The Specials Guide

FOREWORD

The information within this guidance is to aid decision making for prescribing in patients with swallowing difficulties, patients with a feeding tube or medicines which are otherwise unlicensed or being used 'off-label' (indications for which the medicine is not licensed.) Because this information is not readily available, various references have been sourced to compile this guide with the aim that it can be used at the point of prescribing.

Disclaimer: Where manufacturers have been contacted and have provided advice, for example, opening of capsules, crushing of tablets or other manipulations of dosage form, this advice applies to their product only and is confirmation that they are aware of the practice and **is not** a manufacturer endorsement of this practice. Whilst we endeavour to keep the information in this guide up to date and correct, please note this is not always possible and if there is anything that you feel is incorrect or you have any queries please email the Medicines Management Team on: bhrmedicines.management@nhs.net or contact your Prescribing Advisor.

INTRODUCTION

What is a Special?

A 'special' is an unlicensed medicine (i.e. does not have a centrally authorised Marketing Authorisation in the European Union, or a UK Marketing Authorisation) prescribed to meet the individual clinical need of a patient when a suitable licensed medicine is not available[1]. There are a number of scenarios whereby a special may be prescribed:

- Dysphagia (difficulty in swallowing) e.g. in stroke patients
- Patient has a feeding tube (NG/PEG)
- Medicine out of stock/discontinued or otherwise unavailable
- Unable to dissolve/crush tablet or empty capsule contents
- Difficulty measuring the correct amount (usually dosing for children and babies)
- Allergy to ingredients (excipients or additives) e.g. lactose
- A specific strength is required that is not available as a licensed version e.g. cream

Most specials are produced by pharmaceutical companies who must hold a 'Specials manufacturer's licence which is granted by the Medicines and Healthcare products Regulatory Agency (MHRA). This type of manufacture has mostly replaced the traditional method of extemporaneous preparations whereby a pharmacist in a community pharmacy prepares the medicine.

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Why do we use the Specials Guide?

The Specials guide is a reference source which provides up to date information on licensed alternatives, using licensed medicines off-label, specials preparations available (in Drug Tariff) and how to administer for patients with swallowing difficulties or has a feeding tube. The main reference source White and Bradnam Handbook of Drug Administration via enteral feeding tubes last updated in 2015 does not contain newer medicines after its publication and contains medicines which are no longer available and the information is therefore obsolete. In addition, there is no standard reference source which contains information and advice on using licensed medicines off-label or unlicensed medicines.

How to use the Specials Guide

The Medicines Management Team have compiled the Specials guide to provide information the prescriber needs to know before prescribing and administering a special or other alternatives at the point of prescribing. All monographs and sections will have been agreed via the BHR CCGs Area Prescribing Committee (APC).

As this is a guide, please note that the information provided is designed to be an aid and not a direction. The prescriber will need to base their decision to prescribe based on the patient's needs and safety. After prescribing, the patient should be monitored as there has been a change to their medicine or formulation.

Prescribing a special

As with a licensed medicine, accountability for prescribing a special rests with the prescriber. However, with specials there are other considerations[1,4]:

- When prescribing a Special, prescribers must be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy (see GMC ethical guidance on the next page)
- Specials have not been assessed by the regulatory authority for safety, quality and efficacy in the same way as licensed medicines and they have no Summary of Product Characteristics (SPC) outlining the dose, contra-indications, storage and side-effect profile
- Patient Information Leaflets are not routinely available for Specials
- Specials can be obtained from a range of sources by pharmacists and their teams, and are not all manufactured in the same way. This means that the quality, bioavailability and consistency of Specials can vary even where the same product is prescribed
- It can be difficult to identify a special at the point of prescribing
- When prescribing responsibility transfers from one prescriber to another, ensuring a safe and timely supply of the Special can present additional challenges for the prescriber and supplying pharmacist

General Medical Council (GMC) ethical guidance-prescribing unlicensed medicines[2] state that when prescribing an unlicensed medicines you must:

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

Nurse and midwife independent prescribers can prescribe unlicensed medicines[5] (21 December 2009 legislation[6]) on the same basis as doctors, dentists and supplementary prescribers.

When might a special no longer be required[1]?

- As children grow they may be able to take licensed preparations
- Patients who have had a stroke and have experienced difficulties swallowing may find that their dysphagia improves
- The condition treatment may have resolved
- A licensed version has become available[3]

MHRA guidance on the hierarchy for the use of unlicensed medicines[7]

This hierarchy is provided for guidance only and each case should be considered on its individual merit. Notes in blue boxes are additional comments approved by APC.

