medical practitioners would be involved in the care of patients commencing treatment with this therapeutic option.

These factors resulted in the development of a regulatory scheme similar to that used for stimulant medicines, where suitable specialists could be designated as a ‘cannabis-based

product prescriber' and they could appoint a general practitioner or other medical practitioner as a co-prescriber for their patient. Similar to the stimulant regulatory scheme, the patient's situation must meet specific criteria and the specialist prescriber must notify the Department of their prescribing for each patient.

Through the Prescribing Code, the 'cannabis-based product prescriber' notification scheme is applicable to TGA registered products and limited other circumstances: treatment within a clinical trial and prescribing by a TGA Authorised Prescriber (TGA AP).

Five years after cannabis became legally available for therapeutic use, the vast majority of cannabis-based products remain unapproved therapeutic goods. Only one product in S8 (Sativex®, nabiximols) and one cannabidiol-only product in S4 (Epidyolex®) have been approved for marketing across Australia by the TGA.

Unless prescribing of medicinal cannabis products that are unapproved therapeutic goods is within a clinical trial or by a TGA AP, prior authorisation by the Department, is currently required to prescribe each product for each patient, which is consistent with the rules for other S8 medicines that are unapproved therapeutic goods.

However, the situation for cannabis-based products is slightly different to other unapproved therapeutic goods in S8 in that products must comply with a quality standard issued by the TGA, *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*.

It has been argued that, as the TGA is already approving prescribing of unapproved therapeutic goods, authorisation at a State level is redundant; however, these two approvals are for separate purposes.

The TGA is focused on the risk of patients being exposed to an unapproved product rather than an approved product while the focus of the States and Territories is on managing public health risks associated with use of drugs that can cause dependency and addiction.

The TGA will not necessarily have information about a patient's prior history with respect to drug dependency or their concurrent treatment with other S8 medicines. This information will be available to the Department, for use in application assessment. Once ScriptCheckWA is available to prescribers, they will also have access to information about drug dependency, oversupply and treatment with other S8 medicines at the time of prescribing medicinal cannabis.

6.2 New scheme for regulating medicinal cannabis prescribing

During 2022, over a total of over 11,000 applications for authorisation and notification of treatment with medicinal cannabis were received, with 620 applications/notifications unable to be issued or made active and 628 applications/notifications withdrawn by the applicant.

Only 1.2% of total applications/notifications were declined because prescribing met high-risk criteria, and there was no support from a relevant specialist medical practitioner for treatment with medicinal cannabis. A significant number of applications were unable to be issued because the product was in S4 (cannabidiol-only), which meant no application for authorisation was required. In the remainder, the application/notification could not be processed because the applicant provided insufficient information and did not respond to requests from the Department for the required information.

Of the applications declined due to high-risk circumstances, the most common reasons were:

- the patient was recorded as a drug dependent or oversupplied person; or
- the patient was currently being treated with opioid substitution therapy; or
- the patient was aged less than 18 years; or

- the patient had significant psychiatric co-morbidities; and
- the applicant did not provide documentation of support for treatment with medicinal cannabis from a specialist medical practitioner appropriate to the medical condition being treated, such as a psychiatrist, where the cannabis is being prescribed for treatment of anxiety.

It should be noted that the number of applications and notifications is higher than the number of patients treated because patients may be treated with more than one cannabis-based product concurrently or sequentially.

Currently, unless notification is applicable, the Regulations require authorisation to be issued before medicinal cannabis in S8 can be prescribed. This is regardless of whether prescribing would be considered lower-risk or high-risk.

Five years after cannabis was re-scheduled to allow therapeutic use, the majority of both notifications and applications for prescribing authorisation for these products fit within what could be considered lower-risk parameters, including:

- starting dose is low with titration to a maximum of 30mg tetrahydrocannabinol (THC) per day;
- patients are adults (18 years or older);
- patients are not recorded as a drug dependent or oversupplied person and there is no other evidence of substance use disorder during the preceding five years; and
- the medicinal cannabis prescriber is aware of any other S8 medicines being prescribed for the patient.

The above experience, combined with the increased information visibility afforded by ScriptCheckWA, provides an opportunity to reduce the regulatory burden associated with prescribing medicinal cannabis in S8 and creates a more agile regulatory framework for medicinal cannabis in S8.

A number of options were presented for consultation. The Department's preferred option was to use a similar regulatory scheme to that used for opioids, where a number of parameters are used to divide prescribing into high-risk and lower-risk, where the prescriber only requires a patient and regimen specific authorisation to prescribe in high-risk circumstances. This scheme reduces the regulatory burden for prescribers while continuing to limit the risk for vulnerable patients and the community more generally.

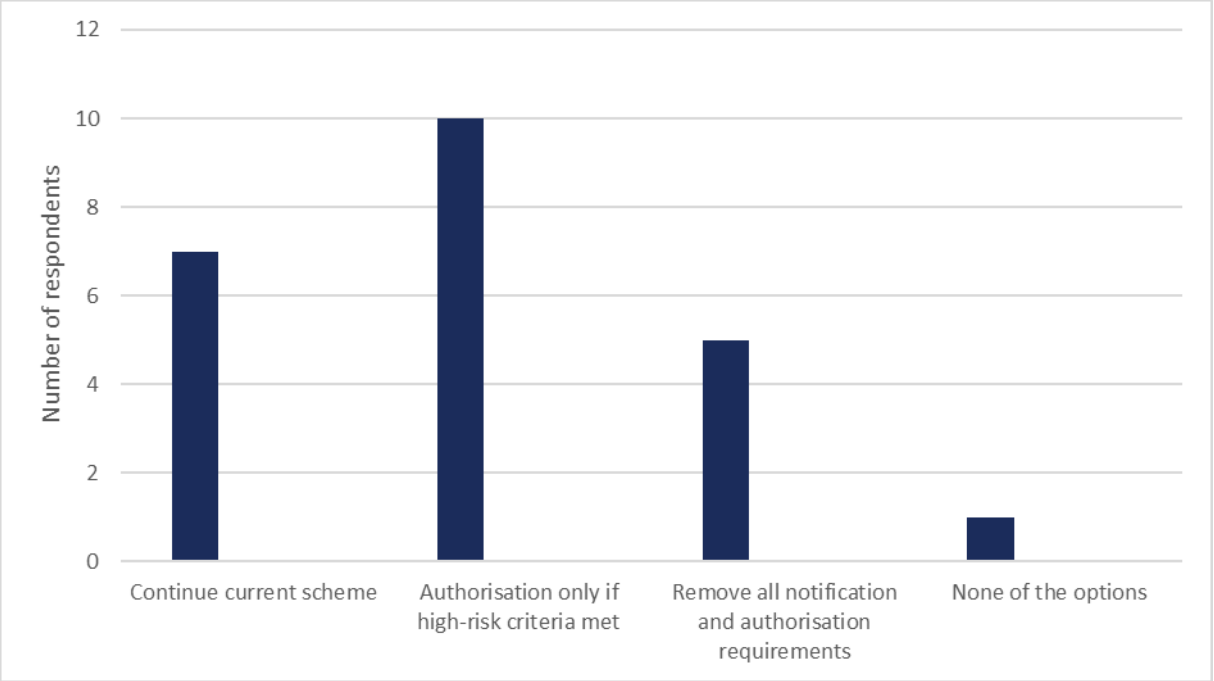
There were 23 responses to this question and there was more support for the Department's proposed scheme than the other options.

Those who supported the proposed alignment with the regulatory controls over opioids, made a number of comments including:

- With the increasing knowledge on prescribing and use of medicinal cannabis over the last few years, it is an appropriate time to move to the proposed regulatory model.
- The easing of requirements may increase the number of prescribers interested in prescribing medicinal cannabis and improve access for patients, although there will still be cost implications for patients.
- The proposed scheme is supported because a person trying to access medicinal cannabis for a health condition should not face greater challenges than if they were being treated with benzodiazepines or opioids.

