



Serious shortage medicines substitution

Shortages of medicines occur when the supply of medicines being made, or being shipped into Australia, cannot meet the usual patient demand.

Shortages are normally uncommon, but they do occur in Australia and can affect critical medicines. Shortages have been worse during COVID-19, due to very high demand. It is expected that COVID-19 will continue to cause shortages for some time, due to disruption of normal manufacturing, transport and importation channels. Many of Australia's prescription medicines are manufactured overseas.

When a medicine is not available, an alternative must be prescribed. Shortages are time consuming to manage, distressing for patients and increase costs. The alternative medicine prescribed may be more complicated, require a different dose, or have other side effects.

What causes shortages of medicines?

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
- shortages or limited 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.

What is done about shortages?

In Australia, medicines companies are required to report shortages of critical medicines to the national regulator, the Therapeutic Goods Administration (TGA). If there is sufficient early warning that a shortage is likely to occur, this lets doctors and pharmacists work with patients, to consider what to do, before it becomes an emergency.

Shortages are continually monitored and the TGA works with companies on alternative approaches to supply of the affected medicines. It is not always possible to prevent a shortage entirely and there is not always a direct alternative available.

In response to COVID-19, and from April 2020, where there is a serious shortage of a critical medicine, new rules apply, which will let pharmacists substitute a medicine, in urgent situations.

What is medicines substitution by the pharmacist?

Where a serious shortage of a particular medicine has been declared, Western Australian laws will allow the pharmacist to provide an alternative medicine, without going back to the original prescriber for a new prescription in every case.

A substitution might include the supply of an alternative, which is:

- 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).

Can any medicine be substituted?

A pharmacist can only substitute a medicine for which you have a current, valid prescription. They can only provide an alternative where there is a serious shortage, of that particular medicine.

The alternative provided will be the same active ingredient of the medicine, but in a different dose or formulation. The pharmacist must make an assessment that it is safe for you to take the alternative product.

What do you need to know about the substituted medicine?

As the alternative medicine may be a different dose or form, when and how much of the medicine you need to take, is likely to be different to normal.

Your pharmacist will talk to you about any changes and the new amounts, or times, to take the dose of your medicine. Make sure you understand the changes and ask for written instructions if at all unsure. Remember that when your usual medicine becomes available again, you will need to return back to your normal dosing.

You may receive a smaller or larger quantity of the medicine. The amount of the alternative provided, at the new dose, should last the same number of days as your normal medicine.

Should you talk to your doctor?

The pharmacist will normally contact your doctor when a medicine is unavailable. They will still do this, even if providing an alternative, unless it is not possible. In some cases, the pharmacist may recommend that a substitution is not safe or that the doctor needs to be contacted first.

Upon taking the medicine, if you notice any changes to how effective the medicine is, or any different effects, then contact the doctor or pharmacist for more advice, as soon as possible.

Some shortages can last a long time. The safest and most appropriate alternative medicine is different for everyone. Medical advice is still recommended regarding the use of any alternative medicine, and particularly where the shortage is likely to last many months.

What else to you need to know?

The substituted medicine may not be eligible for Pharmaceutical Benefits Scheme (PBS) subsidy. If you are not able to pay the full price for the medicine and require your medicines to be subsidised, then you will need a new prescription from your doctor. Ask your pharmacist for more information on medicines substitution and the PBS.

Last updated 15 May 2020

This document can be made available in alternative formats on request for a person with disability.

© Department of Health 2020