Modification of oral formulations

Many people have difficulty swallowing solid dose forms, such as capsules and tablets, and altering these forms (e.g. crushing tablets or opening capsules) can make administration easier. However, it is important to ensure that the alteration of dosage forms does not result in reduced medicine effectiveness, a greater risk of toxicity or an unacceptable presentation in terms of taste or texture. Pharmacists should note that, once a marketed product has been altered (e.g. crushed), it is no longer being used in accordance with the manufacturer's 'Product Information' and may be considered an 'off-label' product.

These guidelines provide a step-by-step approach to:

- the assessment of swallowing ability
- deciding which medications and dose forms can be altered and which cannot
- the processes of alteration and administration
- ongoing monitoring and assessment of therapy
- documenting the key elements of the processes.

Six-step process to ensure desired therapeutic response[1]

1. Assessment of swallowing ability

There are several reasons why orally administered dose forms of some medicines may need to be altered, including a physical inability to swallow whole foods or medications as a result of a disease state or trauma; dysphagia after stroke; a psychological inability to swallow medication; and a refusal, due to deteriorating cognitive state, to take medication. Any of these reasons may lead to a decision to alter solid oral medications for ease of administration. There are complex issues involved in a person refusing or being unable to take medication, and they should be carefully considered and dealt with on an individual basis.

An inability to swallow solid medications may be a transient or episodic disability and, when clinical circumstances change, renewed attempts to encourage taking unaltered dosage forms should be made. The ability of some people to swallow may vary during the day so that, when clinically acceptable, changing to alternative dosing times may reduce the need for product alteration.

A comprehensive consultation by a speech pathologist is commonly used to provide a detailed assessment of a person's ability to swallow, especially in the hospital or aged care facility setting. This has important implications for a person's medicines, diet and risk of aspiration.

2. Review of the medication regimen

Difficulties experienced in swallowing medications should always provide a stimulus for a review of the medication profile with a view to changing to different formulations (e.g. oral liquid, transdermal patch, dispersible tablet, sublingual tablet) of the same medicine, changing to an alternative medicine or stopping medicines that are no longer necessary. The reviewer should differentiate between those oral preparations that need to be swallowed and those that need to be retained in the mouth for optimal effect (e.g. sublingual glyceryl trinitrate tablets and amphotericin lozenges). People who are alert but unable to swallow may be able to manage the latter groups of products.

In many cases, alternative preparations of the required medication may be available. For example, dispersible tablets or sustained-release capsules containing pelletised units which can be opened and dispersed on food. Immediate release dose formulations can usually be crushed without any major concerns. If a liquid formulation of the required medicine is available, be aware that a dose given as a liquid is likely to be absorbed more quickly than the same dose given as a modified-release solid preparation. Smaller doses of the liquid formulation given more frequently may be required to achieve the same total daily dose. A drug given as a liquid dosage form may have a different bioavailability compared with when it is administered as a solid dose form, leading to different pharmacological effects. Pharmacists should refer to the Product Information to establish the equivalency of dose forms. Excipients such as ethanol, sorbitol or sucrose, which are commonly found in liquid dose forms, may also influence choice of formulation.

3. Which formulations should not be altered?

The 'Clinical monographs' in Section B provide information on some specific medicines which should not be altered or crushed (e.g. solid dose forms that are dispersible in water). Pharmacists should regularly consult approved Product Information for updated information on specific dose forms or new formulations.