- There should be no authorisation requirements to prescribe for people for whom palliative care is being provided, and both medical practitioners and nurse practitioners should be able to prescribe medicinal cannabis for this patient cohort.
- Any change to medicinal cannabis regulation, should be supported by appropriate evidence-based education (including professional development) and the development of evidence-based clinical guidelines.

Figure 14: Scheme for regulating cannabis prescribing



However, there were still 30% of respondents who favoured continuation of the current regulatory scheme for medicinal cannabis. This rose to 50% if only responses from organisations representing the medical profession and responses from individual medical practitioners were considered.

Concerns raised by those respondents who supported retaining the status quo included:

- potential for conflicts of interest is considerable especially as there is involvement of businesses marketing medicinal cannabis products in clinics, where prescribing occurs;
- there appears to be direct marketing to consumers, which is worrisome;
- the potential for drug interactions is high because many of the patients are already taking analgesics, hypnotics, neuromodulators, antipsychotics and stimulant medicines;
- local data on use, dosage and adverse events, is limited;
- concern that prescribers are not appropriately screening patients for contraindications or monitoring clinical response;
- the regulatory changes to permit use of cannabis as a medicine are relatively new and need more evidence before making legislative changes; and
- prescribing should not be widened until products are TGA approved.

Those who supported complete removal of notification and authorisation requirements were a mix of individual consumers, healthcare workers (who were not health practitioners) and prescribers. Comments made by this group of respondents included:

- Deregulation is urgent and cannot come soon enough for this field of medicine. We know more about how cannabinoids act on the brain than we do about most other medications.
- Abuse potential is significantly less than other S8 medicines.
- The current regulations actively exclude nurse practitioners as prescribers of medicinal cannabis, even though they are highly trained.

Recommendation 25: The Regulations be amended to regulate the prescribing of medicinal cannabis in the same manner as other S8 medicines (other than stimulant medicines).

6.3 Proposed Prescribing Code criteria for lower-risk cannabis prescribing

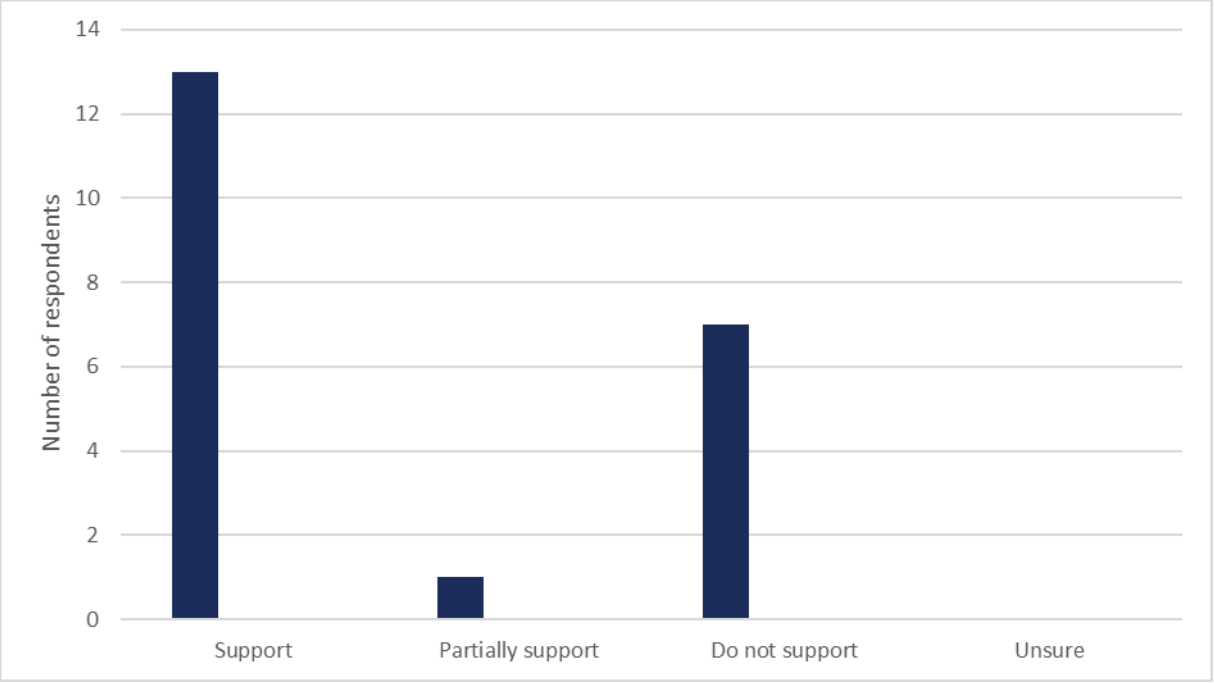
Consultation was undertaken on a number of prescribing criteria, selected to represent lower-risk prescribing of medicinal cannabis. Lower-risk prescribing would not require authorisation. Outside these criteria, authorisation to prescribe for the patient, would be required and the support of a relevant specialist medical practitioner would be expected as part of this process.

Twenty five respondents answered one or more parts of the consultation question about prescribing criteria.

6.3.1 Total daily dose of tetrahydrocannabinol (THC)

There were 21 responses to the question about level of support for a maximum daily dose of 30mg of tetrahydrocannabinol (THC), with a requirement for authorisation above this dose. A number of respondents also provided additional written information about this proposed prescribing criterion.

Figure 15: Authorisation required if total daily THC dose exceeds 30mg



Although the majority (61.9%) of respondents supported the proposal that a maximum daily THC dose of 30mg represented lower-risk prescribing, all respondents with experience prescribing medicinal cannabis or other direct involvement in the medicinal cannabis industry were unsupportive of this cut-off. Five of those (71.4%) who did not support this prescribing criterion had supported there being no notification or authorisation requirements for medicinal cannabis in the previous question. Some respondents supported a daily THC dose cut-off of 40mg/day.

There have been a number of consensus expert opinion articles published in the last few years which provide guidance about safe dosing of medicinal cannabis products for the treatment of chronic pain. These articles use a systematic consensus process, such as the Delphi method, to provide guidance on the use of medicinal cannabis in the clinical setting. Such methods do not replace the use of rigorous randomised controlled trials and have been criticised as potentially resulting in recommendations based on suboptimal evidence.[33]

The widely quoted article by MacCallum and Russo[34] recommended a maximum THC dose of 30mg per day, whereas more recently published articles[35, 36, 37] all support a maximum THC dose of 40mg per day, unless the medicinal cannabis is being prescribed by an experienced medicinal cannabis prescriber. It should be noted that, unlike the other articles, MacCallum and Russo do not specify the condition being treated, although they do provide a table showing levels of evidence for various health conditions, and adult chronic pain is a condition for which these authors conclude there is conclusive/substantial evidence of efficacy. The other conditions in this category are spasticity associated with multiple sclerosis, chemotherapy included nausea and vomiting and treatment of intractable seizures in Dravet and Lennox-Gastaut syndromes. For seizure treatment, the evidence relates to cannabidiol-only products.

There is also some emerging evidence of high-frequency medicinal cannabis use being associated with worsening pain outcomes when cannabis is used to treat chronic pain.[38]

TGA Authorised Prescribers of medicinal cannabis are bound by the requirements of their Human Research Ethics Committee (HREC) approved submission, and it is not uncommon for these approvals to allow prescribing of doses over 40mg THC per day. It is considered reasonable for these prescribers to be able to prescribe higher doses, without further State-based authorisation, provided their prescribing remains within the dose parameters included on their HREC documentation.

The proposed 40mg/day THC dose limit is not an upper limit for dosing but rather a limit above which risk increases and ‘case-by-case’ prescribing authorisation is therefore considered necessary to manage this risk. This is analogous to the situation with opioid treatment, where prescribing authorisation is required when the patient will be treated with a total daily dose of more than the equivalent of 90mg oral morphine per day.

