NHS
City and Hackney
Clinical Commissioning Group

Resources for the prescribing of unlicensed 'specials'

A special is an unlicensed medicine that does not have a centrally authorised Marketing Authorisation in the UK. It is manufactured, imported or supplied to meet the special clinical needs of an individual patient. A special may only be supplied when there is no available licensed medicine which fully meets the patient's clinical needs. They can be prescribed by the prescriber when agreed with the patient or carer that, on the basis of available information, a special is the most appropriate option for the patient.

Appropriate prescribers can prescribe medicines without a licence provided they are happy to assume full liability for the prescription.

There are certain clinical situations where an unlicensed special may be judged to be the only available option, for example:

- For children to achieve the lower doses required and ease of swallowing a liquid rather than a solid dosage form.
- In dermatology, unlicensed creams and ointments containing tars, dithranol, salicylic acid, steroids and other active constituents in a range of concentrations and bases for psoriasis, eczema and other miscellaneous conditions may be required.
- In ophthalmology, preservative-free eye drops.
- For patients who intolerant or allergic to a specific ingredient.
- For patients who require alternatives to solid dosage forms that are not available as a licensed oral liquid.

Issues to consider before prescribing an unlicensed special

Licensing

The Human Medicines Regulations 2012 requires that a medicine placed on the market in the UK holds a Marketing Authorisation (MA).[1] Medicines with an MA have been approved by the European Commission or Medicines and Healthcare products Regulatory Authority (MHRA). For the medicine to obtain an MA the pharmaceutical companies have to provide evidence of the effectiveness; expected side effects; stability; any interactions; bioavailability; acceptability and safety of the formulation. Specials are unlicensed medicines which means they will not have been assessed by the licensing authority for safety, quality and efficacy. Usually they are specially prepared to meet a prescription ordered for individual patients, without the need for the manufacturer to hold an MA for the medicinal product concerned.

Legal

If a prescriber uses a medicine within the terms of the licence, as specified in the Summary of Product Characteristics (SPC) any untoward effects are the legal responsibility of the manufacturer.
However in the case of an unlicensed special, as there is no SPC, the prescriber takes full responsibility in law for any adverse effect caused by the medicine, unless it can be demonstrated that the medicine was faulty. The prescriber is responsible because the medicine is unlicensed and has been made to their specifications.

Professional responsibility and accountability

The General Medical Council (GMC) has guidance for prescribers relating to unlicensed medicines When prescribing an unlicensed medicine, the prescriber **must**[2]:

- Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy.

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- Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so.
- Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine. The Royal Pharmaceutical Society (RPS) has published updated professional guidance for the prescribers of Specials which is endorsed by the Royal College of GPs, the Academy of Medical Royal Colleges and the Royal College of Nursing. The guidance aims to support prescribers in all professions and in all care settings in the safe and appropriate prescribing of Specials.

Quality and efficacy

Specials can be sourced from a variety of suppliers, consequently, the quality and consistency of the product can vary considerably. This can lead to potential differences in pharmacokinetics and clinical responses, which may have a negative impact on patient safety. This is particularly important for drugs with narrow therapeutic windows.

Cost

There is no set pricing for pharmaceutical specials, and there is no national pricing structure governing these products or local regulation of the cost of products to the NHS. As use of specials increases, there is a growing financial burden on the NHS.

Part VIIIB of the Drug Tariff[3] (Arrangements for payment for specials and Imported Unlicensed Medicines) is a tariff of high volume and high cost unlicensed specials and imports. This tariff sets reimbursement prices on a selection of commonly prescribed specials. The prices are set by analysis of a selection of unlicensed specials manufacturer's prices, with a margin included for pharmacy purchase profit.
When an unlicensed special or an imported medicine which is listed in Part VIIIB is prescribed, the pharmacy contractor will be reimbursed the set Drug Tariff price for dispensing the product, no matter how the product is sourced. An additional fee of £20.00 is paid to the pharmacy for dispensing unlicensed medicines.

Clinical appropriateness for the patient
When deciding whether to prescribe an unlicensed product, the first consideration should be to determine if a medicine is needed at all and any unnecessary medicines should be stopped.
Consider:

- Whether a different licensed medicine in the same class or a different class of medicine may be suitable for the patient.
- A newly licensed medicine may have become available.
- The patient's condition may have changed.

The ideal situation is to prescribe an appropriate UK licensed medicine. If a licensed product is not suitable; consider off-label use of a UK licensed medicine. This could be off-label as it is outside of the licensed indications or unlicensed because the tablet has been crushed and dispersed or the capsule has been opened. Note this may not be a suitable option for all patients; consideration should be given to whether the patient or carer is able to administer medication in this manner and the dose required as drawing off aliquots from a dispersed product is not ideal but may sometimes be necessary. In addition, patients, parents and carers may require training and may need advice on health and safety issues particularly if medication is to be crushed or capsules opened.

Unspecified drug codes

Unspecified drug codes refers to products that have been prescribed, but have not yet been added or cannot be added to the internal NHS Business Service Authority drug database and is therefore captured as unspecified.

There should be a significant decline in the number of items shown as Unspecified Drug Code, as the majority of unlicensed products will be captured using the appropriate record on the NHS database. The NHSBSA provides details of unspecified items with a net ingredient cost (NIC) of £60 or over to Medicines Management Team at City and Hackney CCG. Each month practices in City and Hackney are sent an update of the monthly spends on unspecified drug codes with recommendations for alternative licensed formulations which could be prescribed instead. Practices should work closely with their PSP to identify and review ongoing need for an unspecified drug code item.

Document (click title to access)	Comments
Royal Pharmaceutical Society Specials Toolkit	
Barking and Dagenham, Havering and Redbridge Clinical Commissioning Group Specials information pack	Contains useful information on the prescribing of specials. Please note this document was last updated in 2014.
East Lancashire Health Economy Medicines Management Board Specials Database	
UKMi Medicines Q&A - What are the therapeutic options for patients unable to take solid oral dosage forms?	
Specials Recommended by the British Association of Dermatologists for Skin Disease	
Extemporaneous preparations prescribed by the Barts Health dermatology department	This link is only accessible once logged into the GP intranet site.
Oral proton pump inhibitors for children. Barts Health NHS Trust guidelines	This link is only accessible once logged into the GP intranet site.

The medicines management team may be contacted for advice regarding unlicensed specials queries on 0203 816 3224 or CAHCCG.CityandHackneyMedicines@nhs.net. The team is accessible from 9am to 5pm Monday to Friday.

References

1. The Human Medicines Regulations 2012. Available at http://www.legislation.gov.uk/uksi/2012/1916/contents/made

2. General Medical Council. Prescribing unlicensed medicines. Available at https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines

3. NHS Business Services Authority. Drug Tariff. Available at https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff