

Working with medicines

# Structured Administration and Supply Arrangements – Hospitals and Permit Holders

## Regulations

Hospitals and Health Service Permit holders may issue a Structured Administration and Supply Arrangement (SASA) under Part 6 of the Medicines and Poisons Regulations 2016 (the Regulations). These are termed ‘health organisation’ SASAs in the Regulations.

## What is a SASA

A SASA is a written direction by an organisation that authorises a health practitioner to administer or supply a medicine to any patient that meets the circumstances named in the SASA. A prescription or written direction is not required for each individual patient. A ‘health organisation’ SASA should be issued if a medical practice has more than one medical practitioner at the practice.

## Authority

A SASA issued by a medical practitioner can apply to:

* those health practitioners listed in Part 7 of the Regulations;
* in the lawful practice of their profession;
* employment by the hospital or Health Service Permit business; and
* patients under the care of the hospital or Health Service Permit business.

A SASA may only be issued for medicines that are required as part of treatment of an acute medical condition or public health. SASA are not permitted for medicines necessary for management of chronic conditions.

## Issuing a SASA

A SASA must be issued in writing. The document must specify the practitioner(s) authorised and the actions authorised (administration, supply, or both). Copies must be readily accessible to the practitioners authorised by the SASA.

The SASA must specify the medicine authorised. This should include the name, strength, form (or route), dose and quantity. A separate written agreement is required for each medicine covered.

The SASA must specify the circumstances when the medicine may be administered or supplied. This may include the treatment indication (inclusion criteria), any contra-indications (exclusion criteria), place of practice, special training needed by the practitioner, treatment setting or other relevant restriction.

A SASA is valid for a maximum of 2 years. After this time, it should be reviewed, and if still required, then reissued as appropriate.

## Approval

This type of SASA must be issued by the Chief Executive Officer of the hospital or Permit holder business. It must be signed by the most senior medical practitioner in the organisation, e.g. the Director of Medical Services.

Each SASA must be approved by an appropriate clinical governance committee. In most cases a hospital will have an existing Drug and Therapeutics Committee, or other constituted clinical governance body, suitable for this purpose. If not, a committee will need to be established that includes a minimum of a medical practitioner, pharmacist, and registered nurse. Ideally the committee will have the composition and expert members necessary for the robust review of the proposed SASA, medicines and clinical documents.

Copies of all approved SASA must be forwarded to the Department of Health for registration (not approval) at the contact details below. Advice will be given if the SASA does not meet regulatory requirements.

## Medicines permitted

A SASA may apply to the supply of Schedule 2 or Schedule 3 or the administration or supply of a Schedule 4 medicine. The administration or supply of Schedule 8 medicines must be consistent with Part 11 of the Medicines and Poisons Regulations 2016.The medicines administered or supplied must be procured by the hospital or approved Permit holder.

## Working under SASA

Health practitioners working under a SASA must comply with all relevant Regulations for administration or supply. Medicines supplied must be in approved packaging and labelled for the patient as per Part 7 of the Regulations. For prescription only medicines this labelling includes: name and address of the supplier; name of the patient; name, strength, from, quantity and directions for use of the medicine.

For each medicine administered or supplied, the health practitioner must keep an accurate record in the patient’s clinical notes. This must include details of the medicine and quality supplied. These records must be kept for at least two years and produced if requested by authorised officers.

A SASA does not delegate the prescribing authority of the issuer and does not authorise any action beyond that expressly outlined in the written document.

## Notes

The Regulations provide a framework for a hospital or Health Service Permit holder to issue a SASA for an employee deemed competent, to use a medicine, whenever clinically appropriate, without the need to issue individual, patient specific orders each time.

It is up to the individual organisation as to whether these should be issued in their facility, where they should be utilised and when they are suitable. The organisation, via the clinical governance committee, must make their own assessment as to the competence and safety of the practitioner(s) they are authorising, for each medicine and task involved.

It is up to the organisation as to whether any additional or special training is required of the health practitioner before being authorised by a SASA. In general, it is recommended that health practitioners consider their own scope of practice, when applying the authority provided by any SASA.

It is strongly encouraged that each SASA is accompanied by a written guideline that provides clinical support for the user. This may include more information on items such:

* diagnosis and treatment of the condition;
* use of non-pharmacological treatments;
* when to refer, or to otherwise not apply the SASA;
* medicine dosing, correct administration, interactions, contraindications; and
* management of adverse effects.