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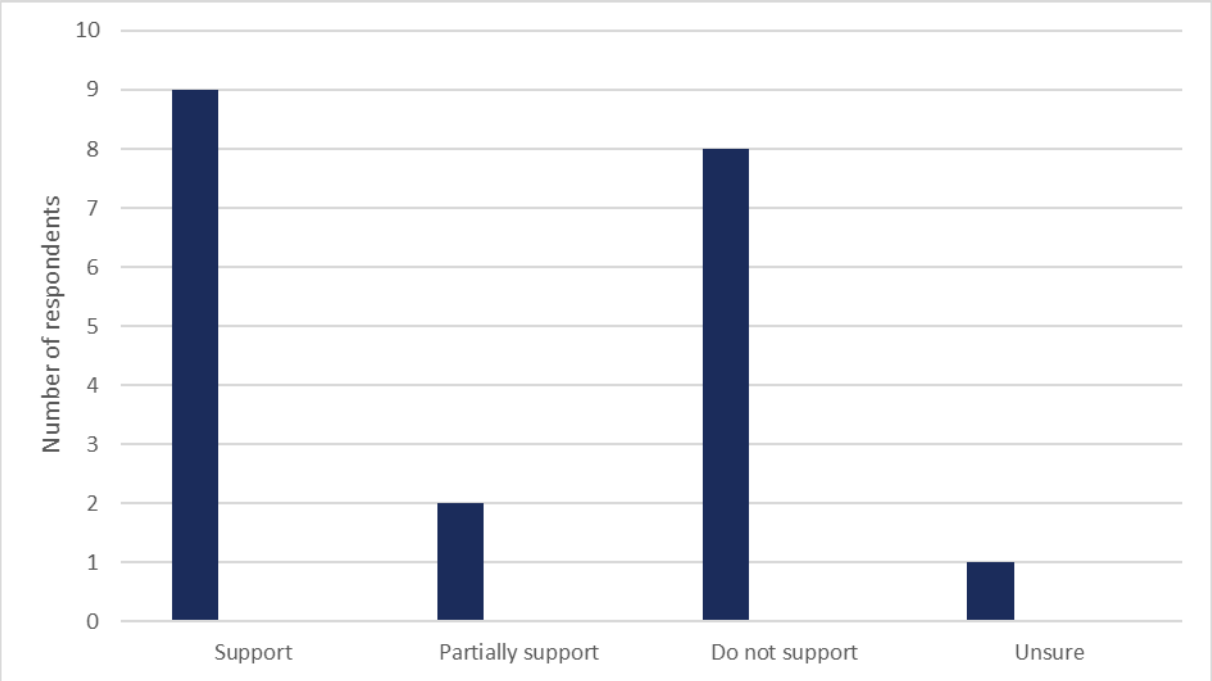
[33] Hill KP, Abrams DI. A cannabis oracle? Delphi method not a substitute for randomized controlled trials of cannabinoids as therapeutics. J Cannabis Research 2021;3(1): 23.
[34] MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. Eur J Int Med 2018;49:12-19.
[35] Bhaskar A, Bell A, Boivin M et al. Consensus recommendations on dosing and administration of medical cannabis to treat chronic pain: results of a modified Delphi process. J Cannabis Research 2021;3(1):22.
[36] Busse JW, Vankrunkelsven P, Zeng L et al. Medical cannabis or cannabinoids for chronic pain: a clinical practice guideline. BMJ 2021374:n2040.
[37] Sihota A, Smith BK, Ahmed S-A et al. Consensus-based recommendations for titrating cannabinoids and tapering opioids for chronic pain. Int J Clin Pract 2021;75:e13871.
[38] Boehnke KF, Scott JR, Litinas E et al. High-frequency medical cannabis use is associated with worse pain among individuals with chronic pain. J Pain 2020;21:570-581.

Recommendation 26: The Prescribing Code to provide for a maximum dose of 40mg/day of THC without authorisation, unless the prescriber is a TGA Approved Prescriber and is approved to prescribe higher doses. Higher daily doses of THC would require the prescriber to apply to the Department for authorisation to prescribe a particular medicinal cannabis regimen to their patient.

6.3.2 Dosage form

The consultation question sought advice on a proposal to require a patient and regimen specific authorisation to prescribe medicinal cannabis product (bud or flower) intended for use by vaporisation. There were 20 responses to this question.

Figure 16: Use by vaporisation to require prescribing authorisation



Those who supported a requirement for prescribing authorisation for bud and flower products were primarily medical practitioners or organisations representing medical practitioners. Comments in support of this requirement were as follows:

- Although vaporisation versus smoked cannabis is likely to have benefits related to the reduction in carcinogenic toxins from combustible smoke, long term safety data, is scant.
- Concern about patients using considerably more than the number of ‘puffs’ prescribed and smoking the product instead of inhaling, via a vaporiser.
- Concern there is a risk of patients using cannabis via vaporisation to increase their dose to a point where they have similar dependency problems to someone who uses illicit cannabis.
- Anecdotal evidence of patients replacing their dispensed cannabis bud/flower product with illicitly sourced cannabis and then claiming the product in the container is legally prescribed and dispensed cannabis.
- Concern about the presentation of plant material as a ‘medicine’ knowing the inherent lack of control over cannabinoid content, amount of absorption and actual mode of use, among other variables.
- Concern about increased prescribing of this dosage form in certain patient cohorts, who are at greater risk of adverse reactions and interactions, including risk of psychosis.

Those who did not support a requirement for authorisation to prescribe this particular dosage form were a more diverse group of respondents, including prescribers, consumers, patients and other respondents associated with the medicinal cannabis industry. A number of these respondents had declared their lack of support for any prescribing authorisation requirements in a previous question. Comments from those who did not support additional restrictions over prescribing bud and flower products included:

- The route of administration should be a decision for the prescriber, based on what is clinically appropriate for the patient.
- Other large States do not require authorisation for patients to be prescribed medicinal cannabis for vaporisation. If WA was to restrict prescribing of bud and flower products in this way, there is a risk of patients simply choosing an interstate-based prescriber/clinic and this could then mean incomplete information will be available in ScriptCheckWA (if both prescribing and dispensing occurred in another State).

A recent review examined the evidence available in relation to cannabis dependence associated with cannabis-based medicines.[39] The authors provided commentary on various factors, which may influence dependence risk. The route of administration is one of these factors, with oral administration routes being considered to reduce the risk of abuse-related subjective and neurocognitive effects. A key recommendation was the need for development of safe use guidelines, with a comment that a preference for cannabidiol (rather than THC) and use of non-inhalation administration routes are considered safer use behaviours.

A cross-sectional survey[40] of patients who used cannabis for treatment of chronic pain, found that, of those participants who self-reported using medically prescribed cannabis only, a lower daily use frequency was associated with a better analgesic outcome. In addition, high level use (cannabis used 5 or more times per day) was associated with a preference for smoking, vaporising and high THC products. Participants who only used cannabis once or twice a day were more likely to be using oral therapies, such as tinctures and high cannabidiol products, which are considered indicators of lower-risk cannabis use behaviours.

Given the reasonably even division between those supporting and not supporting this proposed prescribing criterion, a modified prescribing restriction is suggested, which acknowledges there is variable experience among prescribers with respect to their use of medicinal cannabis to treat their patients.

Recommendation 27: That the Prescribing Code require a prescriber to be issued a patient and regimen-specific authorisation before prescribing medicinal cannabis products intended for vaporisation, unless the prescriber has TGA Authorised Prescriber status for medicinal cannabis products, or the medicinal cannabis product is a product for vaporisation with full marketing approval from the TGA.

