## SHPA Western Australia Branch Committee response to Amendments to the Medicines and Poisons Regulations 2016 and the Schedule 8 Medicines Prescribing Code, Western Australia, October 2022

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

SHPA has been a strong advocate for real-time prescription monitoring (RTPM) for many years, nothing that it is a crucial investment to equip doctors and pharmacists with the necessary tools to detect, monitor and treat medicines misuse and abuse.

This submission is provided on behalf of the SHPA WA Branch Committee, chaired by Mr Peter Smart.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.

### 3 Schedule 4 reportable medicines

### 3.2 Determining which Schedule 4 (S4) medicines are reportable

**Proposed regulatory options in relation to S4 medicines to be monitored via RTPM are:**

**Option 1: Do not designate any S4 medicines as reportable (status quo).**

**Option 2: Designate a list of S4 medicines as reportable and make these S4 medicines visible within the Western Australian RTPM system immediately.**

**Option 3: Designate a list of S4 medicines as reportable but delay implementation via RTPM for a defined period after rollout of RTPM. *(preferred option)***

1. **Which of the three regulatory options above is preferred? Please provide reasons for your response.**

Option 3 is preferrable. There are several schedule 4 medicines that may be prone to misuse or diversion and therefore would be beneficial to monitor supply and access to patients. Delaying the implementation of reporting Schedule 4 medicines will allow healthcare professionals in Western Australia to become familiar with such reportable medicines.

2. **Is the proposed list of Schedule 4 reportable medicines appropriate? If not, why not and what changes would you recommend?**

Yes. The proposed list of Schedule 4 reportable medicines is appropriate and in line with other jurisdictions.

**3. Are there any criteria, other than those detailed, that should be considered when determining which Schedule 4 medicines are designated as reportable? If yes, please describe the criteria**

The criteria outlined in the consultation paper are appropriate.

### 3.3 Restrictions on prescribing and supply of Schedule 4 reportable medicines

### 3.3.1 Restrictions through the Regulations

**Regulatory options for controls over the prescribing of S4 reportable medicines are:**

**Option 1: No restrictions other than those applicable to all prescription only medicines (essentially limited only to which health practitioners have prescribing rights) (status quo).**

**Option 2: Implementation of prescribing restrictions via detailed requirements in the Regulations.**

**Option 3: Implementation of prescribing restrictions via a 'prescribing code' with Regulations that refer to this code. *(preferred option)***

**4. Which of the three regulatory options is preferred? Please provide reasons for your response.**

Option 3 is preferred. A 'prescribing code' is more appropriate for Schedule 4 reportable medicines due to the lower level of risk posed when compared to Schedule 8 medicines.

### 3.3.2 Restrictions through a 'prescribing code'

**Proposed regulatory options are:**

**Option 1: No prescribing authorisation requirements for monitored S4 medicines (status quo, acceptance that visibility of information via RTPM is sufficient to support safe prescribing).**

**Option 2: Mandate prescriber documentation of risk mitigation strategies in defined high-risk clinical scenarios, such as prescribing monitored S4 medicines for people who are currently taking OST or prescribing high doses of monitored S4 medicines to patients recorded as 'drug dependent' or 'oversupplied'.**

**Option 3: Limited authorisation requirements in high risk clinical scenarios, delayed until at least 6 months after prescribing and dispensing data about monitored S4 medicines becomes available in the RTPM system. *(preferred option)***

**5. Which of the three regulatory options is preferred? Please provide reasons for your response.**

Option 3 is preferred. This will allow adequate time for data to be collected to inform any further prescribing restrictions.

**6. If prescribing authorisation was mandated for monitored S4 medicines, in what circumstances should a prescribing authorisation be required and what should be the criteria for exemption from requiring a prescribing authorisation?**

Exemptions to prescribing authorisation for Schedule 4 medicines should be considered for end of life care and hospital inpatient medication administration.

## 3.4 Requirements for prescriptions for Schedule 4 reportable medicines

### 3.4.1 Inclusion of patient's date of birth

**7. Are there any circumstances where it would not be reasonable to include the patient's date of birth on a prescription for a Schedule 4 reportable medicine? If yes, please describe.**

No.

### 3.4.2 Repeat intervals

**For S4 reportable medicines, regulatory options include:**

**Option 1: No repeat interval required on prescriptions for S4 reportable medicines (status quo) *(preferred option)***

**Option 2: No repeat interval required but penalties for direct prescriber supply or pharmacist dispensing of a S4 reportable medicine, where the patient should have at least one week's supply remaining, based on the date of previous supply and the dose.**

**Option 3: Require repeat intervals on prescriptions for S4 reportable medicines.**

**8. Which option is preferred? Please provide reasons for your response.**

Option 1 is preferred. Repeat intervals for Schedule 4 medicines should not be mandatory given that healthcare professionals should be able to view evidence of prescribing and supply of Schedule 4 medicines in real time.

