



Australian Government
Department of Health
Therapeutic Goods Administration

SERIOUS SHORTAGE MEDICINE SUBSTITUTION NOTICE
THIS NOTICE IS FOR ILLUSTRATIVE PURPOSES ONLY

Notice Reference Number: SSN [XX XX]

This Notice applies for the following dates:

From: [DD/MM/YYYY] To: [DD/MM/YYYY]

This Notice applies only to the following medicine

Name of medicine (including strength and formulation): [XX XX]

Schedule: [S2: Pharmacy Medicine, S3: Pharmacist Only Medicine or S4: Prescription Only Medicine]

Details of medicine to be supplied under this SSN

Same formulation but different strength?

Same active but different salt?

Details: [XX XX]

Different dose form?

Details: [XX XX]

Any restrictions on this dose form e.g. dose intervals, no crushing etc.?

Details: [XX XX]

Any limitations on substitution? [age/patient class/other]

Please specify: [XX XX]

Quantity of this formulation (if applicable): [XX XX]

Conditions:

- Total quantity supplied under this protocol to be equivalent to the number of days supplied on original prescription.
- Cannot be used for Reg. 49 prescriptions without discussing with prescriber
- The patient must present with a valid prescription for the medicine to be substituted for.
- The patient/carer must consent to receiving the medicine(s) supplied pursuant to the notice.
- The pharmacist may, in their professional judgement, determine that the patient is not suitable to receive alternative medicine under the notice e.g. known previous hypersensitivity or severe adverse reaction to excipients; specific requirement for tablets and cannot swallow a capsule.

HPRG internal processes

The TGA will publish a Serious Shortage Substitution Notice (SSSN) specifying its decision on specific medicines for substitution.

SSSNs would be communicated by:

- publication on the medicine shortages section of the TGA website
- email to a designated Chief Pharmacist contact in each jurisdiction
- email to a designated contact for relevant medical and pharmacy groups

The decision-maker would be the First Assistant Secretary, Medicines Regulation Division.

The TGA would make decisions on simple substitutions (e.g. 2 x 20 mg IR tablet = 40 mg) internally. For more complex cases, TGA would seek expert advice, eg from clinical colleges

Use of the terminology “serious shortage” is deliberate. There is not a direct relationship with “critical” medicines shortages or the Medicines Watch List.