6.3.3 Number of medicinal cannabis products concurrently prescribed

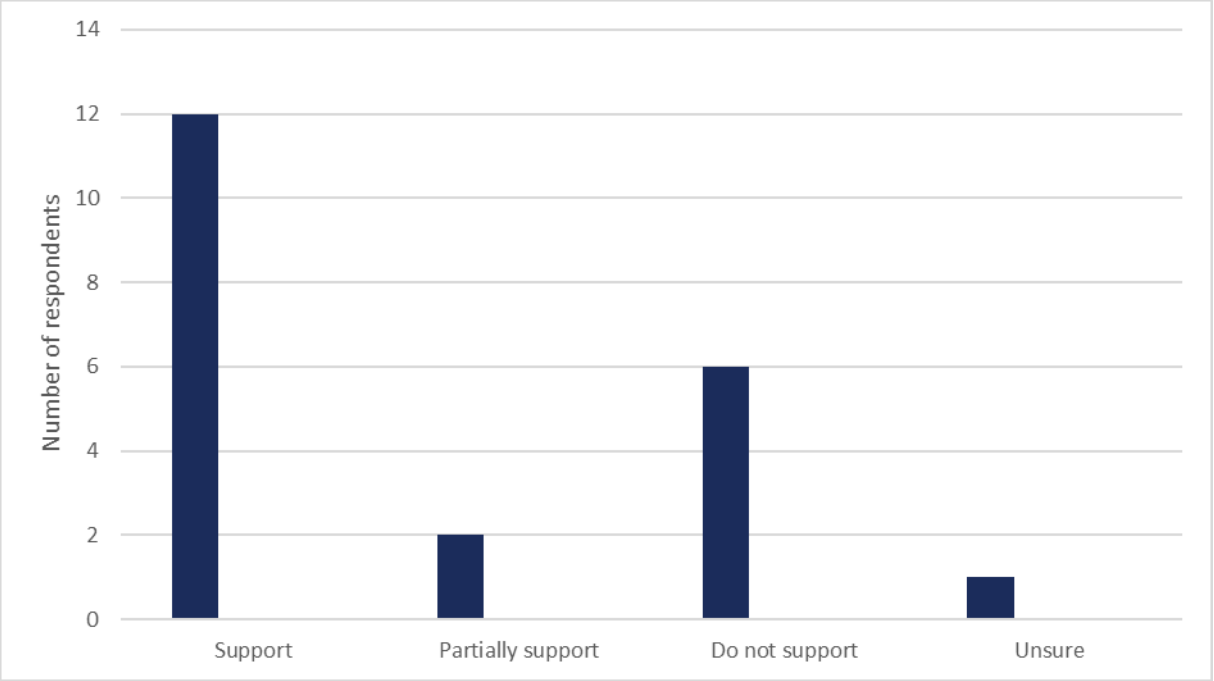
The consultation question asked for support or otherwise for a requirement for prescribing authorisation if more than two cannabis products were being prescribed concurrently. This criterion sought to reduce the risk of unintended adverse outcomes, particularly where the majority of products do not have TGA approved product information documents. This criterion means a patient with chronic pain could still be treated with an oral product (longer acting

[39] Schlag AK, Hindocha C, Zafar R et al. Cannabis based medicines and cannabis dependence: a critical review of issues and evidence. J Psychopharmacol 2021;35:773-785.
[40] Boehnke KF, Scott JR, Litinas E et al. High-frequency medical cannabis use is associated with worse pain among individuals with chronic pain. J Pain 2020;21:570-581.

product), with a product for vaporisation for breakthrough pain (product with more immediate effect) without the prescriber requiring a patient-specific prescribing authorisation.

There was considerable support from the 21 respondents for this prescribing restriction, as shown in the figure below.

Figure 17: No more than 2 cannabis products without authorisation



Reasons for not supporting this prescribing restriction were:

- no support for any prescribing restrictions;
- the number of products used should be a clinical decision; and
- this criterion would be inconsistent with most other States and Territories in Australia.

Again, it is acknowledged that those with TGA Authorised Prescriber status have greater experience with prescribing medicinal cannabis than many other health practitioners, and it is therefore considered reasonable to allow these prescribers to prescribe multiple products without further State based authorisation provided all the products they are prescribing are covered by their TGA Authorised Prescriber documentation.

Recommendation 28: The Prescribing Code to require a prescriber to be issued a patient and regimen specific authorisation before prescribing more than two medicinal cannabis products concurrently, unless the prescriber is a TGA Authorised Prescriber for all types of products being prescribed.

6.3.4 Patient age

It is well accepted that THC may adversely affect neurodevelopment, which is not considered complete until the age of 25 years. For those who are not yet considered an adult (those under 18 years-of-age), it was therefore proposed authorisation would be required to prescribe medicinal cannabis in S8 (which will always contain THC).

There was significant support for this restriction, with 17 of the 22 respondents (77.2%) supporting this prescribing restriction. All States and Territories restrict the prescribing of medicinal cannabis in S8, where the patient is under 18 years-of-age.

Recommendation 29: Prescribing authorisation be required, through the Prescribing Code, to prescribe medicinal cannabis in S8 to a person aged less than 18 years.

6.3.5 Prescribing for patients with significant co-morbidities

6.3.5.1 Patient recorded as a 'Drug Dependent Person' or 'oversupplied person'

There was significant support (14/22, 63.6%) for an authorisation being in place to prescribe medicinal cannabis containing THC to this cohort of patients. Of the 5 respondents who did not support this prescribing criterion, three were those who did not support any restrictions on the prescribing of medicinal cannabis, and others raised concerns about this being a barrier to access, especially where prior use of illicit substances, including cannabis, may have been an attempt to manage symptoms associated with a health condition.

Authorisation to prescribe for people recorded as a DDP or oversupplied person is required for all S8 medicines and is a requirement of the Regulations rather than the Prescribing Code.

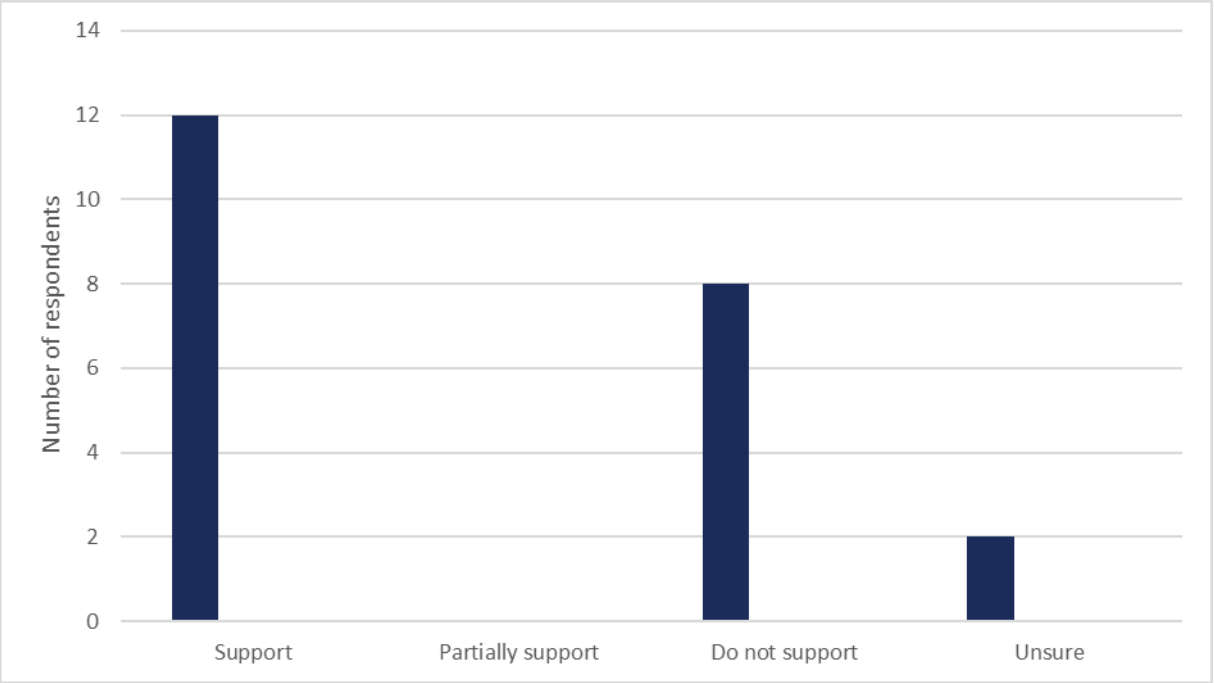
All other Australian States and Territories require authorisation to prescribe in equivalent circumstances.

Recommendation 30: No change to the regulatory requirement for a prescriber to be authorised to prescribe medicinal cannabis in S8 for a person recorded as a Drug Dependent Person or oversupplied person.