## 4 Mandates associated with real-time prescription monitoring

### 4.1 Requirement for practitioners to have access to real-time prescription monitoring

**Regulatory options with respect to health practitioner access to the Western Australian RTPM system are:**

**Option 1: Registration for access to the system remains voluntary (status quo).**

**Option 2: Prescribers and dispensers must complete registration for access to the system. *(preferred option)***

**Option 3: Prescribers and dispensers must complete registration for access to the system and ensure they maintain continued access to the system over time, such as via an annual access check.**

**9. What is your preferred option with respect to mandating access to the Western Australian RTPM system? Please provide reasons for your chosen response.**

Option 2 is preferred. Requirement to complete registration access is imperative to the RTPM system being incorporated into practice. Continued access check would not be necessary if the RTPM system is being utilised regularly as stipulated.

**10. Is a six month delay appropriate before mandating prescribers and dispensers registration for RTPM access? If no, please provide reasons for your chosen response**.

A six-month delay prior to mandating RTPM access is appropriate and in line with other jurisdiction's roll out of RTPM systems. It is imperative that RTPM systems integrate seamlessly with hospital clinical software and medicines supply systems such as dispensing software, to ensure smooth workflows that do not unintentionally create administrative burden, which will contribute to the risk of medication errors in a stressful environment.

### 4.2 Requirements for practitioners to use real-time prescription monitoring

**Regulatory options with respect to health practitioner use of the Western Australian RTPM system are:**

**Option 1: Use of the system remains voluntary (status quo). *(Preferred option)***

**Option 2: Prescribers and dispensers must always view the patient's record on the RTPM system when prescribing and dispensing for that patient.**

**Option 3: As for option 2 but with a number of exemptions, such as when directing administration or administering doses and when the patient lives at a residential aged care facility.**

**11.Which option is preferred? Please provide reasons for your response.**

Option 3 is preferred to ensure mandatory use as voluntary use does not fully encourage or facilitate the detection of inappropriate prescribing and supply of medicines under the RTPM. Some exemptions as

discussed are required, as outlined from the workshops discussed in the consultation paper, and in instances such as supplies of small quantities to patients from hospital emergency departments and while admitted as an inpatient in a health service,

### 5. Regulation of stimulant medicines

### 5.2.2 Regulatory options in relation to initiation of stimulant prescribing

**Through a combination of the Regulations and the Prescribing Code, proposed options to be an initiating prescriber for stimulant medicines are:**

**Option 1: Designate each prescriber individually (Regulations) and limit to specialists only (Prescribing Code) (status quo).**

**Option 2: Limit initiation of stimulant prescribing to members of certain medical specialties named in the Prescribing Code.**

**Option 3: As for Option 2, but also allow designation of an individual prescriber as an initiating 'stimulant prescriber' for any of their patients. This option could potentially be used in the future to authorise a general practitioner with appropriate training to initiate stimulant medicines. *(Preferred option)***

**12.Should designation as a 'stimulant prescriber' continue to be required for each individual medical practitioner? If yes, what benefit does this provide that is not already achieved by allowing all medical practitioners within designated specialist categories, to prescribe stimulant medicines?**

Option 1 is preferred to ensure that only those specialists with appropriate specialist skills in monitoring and diagnosing conditions requiring the use of stimulant medicines are prescribing them. Designating each prescriber individually further controls the supply of stimulant medications.

**13.What type of specialist medical practitioner should be able to initiate treatment with stimulant medicines?**

Those practitioners stipulated in guidelines outlined in the accompanying consultation paper, for initiating stimulant medications such as Psychiatrists, Adolescent and Child Mental Health Specialists as well as Paediatricians in some cases. This may include appropriately trained GPs in future and involve models of shared care.

**14.Should the option of approving a medical practitioner as a 'stimulant prescriber' be retained for use on a 'case by case' basis? If yes, why? If no, why not?**

Yes. Each practitioner should be assessed for appropriate skills, training, and area of practice to prescribe stimulant medications.

