



Medicines substitution during a serious scarcity

Information for prescribers and pharmacists

Background

Disruptions to the supply of medicines can occur for a range of reasons including:

- manufacturing plants being moved, merged, repaired and/or closed
- changes in clinical practices, which can lead to a change in demand
- wholesaler and pharmacy inventory practices
- availability of raw materials
- changes to contract arrangements of hospitals and pharmacies with suppliers
- individual company decisions to discontinue specific medicines
- natural disasters
- manufacturing and/or transportation challenges - locally or from overseas
- unexpected quality issues that lead to product recalls.

In Australia, medicines sponsors are required to report shortages of critical medicines to the Therapeutic Goods Administration (TGA). Health practitioners can view current medicines shortages on the TGA's [Medicine shortage reports database](#) and sign up to receive alerts.

In the case of a serious scarcity of a product, where there is no equivalent registered brand of the same medicine, to maintain continuity of treatment, an alternative must be prescribed and supplied. Under normal circumstances, pharmacists are required to supply a medicine in the exact product formulation, strength and quantity that is specified on the prescription. Alternatives may not be dispensed without the authority of the prescriber and a valid prescription.

In March 2020, in response to increased shortages driven by the COVID-19 pandemic, the TGA announced a national approach to substitution by pharmacists during serious shortages. More recently, amendments to the Commonwealth *Therapeutic Goods Act 1989* provide legislative support for the issuing of [Serious Scarcity Substitution Instruments](#).

Serious scarcity of a medicine

The TGA defines a serious scarcity as the verified disruption of a particular medicine at a national level, where demand cannot be met by the total available stocks of all brands of the medicine, or a Section 19A authorisation for importation of unregistered products. A serious scarcity may be declared where there is strong evidence of an imminent (within weeks) gap in supply, and it is expected there will be significant health consequences for patients if they do not receive the medication prescribed at the intended supply intervals.

In response to a serious scarcity, the TGA will issue a Serious Scarcity Substitution Instrument (SSSI) relating to the substitution of an alternative medicine. Expert clinical advice from relevant professional groups may be sought on the substitution protocol included in any SSSI.

During the COVID-19 pandemic, when domestic transport services are more limited, a SSSI may also be declared in response to significant local-level supply disruption of medicine that cannot be replenished in that region before patient access is affected.

Substitution of medicines during a serious scarcity

A SSSI issued by the TGA is a legislative instrument applicable to all registered pharmacists. Pharmacists practising in Western Australia are permitted to substitute medicines in accordance with any current SSSI.

Further detail about substituting scarce medicines is available on the [TGA website](#).

Pharmacists can supply the alternative medicine product detailed in the SSSI, as a substitute for the prescribed product. These measures are intended to relieve pressure on prescribers and allow patients to receive their medicines from their pharmacist without delay, where it is safe to do so.

Pharmacists must comply with all conditions included in the relevant SSSI.

SSSI will only be issued for certain types of substitution, including substituting supply of:

- a lower, or higher, strength of the same medicine (e.g. 2 x 20 mg tablet instead of 1 x 40mg tablet);
- a different dose form of the same medicine (e.g. capsules instead of tablets)
- a sustained-release form instead of an immediate-release form (or vice versa).

Substitution of a medicine with another product containing a different active ingredient is not permitted and SSSI will not be issued for this purpose.

SSSI will only be issued for Schedule 4 (prescription only) medicines.

Limitations to medicines substitution

SSSI include a list of 'general permitted circumstances', in addition to information about which product and quantity can be substituted for the scarce medicine.

Substitution can only occur when the patient presents the pharmacist with a current, valid prescription for a medicine product that is affected by a serious scarcity.

The pharmacist must be satisfied that:

- the supply is required urgently,
- it is impractical for the patient to return to the prescriber for an alternative prescription and
- the substitution is safe and suitable for the patient's specific circumstances.

The patient must agree to the substitution.

A pharmacist is not required to make a substitution unless they are satisfied it is safe to do so.

Ideally the pharmacist will contact the original prescriber and seek advice and authorisation for any alternative supply. If this is not possible, the substitution may be considered by the pharmacist. For any supply disruption that is expected to be prolonged, the pharmacist should always seek to refer back to the original prescriber, regardless of any urgent substitution made.

If a substitution is made, the pharmacist must notify the prescriber as soon as practicable after supplying the substitute medicine.

The total quantity of any substitute medicine supplied must be equal to the number of days of treatment specified on the original prescription for the medicine that is unavailable. Only one standard supply quantity of the substitute medicine is permitted on any occasion, without contacting the original prescriber.

The pharmacist is expected to counsel the patient regarding the substitution and new dosage instructions. The dispensing label must match the medicine actually supplied and include the correct dosing instructions for the substituted product.

A record of the substitution must be made:

- in the dispensing system/records
- on the original prescription
- on any repeat forms issued.

This should clearly state that a substitution occurred and include the name, strength, dose and quantity of the medicine that was actually supplied.

Pharmaceutical Benefits Scheme

The Commonwealth Government has [implemented changes](#) to allow a Pharmaceutical Benefits Scheme (PBS) subsidy in circumstances where the TGA has issued a SSSI.

[Details of applicable PBS item codes](#) are listed on the Medicines Shortages section of the PBS website.

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