6.3.5.2 Evidence of illicit drug use in the preceding five years

In circumstances where the person had not been formally recorded as experiencing drug dependency, there was less support for requiring authorisation to prescribe medicinal cannabis.

Figure 18: Authorisation required if evidence of use of illicit drugs over last 5 years



Reasons for not supporting this prescribing criterion included:

- patients are more likely to deny a history of illicit use if there is an authorisation requirement, and this may impair the clinician/patient relationship;
- many patients use cannabis illegally before commencing a medical version;

- important that the criteria regarding current or previous drug use are designed within the context of evidence regarding whether access to cannabis-based medicines escalates dependence issues; and
- concern that this criterion is not as specific as being recorded as a DDP or oversupplied person.

The way in which this question was asked within the consultation, may have skewed the results. Further discussion is warranted about what constitutes substance use to the extent that it raises the risk of adverse outcomes if medicinal cannabis is prescribed.

Recommendation 31: Further targeted consultation be undertaken to better define substance misuse, for the purposes of the Prescribing Code, in relation to the risk of adverse outcomes when medicinal cannabis in S8 is prescribed.

6.3.5.3 Patient has current/a history of psychosis or other significant psychiatric co-morbidity

Guidance from the TGA is that use of medicinal cannabis to treat patients with a previous psychotic or concurrent active mood or anxiety disorder, is not generally appropriate.[41] The TGA advice is endorsed by the RANZCP and this specialist college also cautions there is little evidence that medicinal cannabis improves psychiatric disorders.[42]

There was also a view expressed that psychotic episodes in patients, while using illicit cannabis or while treated with medicinal cannabis, should require some form of notification to the Department.

The proposed prescribing criterion would essentially mean that a prescriber would only be authorised to prescribe medicinal cannabis for their patient, where their patient had, or had a history of, a significant psychiatric condition, when the patient's treating psychiatrist supported this therapy.

Thirteen of 21 (61.9%) respondents supported this prescribing criterion.

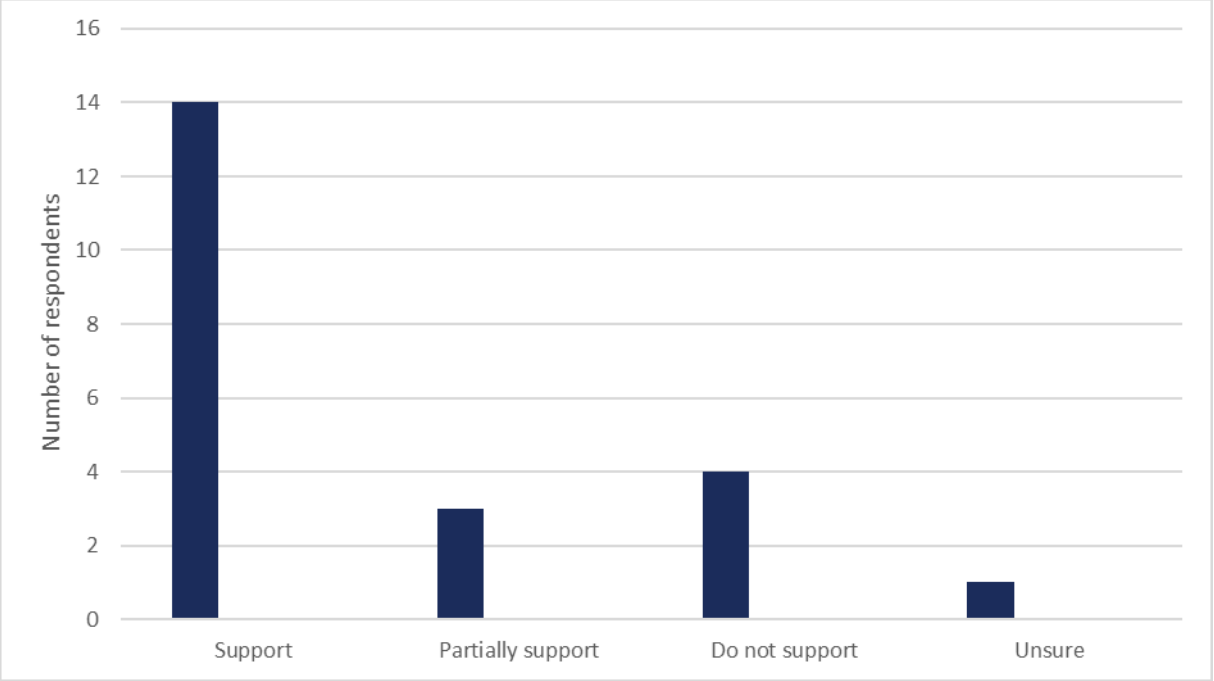
Recommendation 32: The Prescribing Code to include a requirement for authorisation to prescribe medicinal cannabis in S8 to a patient with current, or a history of, a significant psychiatric diagnosis.

6.3.6 Concurrent prescribing with other high-risk S8 treatment regimens

There was a reasonable level of support for this prescribing criterion, with 14 of 22 (63.6%) of respondents in support of prescribers requiring authorisation where the patient is already being treated with other S8 medicines, the prescribing of which would require authorisation.

[41] Therapeutic Goods Administration 2017: Guidance for the use of medicinal cannabis in Australia – Overview, Version 1, December 2017. Available at: https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-australia-overview (accessed 30 January 2023).
[42] RANZCP Clinical Memorandum – Therapeutic use of medicinal cannabis products. January 2021. Available at: https://www.ranzcp.org/files/resources/college_statements/clinical_memoranda/cm-therapeutic-use-cannabis-products.aspx (accessed 30 January 2023).

Figure 19: Authorisation to prescribe cannabis where patient under treatment with other S8 medicines that themselves require prescribing authorisation



Based on written responses, there may have been some misunderstanding of the proposed prescribing criterion. Some respondents appeared to interpret the proposed criterion as meaning authorisation to prescribe medicinal cannabis would always be required if the patient was already under treatment with other S8 medicines.

The intention was that authorisation to prescribe medicinal cannabis would only be required where other S8 prescribing was already considered to be in the high-risk range. Where other S8 prescribing was in the lower-risk range (in other words, no authorisation to prescribe the other S8 medicines was required), there would be no requirement to seek authorisation to prescribe medicinal cannabis to the same patient. Examples of circumstances where this criterion would result in a requirement for authorisation of medicinal cannabis prescribing would be concurrent treatment with more than 90mg morphine dose equivalents of opioids per day or concurrent treatment with benzodiazepines in S8 (alprazolam or flunitrazepam).

Recommendation 33: The Prescribing Code to include a requirement for authorisation to prescribe medicinal cannabis in S8 for a patient concurrently being treated with other S8 medicines that themselves require prescribing authorisation.

