

Serious Shortage Medicine Substitution

Shortages of medicines can occur and may arise due to several 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 (also known as a Serious Scarcity Substitution Instrument (SSSI)) is a legal notice developed by the TGA to assist in serious drug shortages.

Under a SSSI 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. A SSSI allows the pharmacist to supply of a substitute medicine without the patient having to go back to the prescribing doctor for a new prescription.

Which medicines can be substituted?

Substitution is only allowed where the TGA has issued a SSSI for the particular medicine that is in serious shortage. Information about the conditions and specified permitted circumstances that apply to medicine substitution are published on the [TGA website](#).

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 SSSI

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 Schedule 8 drugs (Drugs of Dependence) is not permitted.

What are the conditions of substitution?

Some of the general permitted circumstances for substitutions in accordance with a published SSSI include, but are not limited to:

- > The patient or carer has evidence of a valid prescription for the medicine in serious shortage

- > The pharmacist does not have access to the medicine
- > The prescriber has not indicated on the prescription for the medicine in shortage that substitution is not permitted
- > The pharmacist has exercised professional judgement and determined that the patient is suitable to receive the substitute medicine
- > The patient or carer has consented to receiving the substitute medicine
- > The total quantity of substitute medicine supplied by the pharmacist must be equivalent to the quantity that would have been dispensed for the medicine in serious shortage for the prescribed duration and dosage regimen
- > The pharmacist makes a record of dispensing the substitute medicine at the time of dispensing
- > The pharmacist notifies the prescriber of the substitution at the time of, or as soon as practical after, dispensing the substitute medicine

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.

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 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.

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

Substituted medicines may not be subsidised through the PBS; your pharmacist will be able to check this for you. If it is not subsidised through the PBS you may have to pay the full amount for the medicine. You can choose not to have a substituted medicine and instead may contact your doctor to discuss other alternatives, including other PBS subsidised treatments.

For more information

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