Government of Western Australia
Department of Health

Serious shortages medicines substitution

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 now required to report shortages of critical medicines to the Therapeutic Goods Administration (TGA). Health practitioners can view current medicines shortages on the Medicines Shortages Information Initiative or sign up to receive alerts.

In the case of a severe shortage, 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 COVID-19, the TGA announced a national approach to Serious Shortages Medicines Substitution.

Serious medicines shortages

The TGA defines a serious shortage 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 shortage 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 shortage, the TGA may issue a Notice 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 Notice.

During the COVID-19 pandemic, when domestic transport services are more limited, a Notice 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 shortage

Where the TGA has issued a Notice with a substitution protocol, the Western Australian Department of Health may issue a corresponding Structured Administration and Supply Arrangement (SASA) to authorise the substitution of an alternative medicine.

In these cases, an alternative medicine product may be supplied, as a substitute to 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.

A SASA that permits substitution will only apply to authorised medicines that are affected by the serious shortage Notice, and may not be employed for any other shortage, regardless of the reason. A substitution SASA may cover any Schedule 4 medicine and apply to any pharmacy.

Only certain types of substitution are permitted, 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. Substitutions made by the pharmacist must comply with the conditions, including any dose conversions stipulated in the SASA and TGA Serious Shortages Medicines Substitution Notice.

Limitations to medicines substitution

The patient must present the pharmacist with a current, valid script of a medicine product that is affected by a serious shortage.

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 that 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, in any particular instance, unless 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.

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 protocol relating to substitution, including any new dosing must be adhered to. Any conditions relating to supply specified must also be fully observed.

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

As the pharmacist is supplying a different product to that specified on the PBS prescription, the substituted items would not be eligible for subsidy under the Pharmaceutical Benefits Scheme (PBS). This is the case, even if the substituted medicine is ordinarily a PBS item.

The substituted item may be supplied as a non-PBS (private) prescription item.

At present, there are no medicines subsidised by the PBS for the purpose of substitution in a serious shortage. The Commonwealth Government may, at a future date, choose to permit a specific substituted medicine to be eligible for PBS subsidy.

Pharmacists should seek further information on the PBS status of substituted medicines from the PBS on a case by case basis.

Last updated 15 May 2020

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