7 Other miscellaneous regulatory changes

7.1 Retention of Schedule 8 repeat prescriptions by original pharmacy

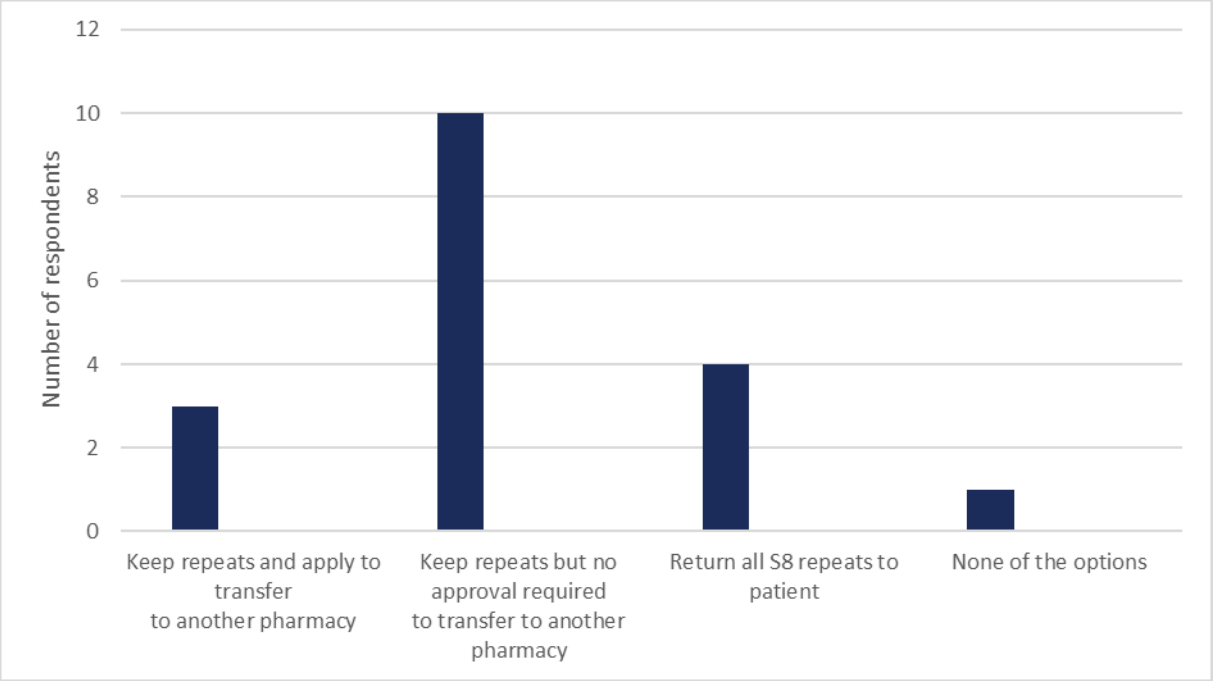
Regulations 23(1)(e) and 24(2) require repeats on S8 prescriptions to be retained at the pharmacy at which the original supply was dispensed. This requirement was originally introduced into the previous Poisons Regulations 1965 at the beginning of 2006, as a mechanism to reduce the risk of prescription forgery.

At the time, it was considered necessary for the Department to approve transfer of repeats to another pharmacy because otherwise, there was no ability for the regulator to know that those repeats had been appropriately transferred.

The availability of RTPM data means the Department will be immediately aware a repeat has been dispensed and will also know whether this is at the pharmacy at which the original prescription was dispensed or not.

There were eighteen responses to this consultation question with 55.5% supporting continued repeat retention, but removal of the current requirement for pharmacists to seek approval from the Department to transfer any remaining repeats to another pharmacy.

Figure 20: Management of repeats for paper-based S8 prescriptions with repeats



Because fully electronic prescriptions are not stored at a particular pharmacy, repeat retention is not a relevant concept for prescriptions issued in this manner. The forgery mechanism the repeat retention clause was intended to reduce would be unlikely to be used when an electronic prescription is issued. The security features of electronic prescriptions and the systems used to generate these prescriptions greatly reduce the risk of fraudulent activity.

In other words, where applicable, pharmacists should provide patients with their token for the next repeat on electronic prescriptions for S8 medicines. The Active Script List management solution is already based on a patient using one pharmacy at a time for all their prescriptions.

Some respondents believed the repeat retention requirement was intended to improve patient safety by promoting continuity of care. While it is acknowledged that quality use of medicines can be enhanced where a patient has all their prescriptions dispensed at the same pharmacy; this was not the intent of this regulatory requirement and it was added as a forgery deterrent only.

Recommendation 34:

• Retain the requirement for a pharmacist to keep the remaining repeats of paper-based prescriptions at the pharmacy at which the original prescription was dispensed.

• The Regulations to continue to allow a pharmacist to transfer the remaining repeats to another pharmacy.

• The Regulations be amended to remove the requirement for a pharmacist to seek authorisation from the Department before transferring repeats for paper-based S8 prescriptions (handwritten or computer generated prescriptions) to another pharmacy.

• The Regulations to clarify that repeat retention for S8 prescriptions does not apply to fully electronic prescriptions.

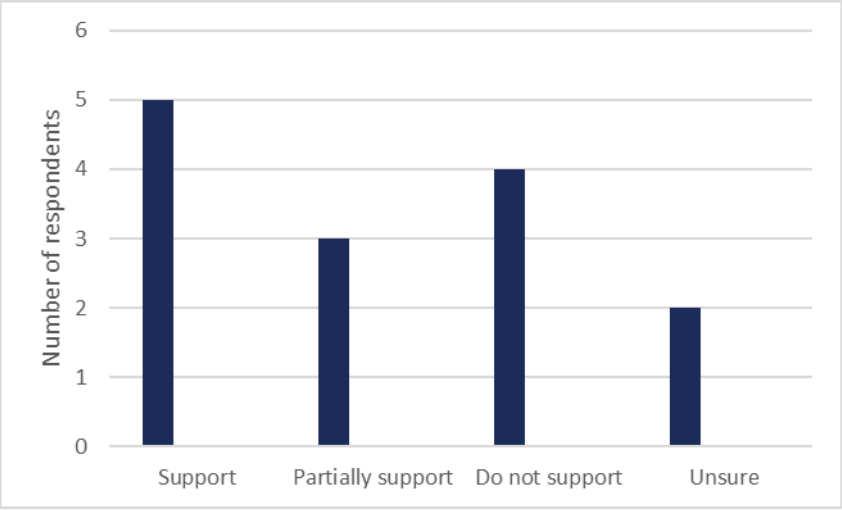
7.2 Use of veterinary medicines to treat humans

Regulation 39 makes it an offence for a health professional to administer or supply a veterinary medicine for human use. For multiple reasons, many veterinary medicines are not suitable for use by humans. In particular, veterinary anabolic steroid products pose significant risks to human health and have a history of misuse as performance and image enhancing drugs.

However, there are some very limited circumstances where a veterinary medicine may be the only available option for treatment of a serious human health condition. For example, the Therapeutic Guidelines mention use of subcutaneous ivermectin treatment for patients who have not responded to other therapy for the treatment of strongyloidiasis[43]. The only available parenteral forms of ivermectin in Australia are veterinary products. It is therefore proposed that the option of approval, by the CEO of Health, of use of a specific veterinary preparation to treat a named patient be included in Regulation 39.

The online consultation question asked respondents to indicate their level of support for an option to allow veterinary medicines to be prescribed for humans, in limited and strictly controlled circumstances. There were only 14 responses to this question (35.8% of total responses).

Figure 21: Option to approve prescribing of veterinary medicine for human use



[43] Strongyloidiasis [published April 2019]. In: Therapeutic Guidelines [digital]. Melbourne: Therapeutic Guidelines Limited; October 2021 <https://www.tg.org.au>

A number of relevant considerations were raised:

- There would be a need to ensure the patient is made aware of being treated with a veterinary product.
- Concern there may be liability issues for practitioners that may not be covered by professional indemnity insurance.

Recommendation 35: Continue to prohibit the prescribing of veterinary medicines for human use but amend the Regulations to allow a medical practitioner to be authorised, in writing, by the CEO of Health, to prescribe a named veterinary medicine product (registered by the Australian Pesticides and Veterinary Medicines Authority), which contains a named S4 medicine to treat a named human patient and to also allow the CEO of Health to add other conditions to any such authorisation. These regulations should restrict the CEO of Health to only issuing an authorisation where the health of the person would be significantly compromised if the veterinary medicine was not used and where no equivalent or suitable human medicine product is available to treat the patient's health condition.

7.3 Schedule 3 medicines in Appendix M of the Poisons Standard

In January 2018, following National endorsement by the Australian Health Ministers' Advisory Council (now the Health Chief Executives Forum), Appendix M was included in the National Poisons Standard. Appendix M provides for imposition of additional conditions on S3 (pharmacist-only) substances to support their down-scheduling from S4 (prescription-only). The concept of Appendix M is that there may be prescription-only medicines, where a case can be made for the substance meeting the S3 factors but where there are some specific additional public health risks that are above those normally considered acceptable for S3 substances. The Scheduling handbook: Guidance for amending the Poisons Standard[44] lists a number of criteria which would be assessed as part of the inclusion of a substance in Appendix M. The inclusion of these criteria followed public consultation by the TGA, from February to April 2019[45].

