Specials

Introduction

Specials are a category of unlicensed medicines manufactured for individual patients specifically to meet their clinical needs. They are manufactured without a marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) therefore are not assessed for safety, efficacy, and quality. The use of a special should only be considered when the use of a licensed preparation is not possible. Regulation 167 of The Human Medicines Regulations (2012) allows appropriate prescribers to prescribe medicines without a marketing authorisation providing that they accept full liability for the prescription.

Prescribing of special items should be justifiable and undertaken within the prescriber's clinical competence after careful consideration. When using a special the prescriber takes full legal responsibility for adverse drug reactions.

There may be certain clinical situations where a special is judged to be the most appropriate or only available option i.e. for use in children where certain strengths are not able to be obtained from licensed products or for patients with dysphagia who require alternatives to solid dosage formulations

Considerations

Specials are usually significantly more costly compared with standard preparations. There is no set pricing for most specials and no national pricing structure governing the cost to the NHS although part VIIIB of the Drug Tariff lists high volume and high-cost unlicensed specials with set reimbursement prices. ePACT data shows that approximately 2700 items per annum for a special medicine are prescribed in Sheffield, costing approximately £200,000.

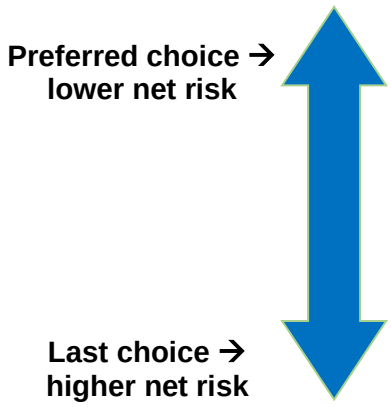
As specials can be sourced from a variety of suppliers, the quality and consistency of the product may vary considerably. This can lead to potential difference in the pharmacokinetics and clinical responses to a drug.

Before prescribing a special, consideration should be given to whether the medicine is necessary to supply in each patient's individual circumstances. Further, consideration should first be given to alternative options, it may be considered to use a licensed product in an off-label way i.e. tablet crushing.

The NEWT guidelines (subscription required or contact Sheffield SY ICB Medicines Optimisation Team who has access to NEWT) provides information on medicines administration for people with swallowing difficulties or enteral feeding tubes.

There is also further advice on the Specialist Pharmacy Service (SPS) website on using medicines safely and effectively in patients with swallowing difficulties.

MHRA guidance on the hierarchy of risk on basis of product origin:



1	UK licensed medicines
2	Off-label use of a UK licensed medicines e.g. crushing a tablet form
3	An imported product licensed in the country of origin
4	A UK manufactured special made in Good Manufacturing Practice (GMP) inspected facilities
5	An imported product not licensed in the country of origin

Alternatives to specials for children

If considering alternatives for children, advice can be sought from either the Medicines Optimisation Team at SY ICB or the pharmacy department at Sheffield Children's Hospital (SCH) (0114 271 7259) if the child is under their care. If a special is to be initiated, SCH routinely send information to prescribers and parents/ carers advising on which preparation has been started and where a supply of the special can be sourced from. The Neonatal and Paediatric Pharmacists Group and Royal College of Paediatrics and Child Health have produced a list of recommended strengths of specials for use in children for 13 medicines – appendix 1.

References:

- PrescQIPP (2016), Bulletin SPOT list, Accessed 02/02/2023 https://www.prescqipp.info/resources/category/326-spot-list
- Medicines and Healthcare products Regulatory Authority. The supply of unlicensed medicinal products ("specials"), MHRA Guidance Note 14. 2014. Accessed 02/02/2023 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf
- Specialist Pharmacy Service. Swallowing difficulties [Internet]. Swallowing difficulties-SPS. Specialist Pharmacy Service; 2021 Accessed 18/04/2023. Swallowing difficulties – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
- The Human Medicines Regulations (2012). 2012, No. 1916, PART 10- Exceptions, Regulation 167. Accessed 02/02/2023 The Human Medicines Regulations 2012 (legislation.gov.uk)

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NPPG Neonatal & Paediatric Pharmacists Group

RCPCH Royal College of Paediatrics and Child Health Leading the way in Children's Health

Appendix 1

The list below gives the 13 unlicensed medicines where a recommended strength in Paediatrics has been endorsed by NPPG and RCPCH and published under the prescribing and dispensing section for most drugs (except clopidogrel) on the BNFC app.

Drug name	Concentration
Azathioprine	50mg/5mL
Calcium carbonate (for use as a phosphate binder)	500mg/5ml
Chloral Hydrate	500mg/5mL
Clopidogrel	25mg/5mL*
Ethambutol	400mg/5mL
Hydrocortisone	5mg/5mL
Isoniazid	50mg/5mL
Phenobarbitone (alcohol free)	50mg/5mL
Pyrazinamide	500mg/5mL
Lisinopril (as base)	5mg/5ml
Sodium chloride	5mmol/mL
Spironolactone	50mg/5mL
Tacrolimus	5mg/5mL

Using standardised concentrations of unlicensed liquid medicines in children - joint position statement. NPPG Executive Committee. Version 9. July 2023. NPPG-Position-Statement-18-01-V9-July-2023.pdf

*Clopidogrel concentration is agreed, but not published in BNFC due to no drug monograph publication as of yet.