Use of "Specials"
Guidelines for good practice and points to consider

- A licensed preparation should always be used wherever possible. It may be possible to switch to a licensed preparation of a different drug within the same class.
  - First Choice: Use a licensed medicine in a suitable formulation (includes change to different drug in same therapeutic class)
  - Second Choice: Use a licensed medicine in an unlicensed manner
  - LAST RESORT: Use an unlicensed special
- If a licensed preparation is unsuitable or not available, advice should be sought on appropriate alternatives from the "A-Z of possible alternatives to using a special", the patient's Community Pharmacist, the acute trust Medicines Information department or the CCG Medicines Management Team. Advice can also be provided on the correct process for administering crushed tablets or capsule contents safely.
- Use of an unlicensed preparation or use of a licensed preparation administered in an unlicensed manner should be authorised in writing by an appropriate prescriber (see paragraph).
- Patients (or their carers) receiving an unlicensed medicine should be informed and their consent obtained.
- A Patient information leaflet and other specials related links available on the Specials section of the Derbyshire Medicines Management website

1. Specials are unlicensed medicines and should only be prescribed when there is no available licensed medicines which fully meets the patient's special **clinical** needs. They are usually considerably more expensive than standard preparations and can reach prices of over £1000 for a single item. For the most commonly prescribed Specials the price paid by the NHS in primary care is listed in the Drug Tariff. Specials not listed in the Drug Tariff are reimbursed at the invoice price and prices can vary enormously depending of which supplier is used.

2. Ongoing need should be reviewed and if necessary a change in medication or route of administration should be considered. The alteration of medication formulations (e.g. crushing tablets) to aid administration to patients with swallowing difficulties will render a licensed preparation unlicensed. As such, consideration should be given to the legal implications:

2.1. Once a preparation becomes unlicensed, the manufacturer assumes no liability for any harm that may occur to the patient receiving the medication or the person administering.

2.2. According to the Medicines Act 1968, the use of an unlicensed or off-label preparation can only be authorised by:
"doctors; dentists; and, in some circumstances, supplementary prescribers (who can be a pharmacist, nurse, midwife, community nurse, optometrist, physiotherapist, radiographer, or chiropodist/podiatrist). In addition to these health professional groups, the following can prescribe a licensed medicine off-label: nurse independent prescribers, pharmacist independent prescribers, and optometrist independent prescribers. However, all healthcare professionals who can prescribe as outlined above are subject to: their individual clinical competence; the professional codes and ethics of their statutory bodies; and the prescribing policies of their employers."

2.3. Authorisation for unlicensed administration must be obtained from the relevant practitioner (doctor or dentist, nurse or pharmacist and this should be confirmed in writing by including the relevant information in the prescription details. The prescriber will take responsibility for the off-licensed use of the drug concerned.

2.4. Staff administering medication to patients should not alter the formulation of a product e.g. crushing a tablet unless they have specific written authorisation from the relevant prescriber.

2.5. Liquid specials can be obtained from a specials manufacturer as an alternative to crushing tablets or opening capsules. These products are covered by the Consumer Protection Act 1987 which makes a producer liable for damage caused by a defective product. However such products are still unlicensed, often have a short shelf life and can be very expensive. Such products may be considered when crushing tablets or opening capsules is not considered appropriate due to the nature of the medicine itself (e.g. enteric coated tablets, modified release preparations, buccal or sublingual formulations, medicines that may be toxic when crushed e.g. cytotoxic medicines, antibiotics) or for logistical and practical issues.

2.6. Patients (or their carers) receiving an unlicensed medicine should be informed and their consent obtained. A patient information leaflet explaining the issues around specials and unlicensed medicines is available on the Specials section of the Derbyshire Medicines Management website. There is a patient information leaflet specifically for children's unlicensed medicines available on the Medicines for Children Website (www.medicinesforchildren.org.uk).

2.7. When prescribing responsibility transfers from one prescriber to another there must be a planned transfer of information that ensures a safe, consistent and timely supply of the Special is maintained for the patient.

3. Although specials can be for any type of medication (oral liquids, topical preparations, ear/eye and nose drops etc.), the most common formulation are oral liquids. These may be required for patients who have enteral feeding tubes or for patients with short or long term swallowing difficulties. When a liquid preparation is required the following additional considerations should be made:

3.1. Prescriptions should always be given in "milligrams" rather than "millilitres" to avoid confusion – there may be a number of different strengths available.

3.2. In children, Specials may be the only option for the prescriber for some conditions and in some circumstances are routinely prescribed. The risks of prescribing for children are higher than for adults and so prescribers need to be vigilant at all times.

3.2.1 Only clinical staff should transfer information from discharge summaries or outpatient letters.

3.2.1. Particular care should be taken with children's prescriptions.

3.2.2. Always include the strength of the preparation and be aware that some formulations are not suitable for children.

3.3. Oral syringes are readily available from Community Pharmacies for measuring doses of manufactured solutions and suspensions below 5ml. NB if tablets or capsule contents are dispersed in liquid (rather than dissolved) it may not be appropriate to attempt to measure and administer a part dose.

3.4. Patients prescribed liquids for swallowing difficulties should be reviewed regularly for on-going need and ability to swallow tablets or capsules.

4. It may not always be possible to avoid prescribing specials due to specific patient or medication factors. Information is available on some commonly prescribed specials and alternative preparations which *may* be suitable for consideration in the "A-Z of possible alternatives to using a special". If necessary seek advice from the patient's community pharmacist, the Acute Trust Medicines Information Department or the CCG Medicines Management Team. Advice can also be provided on the correct process for administering crushed tablets or capsule contents safely.

References and Useful Resources

Royal Pharmaceutical Society. Prescribing Specials; Guidance for the prescribers of Specials. June 2016. www.rpharms.com/support-pdfs/professional-standards---prescribing-specials.pdf

Royal Pharmaceutical Society. Professional guidance for the Procurement and Supply of Specials. December 2015. www.rpharms.com/support-pdfs/rps---specials-professionalguidance.pdf