### 5.3.2 Proposed regulatory options for notification of stimulant prescribing

**Regulatory options in relation to notification of commencing and ceasing prescribing stimulant medicines for a patient are:**

**Option 1: Require notification of prescribing and cessation of prescribing for every patient, unless high-risk criteria are met when an application for authorisation to prescribe is required (status quo).**

**Option 2: Require notification of cessation of prescribing only, where the reason for cessation would mean subsequent prescribing of stimulant medicines for the patient would be considered high-risk according to the criteria in the Prescribing Code. *(Preferred option)***

**Option 3: No notification requirements for either commencement or cessation of prescribing stimulants for any patient.**

**15.Which option is preferred? Please provide reasons for your response**.

Option 2 is preferred. With the increasing use of RTPM systems, the notification process should not be necessary at point of commencing. However, hospital-initiated stimulants may not be recorded if entering dispensing data onto RTPM systems is not mandatory in these settings.

### 5.4 Appointment and notification of co-prescribers

**Regulatory options in relation to continuation of established, stable treatment with stimulant medicines treatment are:**

**Option 1: Continue to require notification of co-prescriber appointment with annual specialist prescriber review (status quo).**

**Option 2: Continue to require notification of co-prescriber appointment but increase mandatory specialist review period to three years.**

**Option 3: Rescind requirement for notification of co-prescriber appointment and retain annual mandatory specialist review.**

**Option 4: Rescind requirement for notification of co-prescriber appointment and increase mandatory specialist review period to three years. *(Preferred option)***

**16.Which option is preferred? Please provide reasons for your response**.

No comment.

### 5.5 Prescribing Code criteria for stimulant medicines

**17. Please provide advice about whether you support, do not support, or do not have an opinion for each proposed requirement in the Prescribing Code for the prescribing of stimulant medicines. If you do not support a proposed requirement, please provide your reasons and, if appropriate, an alternative requirement.**

SHPA supports the proposed prescribing code requirements for stimulant medicines.

**18.Are there other requirements you think should be included in the Prescribing Code for stimulant medicines? Please describe and provide reasons.**

No.

## 6 Regulation of cannabis-based products in Schedule 8

### 6.2 Proposed changes to regulation of prescribing of medicinal cannabis

**Regulatory options in relation to prescribing cannabis-based products in Schedule 8 are:**

**Option 1: Continue to require notification or authorisation in all circumstances (status quo).**

**Option 2: Remove notification requirements and only require authorisation where high risk criteria, as detailed in the Prescribing Code are met. *(Preferred option)***

**Option 3: Not require any notification or authorisation when prescribing cannabis-based products in Schedule 8.**

**19.Which option is preferred? Please provide reasons for your response.**

Option 2 is preferred, as this will remove administrative burden for pharmacists and prescribers, whilst ensuring checks and balances are in place for clinical situations that are deemed to be high-risk.

### 6.3 Proposed Prescribing Code criteria for lower risk cannabis prescribing

**20.Please provide advice about whether you support, do not support, or do not have an opinion for each proposed criterion in the Prescribing Code for the prescribing of cannabis-based medicines in Schedule 8. If you do not support a proposed criterion, please provide your reasons and, if relevant, an alternative criterion.**

SHPA supports the proposed prescribing code criterion for cannabis-based medicines in Schedule 8.

**21.Are there other requirements you think should be included in the Prescribing Code for cannabis-based products in Schedule 8? Please describe and provide reasons**

No.

### 7 Retention of Schedule 8 repeat prescriptions by original pharmacy

**Proposed regulatory options are:**

**Option 1: Retain the requirement for repeats of paper-based prescriptions to be kept by the pharmacy that dispensed the original and continue to require pharmacists to apply to transfer remaining repeats of paper-based prescriptions to another pharmacy (status quo).**

**Option 2: Retain the requirement for repeats of paper-based S8 prescriptions to be kept by the pharmacy that dispensed the original and continue to only allow transfer of remaining repeats to another pharmacy business. Remove the requirement for authorisation of repeat transfer by the CEO of Health. Clarify that fully electronic prescriptions are not subject to these rules. *(Preferred option)***

**Option 3: Remove all requirements for retention of repeats of paper-based S8 prescriptions by the pharmacy that dispensed the original.**

**22.Which option is preferred? Please provide reasons for your response.**

Option 2 is preferred as well as clarifying the repeat requirements of electronic prescriptions.

### 8 Use of veterinary medicines to treat humans

**23.Are there any other mechanisms that could be used to allow use of veterinary medicines to treat humans in specified circumstances? If yes, please provide detail of the mechanisms and the circumstances where their use should be applicable**.

No comment.

### 9 Schedule 3 medicines in Appendix M of the Poisons Standard

**24.Are there any reasons Appendix M should not be adopted by reference? If yes, please provide an explanation for each reason.**

No.

**25.Are there any reasons a pharmacist should not be required to record supply of a Schedule 3 medicine that is also listed in Appendix M? If yes, please provide an explanation for each reason**

No.