Examples of possible requirements that could be included in Appendix M are:

- a requirement for specific pharmacist training on provision of the medicine;
- the patient must be supplied with specific information (patient education) when the medicine is supplied;
- limitations on the duration/quantity and/or frequency of supply;
- need for evidence of a prior diagnosis by a medical practitioner;
- requirement for periodic review by a medical practitioner; and
- record keeping of supply by the supplying pharmacist, including clinical decision points used when determining the patient's therapeutic need.

There are currently no regulations in WA that adopt or otherwise reference Appendix M. This would mean any restrictions detailed in Appendix M, would not be mandatory but the substance would still be able to be legally supplied as a S3 medicine, as a consequence of the adoption of S3 of the Poisons Standard, by reference, into the Medicines and Poisons legislation. Essentially, this would mean supply of these particular S3 medicines could be seen as inconsistent with the nationally agreed scheduling classification and could create potential for patient harm.

[44] Therapeutic Goods Administration. Scheduling handbook: Guidance for amending the Poisons Standard, July 2019. Available at: https://www.tga.gov.au/publication/scheduling-handbook-guidance-amending-poisons-standard
[45] See https://www.tga.gov.au/consultation/consultation-proposed-criteria-appendix-m-poisons-standard-support-rescheduling-substances-schedule-4-prescription-only-schedule-3-pharmacist-only

It is recommended that the requirements of Appendix M be adopted, by reference, such that when a pharmacist makes a supply of any S3 medicine that is also included in Appendix M, the requirements of the Appendix M entry for that substance must be met.

To effectively monitor for compliance with the requirements of Appendix M, the regulator would require evidence of supply. With the exception of pseudoephedrine in S3, there are no requirements for a patient related record to be made when a S3 medicine is supplied by a pharmacy business. It is therefore proposed that, on each occasion of supply, the supplying pharmacist be required to record supply in the patient's clinical record for any S3 substance that is also included in Appendix M. In the pharmacy setting, the patient's clinical record could be the dispensing system i.e. the same software system as is used to record dispensing of prescriptions. A separate clinical record could also be used but ideally this would feed into National health information systems, such as My Health Record.

Recording the supply of a S3 Appendix M medicine would also mean that a patient-specific label could be generated for the product. Labelling could be seen as a further way of differentiating these S3 medicines, which have been assessed as having additional public health risks, from other S3 medicines. The addition of a patient-specific label makes it clearer to consumers that the medicine is intended for a specific person and would be a disincentive to sharing the medicine with family or friends. It is therefore proposed that, when a pharmacist supplied a S3 medicine, which is also in Appendix M, that a patient-specific label be applied.

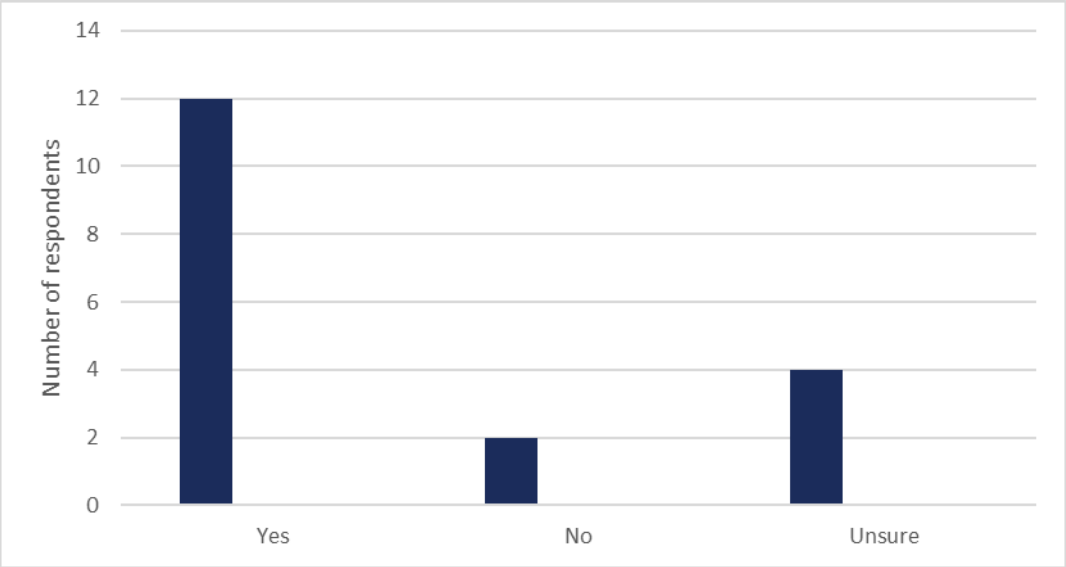
The label should include:

- the name, strength and dosage form of the medicine;
- the quantity supplied;
- the name of the patient;
- the directions for use given by the pharmacist;
- the name of the supplying pharmacist;
- the name and address of the pharmacy;
- the date supplied; and
- the number generated by the recording system[46].

There were 18 responses to the question as to whether Appendix M should be adopted, by reference, into the Regulations,

[46] This number may be described as a 'prescription' number on the dispensing system but is a unique identifying number generated when a supply transaction is entered onto the dispensing software system. The number can be used to find the transaction.

Figure 22: Adoption of Appendix M, by reference?



Comments made by respondents included:

- Appendix M is a valuable piece of flexibility for our medicines scheduling system.
- Significant consultation and evidence was utilised during the development of Appendix M and therefore WA should align with the National Poisons Standard.
- Concern that the record keeping and other requirements in Appendix M would take up a lot of time for already overstretched pharmacists, which could result in pharmacists not following guidelines and recommendations for supplying these S3 medicines.
- Pharmacists should be required to record supply of all S3 medicines and that information should be made available to other healthcare providers, via MyHealth Record.
- The value of Appendix M, is questioned, given that pharmacists can already dispense an additional supply of many medicines used chronically.
- If additional measures are required for pharmacists to safely supply, the medication may not be suitable for S3 and should remain a prescription-only medicine.

Recommendation 36:

• The Regulations be amended to adopt the requirements of Appendix M of the current Poisons Standard, by reference.

• The Regulations be amended to require details of every supply of a S3 medicine, which is also listed in Appendix M to be recorded by the pharmacist in the patient's clinical record.

• The Regulations be amended to require the pharmacist to add a patient-specific label with details as described above.

8 Regulations that require clarification

8.1 Use of electronic signatures

During the COVID-19 Pandemic, allowances were made for pharmacists to supply prescription medicines to patients, once they have received a 'digital image' of a paper-based prescription from the prescriber. This process was intended to support provision of care, via telehealth, and was introduced prior to the rollout of fully electronic prescriptions.

An unintended outcome associated with these changes has been prescribers choosing to add an 'electronic signature' to their computer-generated prescriptions and then send an image of

that prescription to a pharmacy. In many cases, the mechanisms used to transmit the prescription to the pharmacist negate the validity of the electronic signature. For example, if a photo of the prescription, taken after it has been printed, is used, the pharmacist would be unable to verify the electronic signature. Similarly, if an image file format, such as a .jpg or .png file is used and the electronic signature was generated in some other file format, the pharmacist may be unable to verify the validity of the electronic signature.

While the use of 'digital images' alone for dispensing ceased at the end of March 2022, there are long-standing provisions for pharmacists to supply a quantity of a prescription medicine in an emergency, if directed to do so by a prescriber, such as via a telephone call, fax, or email. Where fax or email is used, it is common for a 'digital image' of the prescription to be used to direct supply by the pharmacist. In this circumstance, although transmission of the direction to the pharmacist remains electronic, it would not necessarily be in a manner that allowed the pharmacist to validate an 'electronic signature'.

The Regulations current require prescriptions of a type intended to be paper-based at the point of provision to the patient, such as computer generated or handwritten prescriptions, to simply be 'signed' by the prescriber. This has led to interpretation by prescribers that, if they are sending an image of the prescription to a pharmacy, they can legally use an 'electronic signature'.

The purpose of a prescriber adding their signature to a prescription is to provide the pharmacist with evidence that the prescription was created by a health professional authorised to prescribe scheduled medicines. If an 'electronic signature' is applied to the prescription but cannot be verified by the dispensing pharmacist, this assurance of prescription validity is unavailable.