1. An unlicensed product should not be used where a product available and licensed within the UK could be used to meet the patient's special need.

2. Although the MHRA does not recommend "off label" (outside of the licensed indications) use of products, if the UK licensed product can meet the clinical need, even "off-label", it should be used instead of an unlicensed product. Licensed products available in the UK have been assessed for quality safety and efficacy. If used "off-label" some of this assessment may not apply, but much will still be valid. This is better than the use of an un-assessed, unlicensed product. The fact that the intended use is outside of the licensed indications is therefore not a reason to use an unlicensed product. It should be understood that the prescriber's responsibility and potential liability are increased when prescribing off-label.

Please note: the above point applies to off-label use of a licensed product where **the whole intact dosage form** is use e.g. amitriptyline tablet prescribing for neuropathic pain. It does not apply to situations where a licensed dosage form is being manipulated for unlicensed use e.g. crushing of tablets or opening of capsules for suspension in water or other suspending agent where the risks/effects of manipulation needs to be considered by the prescriber based on the quality of supporting information and patient/carer ability to understand and correctly follow the instructions for dosage manipulation. A similar level of caution should be applied in these situations as for point 4 below- 'unlicensed specials' which are essentially manipulations of a licensed dosage form also.

3. If the UK product cannot meet the special need, then another (imported) medicinal product should be considered, which is licensed in the country of origin.

4. If none of these options will suffice, then a completely unlicensed product may have to be used, for example, UK manufactured "specials", which are made in Good Manufacturing Practice (GMP) inspected facilities, but which are otherwise un-assessed (GMP inspection of "specials" manufacturers is not product specific). There may also be other products available which are unlicensed in the country of origin.

5. The least acceptable products are those that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK). For example, the use of products from countries where they are classed as supplements, not pharmaceuticals, and may not be made to expected standards of pharmaceutical GMP. These should be avoided whenever possible.

Please note: If there is more than one alternative treatment option, the above MHRA hierarchy will be referred to for guidance. However, there may be instances whereby there is a significantly more cost-effective option and these will be considered for individual monographs and approved by the BHR CCGs APC on a case by case basis.

Prescribing specials: a checklist for prescribers[1]

1. **Establish a clinical need:**
    - Does the patient need a medicine? Is it essential?
    - Is there a licensed preparation which could meet the patient's needs?[4]
    - What are the unlicensed alternatives?

2. **Understand the patient's experience and make a shared decision**
    - How often will prescriptions be needed (check shelf-life with pharmacist)?
    - How long does it take to obtain the special?
    - Consider other practical implications of prescribing such as who will be administering the medicine

3. **Identify medicines and preparations**
    - What is the rationale for using a Special?
    - Is there evidence or accepted practice to support usage?
    - Is the dose critical?
    - Is the patient a child?
    - Does the medicine have a narrow therapeutic window?
    - Is there a requirement to specify the exact formulation?

4. **Monitor and review**
    - How often will the patient be reviewed?
    - What monitoring is required?

5. **Ensure effective prescribing governance**
    - How long is the patient expected to need this medicine?
    - If you are being asked to continue prescribing, has all the necessary information been communicated to you and documented?

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References

1. Royal Pharmaceutical Society. Prescribing Specials, guidance for the prescribers of specials. April 2016 (review date April 2020) https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/professional-standards---prescribing-specials.pdf date accessed 13 June 2019

2. General Medical Council Ethical guidance, Prescribing unlicensed medicines https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines date accessed 13 June 2019

3. MHRA Inspectorate, Birse M. Supply of unlicensed medicines when an equivalent licensed product becomes available. 9 October 2015 https://mhrainspectorate.blog.gov.uk/2015/10/09/supply-of-unlicensed-medicines-when-an-equivalent-licensed-product-becomes-available/ date accessed 13 June 2019

4. MHRA. Off-label or unlicensed use of medicines: prescribers' responsibilities. Article date: April 2009. Published 11 December 2014 https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities date accessed 13 June 2019

5. NMC circular 04/2010. Nurse and midwife independent prescribing of unlicensed medicines. Issued 10 March 2010. https://www.nmc.org.uk/globalassets/sitedocuments/circulars/2010circulars/nmccircular04_2010.pdf date accessed 13 June 2019

6. The Medicines for Human Use (Miscellaneous Amendments) (no.2) Regulations. SI 2009 3063

7. MHRA guidance note 14. The supply of unlicensed medicinal products ('specials'). Revised 2008. Published 2014. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf date accessed 13 June 2019