

## Serious Shortage Medicine Substitution

Shortages of medicines can occur and may arise due to a number of factors including higher than usual demand for certain medicines, challenges in manufacturing processes or in timely transportation both locally and from overseas.

The Commonwealth Therapeutics Goods Administration (the TGA) continually monitors medicine supplies in Australia and works with manufacturers and clinicians to ensure alternative supply arrangements are in place where necessary to minimise the impact of any shortages.

### 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.

### Can any medicine be substituted under a Serious Shortage Medicines Substitution Notice?

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 should you know about the substituted medicine?

As the substituted medicine may be a different dose or form of the medicine, how much and how often you need to take the medicine may be different. Your pharmacist will talk to you about the

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differences and how best to take the substituted medicine. Instructions for how to take the medicine will be printed on the label and you can also ask for written instructions and an update to your medicines list. In some cases, you may receive a smaller or larger quantity of the medicine, however the new supply should last the same number of days as your usual medicine.

## 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 below conditions must be met:

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

The pharmacist will speak with you about the potential to substitute a medicine if your medicine is unavailable and to determine whether the above conditions are fully met. It may be necessary to discuss the best option for you with your doctor.

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

At the time of publication of this factsheet, substituted medicines are not subsidised through the PBS. This means you may have to pay the full amount for the medicine. You may opt not to have a substituted medicine and instead may contact your doctor to discuss other alternatives, including other PBS subsidised treatments.

## How is substitution given legal effect in South Australia?

On 27 January 2021, new regulations came into effect under the [Controlled Substances \(Poisons\) Regulations 2011](#) and published in the [SA Government Gazette](#) which gives legal effect to the conditional substitution of a prescribed medicine in accordance with a [Therapeutic Goods Administration \(TGA\) Serious Medicine Shortage Substitution Notice](#).

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## For more information

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