Recommendation 37: The Regulations be amended to make it clear that only a handwritten signature (also known as a 'wet' signature) can be used to sign a paper-based prescription.

8.2 Residential care medication chart

In the Regulations, the current definition of a residential care chart is as follows:

residential care chart means a chart recording medicines used, or to be used, for the treatment of a care recipient in a residential care facility that is —

(a) in a form developed by the Australian Council for Safety and Quality in Health Care; or

(b) a medication chart prescription as defined in the *National Health (Pharmaceutical Benefits) Regulations 1960* (Commonwealth) Regulation 19AA(1).

The Commonwealth regulations referenced in the definition have been superseded. In addition, eNRMC are currently under development with the support of the Commonwealth Government.[47] In part, the development and funding of eNRMC has been driven by recommendations 64 and 68 of the Royal Commission into Aged Care Quality and Safety Final Report.[48]

eNRMC have a number of benefits for residents, residential aged care providers and staff in facilities, prescribers and pharmacists, including:

- decreasing medication safety risks, such as inconsistencies between prescriber records and paper-based medication charts;
- increasing visibility of residents' medication records for prescribers, pharmacists and aged care staff;

[47] See https://www.health.gov.au/health-topics/aged-care/providing-aged-care-services/delivering-quality-aged-care-services/electronic-national-residential-medication-charts
[48] Available at: https://agedcare.royalcommission.gov.au/publications/final-report (accessed 30 January 2023)

- supporting more timely provision of medications;
- allowing tailored alerts and reminders; and
- reducing administration burden for aged care providers, prescribers and pharmacists.

To be considered suitable for use as a mechanism to prescribe PBS medicines, an eNRMC must meet the Commonwealth's technical and legislative requirements, including the Australian Digital Health Agency's current Electronic Prescribing Conformance Profile.[49]

Regulation 14 allows a residential care chart to be used as a prescription but only when the chart is handwritten rather than electronic; however, if an eNRMC was generated by an approved electronic prescribing system (Regulation 19), this type of chart would be considered a prescription.

Recommendation 38: The Regulations be amended to more clearly support the use of eNRMC, provided the system used to create the chart for each resident is an approved electronic prescribing system.

9 Next steps

The usual processes for the drafting and enactment of subsidiary legislation, such as regulations, will be followed[50]. The first step is to obtain approval from the Minister for Health to the Recommendations in this report.

Further focused consultation with key stakeholder groups, may also be undertaken in relation to other aspects of the Prescribing Code. The proposed changes to the Regulations present an opportunity to review the content, layout and language of the Prescribing Code.

[49] Available at: https://developer.digitalhealth.gov.au/specifications/ehealth-foundations/ep-3444-2021/dh-3442-2021 (accessed 30 January 2023).
[50] Available at: https://www.legislation.wa.gov.au/legislation/statutes.nsf/RedirectURL?OpenAgent&query=gettinggovernmentlegislationdraftedandenacted.pdf (accessed 30 January 2023).

10 Appendix 1 Glossary of terms

Term	Definition
Benzodiazepines	A class of prescription medicine prescribed to treat anxiety disorders, to relieve insomnia, to control epilepsy and to sedate people before certain medical procedures. All benzodiazepines are central nervous system depressants. Flunitrazepam and alprazolam are classified as Schedule 8 medicines. Other benzodiazepines used as medicines in Australia are classified as Schedule 4 medicines.
Cannabis-based products	Term used to describe medicines that contain substances that naturally occur in cannabis, such as cannabidiol and tetrahydrocannabinol (THC). Also commonly referred to as 'medicinal cannabis'. Most cannabis-based products are in Schedule 8. Medicines that contain cannabidiol with negligible amounts of THC are classified as Schedule 4 medicines.
Chief Executive Officer of Health	Chief Executive Officer of the Department of Health, who is the Director General of the Department. Under Section 9 of the *Health Legislation Administration Act 1984*, CEO powers and duties under the Medicines and Poisons legislation may be delegated to other persons, usually officers employed within the Department of Health (commonly referred to as CEO delegates).
Drug Dependent Person	Defined in Section 77 of the *Medicines and Poisons Act 2014* as meaning "a person, who has acquired, as a result of repeated administration of drugs of addiction or Schedule 9 poisons, an overpowering desire for the continued administration of a drug of addiction or a Schedule 9 poison". A person can only be reported to the CEO of Health as a 'Drug Dependent Person' (DDP) by a health practitioner, who is able to make a medical diagnosis of drug dependency. There are legislated requirements in relation to how the CEO of Health decides to add the person's details to the Record, what the Department of Health has to do when a DDP report is received and what the Department must tell the person, who is the subject of a DDP report. Further information is available at: https://www.healthywa.wa.gov.au/Articles/A_E/Drugs-of-dependence
Opioids	These are morphine-like drugs. The term encompasses naturally occurring opiates, such as morphine and codeine, which are derived from the opium poppy, semi-synthetic opioids, such as oxycodone and synthetic opioids, such as fentanyl. Opioids are primarily used as medicines for their analgesic effects but may also be used for their anti-diarrhoeal and cough-suppressant effects.

Over Supplied Person	Defined in Section 77 of the *Medicines and Poisons Act 2014* as meaning **"**a person who has over a period of time obtained, or obtained prescriptions for, quantities of drugs of addiction that are greater than is reasonably necessary for therapeutic use". Sometimes the term 'doctor shopper' is used to describe an oversupplied person. A person can only be reported to the Department as oversupplied if they are a registered health practitioner with authority to prescribe, supply or dispense scheduled medicines. There are legislated requirements in relation to how the CEO of Health decides to add the person's detail to the Record, what the Department of Health has to do when a oversupplied person report is received, and what the Department must tell the person who is the subject of an oversupplied person report.
Poisons Standard	Issued by the Commonwealth Government and available on the Federal Register of Legislation website. Available via the Therapeutic Goods Administration website at: https://www.tga.gov.au/publication/poisons-standard-susmp Contains decisions regarding the classification of medicines and poisons into Schedules for inclusion in relevant State and Territory legislation. Also includes model provisions about containers and labels and recommendations about other controls on medicines and chemicals. The Western Australian Medicines and Poisons legislation adopts the Schedules of the Poisons Standard, by reference. A number of other sections and appendices of the Poisons Standard are also adopted, by reference, in WA.
Prescribing Code	Referenced by the Medicines and Poisons Regulations 2016. Sets out the criteria with which prescribers must comply when prescribing Schedule 8 and, in the future, Schedule 4 reportable medicines. Criteria relate to the prescriber (type of health practitioner), the medicine (for example, dose and dosage form) and the patient (for example, whether they are recorded as a DDP).
Regulator	For the purpose of the *Medicines and Poisons Act 2014* and the Medicines and Poisons Regulations 2016, the Western Australian Department of Health is the 'regulator'. This WA Government Department assists the Minister for Health in administering this legislation.
ScriptCheckWA	The Western Australia Real Time Prescription Monitoring system.
Stimulant medicines or stimulants	Dexamfetamine, lisdexamfetamine and methylphenidate, which are all Schedule 8 medicines. Used to treat Attention Deficit Hyperactivity Disorder and some other neurological and psychiatric conditions. Also known as 'psychostimulants'.

11 List of respondents

Fifteen respondents indicated their identity could be published. The other 24 respondents wished to remain anonymous.

Responses from organisations	
1	ADHD WA
2	Australian College of Nurse Practitioners (WA Chapter)
3	Injury Matters
4	Pharmaceutical Society of Australia (WA Branch)
5	Pharmacy Registration Board of WA
6	RACP Australasian Chapter of Addiction Medicine (WA Chapter)
7	Royal Australian College of General Practitioners (WA Faculty)
8	Society of Hospital Pharmacists of Australia (WA Branch)
9	Western Australian Network of Alcohol and other Drug Agencies
Responses from individuals	
10	Dr Amanda Villis
11	Dr Philip Finch
12	Dr Richard O'Regan
13	Lena van Hale
14	Michelle
15	Wayne

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