Organisations are expected to regularly review performance of SASA they have issued. This should include ongoing compliance with Regulations, continued need for the SASA, any updating needed to meet best practice, and aspects of consumer safety (e.g. incidents and adverse events). Any unsafe SASA should be withdrawn and any unsafe practitioner removed from the authority.

## Writing a SASA

A SASA must be a specific written document that contains all the minimum elements listed above. A suggested template for use is provided in the Appendix to this Guidance Note.

## Compliance

Hospitals and Permit holders may be required to participate in routine audit assessments to monitor compliance with these requirements.

Where a SASA is deemed to be non-complaint or a risk to public safety, organisations will be instructed to withdraw the SASA from use immediately.

Non-compliance with the Regulations may result in regulatory actions such as restrictions or loss of medicines authorities, notification to the relevant Australian Health Practitioner Board and/or prosecution under the legislation.

## For more information

Medicines and Poisons Regulation Branch

Mailing address: PO Box 8172, Perth Business Centre, WA 6849

Phone: 9222 6883

Email: MPRB@health.wa.gov.au

## APPENDIX 1 – Template Example

# *Hospital/Health Service*

# *Letterhead*

### <<Structured Administration and Supply Arrangement – TITLE>>

*TEXT PROVIDED AS AN EXAMPLE ONLY –* ***NOT A RECOMMENDATION***

*(fill in <<sections>> and delete example text in red)*

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| **SASA Details** |
| Title: | *<<First dose ceftriaxone for meningococcal disease in children>>* |
| Identifying Number: | *<<2016/1/PUBHOSP>>* |

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| **Issuing Authority** |
| Hospital Name: | *<<Perth Public Hospital (PPH)>>* |
| Address: | *<<Government Ave, PERTH>>* |
| Contact: | *<<Switch Board – 9876 5432>>* |

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| **Authorised Persons** |
| Practitioners: | *<<Registered Nurses at PPH>>* |
| Location: | *<<PPH Emergency Department only>>* |
| Qualification: | *<<Must have completed ED competency training on meningitis treatment in children>>* |

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| **Authorised Medicine** |
| Medicine Name: | *<<Ceftriaxone>>* | Brand: | *<<any stocked brand>>* |
| Form: | *<<Injection>>* | Strength: | *<<1 gram vial>>* |
| Dose: | *<<50 mg per kg bodyweight>>* | Quantity: | *<<Up to 2 vial max>>* |
| Route: | *<<Intravenous injection>>* |
| Instructions: | *<<Administer as a single dose>>* |

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| **Approved Circumstances** |
| Authorised to: | *<<Administer by IV injection>>* |
| Place: | *<<Emergency Department, Perth Public Hospital>>* |
| Patients: | *<<Children>> - specify age range>>* |
| Medical Condition:  | *<<Emergency empirical antibiotic treatment of suspected meningococcal disease>>* |

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| **Clinical / Other Information** |
| Patient Inclusion | *<<LIST CRITERIA – see “ED clinical guideline for treatment of meningitis in children” for diagnostic algorithm.>>* |
| Patient Exclusion: | *<<LIST CRITERIA – seek medical advice for patient with severe penicillin or cephalosporin allergy (e.g. anaphylaxis) – DO NOT GIVE without instruction.>>* |
| Special Instructions: | *<<LIST CRITERIA – “ED clinical guideline for treatment of meningitis in children” for dose calculations and method of administration.>>* |
| Administration Notes: | *<<Seek medical advice after administering first dose.**All subsequent doses to be approved by treating team and prescribed on medication chart.>>* |
| Clinical Guidelines | *<<See “ED clinical guideline for treatment of meningitis in children” for administration notes.>>**<<Dose should be administered within 30 minutes of presentation to ED.* *If suspicion of meningitis is high, do not delay therapy for taking of culture samples.>>* |

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| **Approval** |
| Date of Issue: | *<<2 February 2024>>* |
| Date of Expiry: | *<<2 February 2026>>* |
| Clinical Governance Committee |
| Committee: | <<PPH Drug and Therapeutic Committee>> |
| Chairman Name: | <<Professor G Practitioner, Chair, PPH DTC>> |
| Date: | *<<1/2/2024>>* | Signature: | ***<<Dr G Practitioner>>*** |
| Senior Medical Practitioner |
| Name: | <<Dr A Medic>> |
| Position: | <<Director of Medical Services>> |
| Date: | *<<2/2/2024>>* | Signature: | ***<<Dr A Medic>>*** |
| Chief Executive  |
| Chairman Name: | <<C.E.Zec>> |
| Date: | *<<2/2/2024>>* | Signature: | ***<<C Zec>>*** |