

## Serious Shortage Medicine Substitution

Under changes to the Controlled Substances (Poisons) Regulations 2011, in effect from 27 January 2021, pharmacists may legally substitute a prescribed medicine that is in serious shortage for another medicine specified and in accordance with certain conditions of a Therapeutic Goods Administration (TGA) [Serious Shortage Medicine Substitution Notice](#).

### What is a Serious Shortage Medicine Substitution Notice?

A TGA Serious Shortage Medicine Substitution Notice is a mechanism developed by the TGA to address serious drug shortages.

Under a Serious Shortage Medicine Substitution Notice a pharmacist may conditionally substitute a specific medicine for another medicine that has been prescribed but that is unavailable at the time of dispensing due to a serious national shortage. The Notice allows the supply of a substitute medicine without the patient having to return to the prescribing doctor for a new prescription.

### What medicines can be substituted?

A pharmacist can only substitute a Schedule 4 (Prescription Only) medicine when a patient has a current and valid prescription for that medicine. They can only provide an alternative where there is a serious shortage of that particular medicine and according to the conditions of the Notice.

A substitute might include the supply of:

- > a lower or higher strength of the same medicine (e.g. two 20 mg tablets where the 40mg tablets are in serious shortage).
- > a different dose form of the same medicine (e.g. capsules instead of tablets)
- > a sustained-release form of a medicine, instead of an immediate-release form (or vice versa).
- > Substitution of one medicine for a different medicine (containing a different drug/(active ingredient) is not permitted.
- > Substitution of Schedule 8 drugs (Drugs of Dependence) is also not permitted.

### What are the conditions of substitution?

Particular conditions must be met when substituting a medicine under a Serious Shortage Medicine Substitution Notice. All of the following conditions must be met:

- > the patient must present with a valid prescription for the medicine that is in shortage

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- > the pharmacist is unable to obtain the drug prescribed by the prescriber
- > the pharmacist complies with the conditions specified in the Notice
- > the patient or carer consents to their prescribed medicine being substituted
- > the pharmacist notifies the prescriber about the substitution as soon as practicable in writing, or earlier if specified in the Notice
- > the pharmacist is satisfied that dispensing the substitute drug to the patient is appropriate

Requirements under South Australia's Controlled Substances (Poisons) Regulations 2011 in relation to the supply and dispensing of drugs on prescription must be complied with.

Pharmacists should refer to the specific Serious Shortage Medicine Substitution Notice published on the TGA [website](#) to ensure they understand the conditions and restrictions relating to substitution of a medicine.

## Is it mandatory to dispense medicines under a Serious Shortage Medicine Substitution Notice if there is one in place?

No. The pharmacy may have stock of the prescribed medicine despite a national or local shortage. If the patient refuses or does not fulfil all the criteria in the Notice (including cases where in the pharmacist's professional judgement the supply is not appropriate), the pharmacist should consider referring the patient back to the prescriber for further advice about treatment options.

## Are substituted medicines subsidised through the Pharmaceutical Benefits Scheme (PBS)?

At the time of publication of this factsheet, medicines substituted under a Serious Shortage Medicine Substitution Notice are not subsidised through the PBS and patients should be advised accordingly. The patient may choose to contact their doctor to discuss other alternatives, including other PBS subsidised treatments rather than accepting a substituted medicine.

## Further information

For information about the TGA Serious Shortage Medicine Substitution Notices refer to [TGA website](#).

For legislative requirements refer to the [Controlled Substances \(Poisons\) Regulations 2011](#), regulation 35B.

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## For more information

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