

# Prescribing medicines for adults who are unable to swallow oral solid dosage forms – a summary

## STEP 1: Clinical Evaluation

- Consider a swallowing screening assessment by an appropriately trained healthcare professional, prior to making a referral to the Speech and Language Therapy

## STEP 2: Medication Review

- Check that each medicine is still required

## STEP 3: Use a licensed medicine in a suitable formulation

- Consider changing drug or formulation if necessary taking into consideration possible differences in bioavailability and ingredients.

## STEP 4: Use a licensed medicine in an unlicensed manner

- Before prescribing a licensed medicine to be used in an unlicensed manner by manipulation, be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative that does not require manipulation.
- Care staff may only administer licensed medicines in an unlicensed manner on the instruction of the prescriber. A written direction must be documented in the patient's care plan.

## STEP 5: Use an unlicensed 'special'.

- Special-order ('special') liquid medicines are unlicensed and can be expensive. They should only be used if there is no licensed medicine that meets the patient's needs.
- If possible specify a batch produced formulation from a licensed specials manufacture.

### Consent

As with any intervention the patient must give informed consent. Where necessary it is important that the patient's carers are involved in this process and where doses are manipulated ensure that they are happy and able to administer the medicine in this way

## 4. Recommendations

### STEP 1

#### Clinical Evaluation

If you have concerns about swallowing safety a suitably trained health care professional could undertake a swallowing screening assessment<sup>2</sup> (Appendix 1) prior to making a referral to the Speech and Language Therapy department.

The speech and language therapists may be able to recommend simple interventions to help patients swallow.

### STEP 2

#### Medication Review

There are many reasons why withdrawing a medicine might be beneficial, ranging from a serious adverse reaction to a lack of clinical response. A change in circumstances of a patient or their disease state may make the risk benefit profile unfavourable<sup>3</sup>.

Carry out a medication review (e.g. NO TEARS<sup>4</sup>) consider:

- **N**eed and Indication
- **O**pen questions to gauge concordance
- **T**ests and monitoring
- **E**vidence and guidelines
- **A**dverse events
- **R**isks of treatment
- **S**implification of existing regiment.

Some medicines should not be stopped abruptly following long term use, a pharmacist can advise on which medicines these are.

## STEP 3

### Use a licensed medicine in a suitable formulation<sup>5</sup>

For example:

Licensed liquid preparation

Soluble tablets

Powders or granules for suspension

Sublingual or buccal product

Transdermal products

Rectal products

Aim to use a licensed medicine, rather than an unlicensed dosage manipulation, consider switching to a licensed medicine that the patient can swallow such as a different agent in the same class, or to a different route of administration. As the bioavailability of products may vary between formulations care must be taken to ensure that the patient receives the same therapeutic dose e.g. Suspension of phenytoin 90mg in 15ml may be considered to be approximately equivalent in therapeutic effect to capsules or tablets containing Phenytoin sodium 100mg<sup>6</sup>. Some formulations may have significantly different ingredients and care must be taken to ensure that these are suitable for the patient e.g. Effervescent tablets often have a high sodium content.

For example, consider:

- Fluoxetine liquid (licensed preparation) as an alternative to sertraline tablets.
- HRT patches instead of tablets.

In exceptional circumstances, where there is an evidence base for its use, a licensed product may be manipulated and used in an unlicensed way in preference to another licensed form. Where this best meets the needs of the patient this is regarded as reasonable practice<sup>7</sup>.

## STEP 4

### Use a licensed medicine in an unlicensed manner

For example by crushing / dispersing tablets in water or by opening capsules<sup>5</sup>

In some cases it may be deemed preferable to give a licensed product via an unlicensed route (e.g. an injection given orally), rather than to use an unlicensed product<sup>7</sup>.

Local or regional Medicines Information services can provide advice on administration of medicines and additional drug information to help prescribers determine the best option for the patient. Appendix 2 provides further sources of information.

Practical guidance on drug administration is given in Appendix 3.

#### Legal and ethical aspects

- Before prescribing a medicine off-label, be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative.
- As with any intervention the patient must give informed consent, where necessary it is important that the patient's carers are involved in this process and ensure that they are happy and able to administer the medicine in this way.
- The supply and administration of a medicine in an unlicensed manner may only be carried out on the specific written instruction of an independent prescriber<sup>8</sup>.
- Care staff may only give licensed medicines in an unlicensed way if there is a written direction in the patient's care plan.
- Further professional considerations are discussed in Appendix 4.

## **STEP 5**

### **In the few situations where there is no licensed option, consider using an unlicensed 'special'.**

Medicines legislation requires that medicinal products are licensed before they are marketed in the UK. However, some patients may have individual clinical needs that cannot be met by licensed medicinal products. In order that these needs may be met, the law allows manufacture and supply of unlicensed medicinal products (commonly known as 'specials') subject to certain conditions<sup>9</sup>.

Special-order ('special') liquid medicines are unlicensed and often expensive. Medicines and Healthcare products Regulatory Agency (MHRA) guidance<sup>7</sup> states that before prescribing an unlicensed medicine ensure that an alternative, licensed medicine would not better meet the patient's needs.

Special-order medicines may be produced as batch-prepared products or individual bespoke preparations. Batch prepared products are preferred as they have a higher level of assurance and have a known shelf life, which may be longer than bespoke medicines. It is recommended that the prescriber discussed with the supplying pharmacy which products are available and specifies the manufacturer's name on the prescription. This will also make it clear that the prescriber is aware that an unlicensed medicine is being requested and ensure consistency of subsequent supplies. Specials manufacturers may now publish price lists.

Manufacturers of specials must hold a Manufacturer's Specials Licence (MS) granted by the licensing authority and their manufacturing sites are inspected for compliance with Good Manufacturing Practice<sup>8</sup>. Products made by these manufacturers will have a MS number on the label<sup>6</sup>. Where an unlicensed drug is included in the BNF, this is indicated in square brackets after the entry<sup>6</sup>.

Guidance on the key professional responsibilities for pharmacists when providing advice about or supplying specials, and support in making appropriate choices for their patients is available from the Royal Pharmaceutical Society<sup>10</sup>.

A complete version of the guidance is available at: [All Wales Medicines Strategy Group - Prescribing medicines for adults who are unable to swallow oral solid dosage forms](#)