



ROYAL
PHARMACEUTICAL
SOCIETY

Prescribing Specials

Guidance for the
prescribers of Specials

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ACADEMY OF
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PREFACE

The Royal Pharmaceutical Society (RPS), the professional body for pharmacists and pharmacy, is delighted to publish this professional guidance for the prescribers of Specials. This is an update of the resource first published in 2011 by the National Prescribing Centre. In 2011 the National Prescribing Centre became part of the National Institute for Health and Care Excellence (NICE). The Royal Pharmaceutical Society (RPS) is updating the guidance in agreement with NICE and the intention is that RPS will maintain the guidance in the future.

Prescribers and pharmacists both have a responsibility to ensure that where Specials are prescribed they are the most appropriate choice and patients are supported to use them effectively. This updated guidance for prescribers, along with the 2015 RPS *Professional guidance for pharmacists on the procurement and supply of Specials*, will help to support the appropriate prescribing of Specials for patients.

SCOPE AND PURPOSE

Specials are a category of unlicensed medicines that are manufactured or procured specifically to meet the special clinical needs of an individual patient. This guidance aims to support prescribers in all professions and in all care settings in the safe and appropriate prescribing of Specials.

Whilst this guidance focuses on the prescribing of Specials the principles are broadly applicable to the prescribing of other unlicensed medicines.

Decisions about the prescribing of Specials rely heavily on professional judgment based on understanding individual patient need. To reflect this, the updated guidance continues to be based around five principles that can be used to guide prescribing decisions. New to this updated guidance are Case Studies that illustrate the challenges that we have to meet to ensure that patients receive optimal treatment.

The updated guidance also reflects regulatory changes (such as the update to the Medicines and Healthcare products Regulatory Agency Guidance Note 14), changes in clinical practice and the challenges that the constantly changing NHS environment presents.

The use of Specials presents healthcare professionals and patients with specific challenges, particularly when patients move between care settings. The importance of ensuring that patients and prescribers are aware of the complexities and risks associated with transferring the prescribing and supply of Specials across settings is given more emphasis in this updated guidance.

Communication between prescribers and pharmacy colleagues is also emphasised. We encourage pharmacists and prescribers to work together to ensure that patients are prescribed Specials appropriately and are supported to adhere to their treatment.

The document will be updated every four years, or sooner if relevant changes in legislation or policy are introduced. This guidance is applicable across GB.

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I. INTRODUCTION

Specials are a category of unlicensed medicines that does not have either a centrally authorised Marketing Authorisation in the European Union, or a UK Marketing Authorisation and are manufactured, imported or distributed to meet the special clinical needs of an individual patient. A special clinical need does not include reasons of cost, convenience or operational need^{2, 3}.

Specials, like all unlicensed medicines, should only be prescribed when there is no available licensed medicine which fully meets the patient's special clinical needs. They can be prescribed when it is judged by the prescriber, and agreed with the patient or carer that, on the basis of available information, the use of a Special is the most appropriate option for the patient^{2, 4}.

Whilst this guidance relates primarily to the prescribing of Specials, it will have relevance to other categories of medicines used outside the terms of their Marketing Authorisations, such as medicines used for indications for which they are not licensed or where the dosage form is manipulated. The guidance also has relevance to the prescribing of extemporaneously dispensed medicines prepared in a pharmacy⁵.

As with a licensed medicine accountability for prescribing a Special rests with the prescriber⁶. However, with Specials there are additional considerations for prescribers in any care setting. These additional considerations are described below and illustrated throughout the document by Case Studies.

- When prescribing a Special prescribers must be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy⁴.
- 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 (SmPC) 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 (Appendix 1 contains some FAQs which explain about how Specials are made). See Case Study 3.
- It can be difficult to identify a Special at the point of prescribing. See Case Study 1.
- 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 the supplying pharmacist. See Case Study 2.

This means that whilst prescribing a Special may carry benefits it can also be associated with the potential for additional risk compared to prescribing a licensed medicine. When patients are having their care transferred between different settings and prescribing responsibility changes, the potential risks increase⁷. **In these cases there must be a planned transfer of information that ensures a safe, consistent and timely supply of the Special is maintained for the patient^{8, 9}.**

Before prescribing a Special, prescribers should be satisfied that the patient's clinical needs cannot be met by a licensed medicine. This guidance for prescribers includes five principles based on good prescribing practice that highlight specific issues to support prescribers in the safe and appropriate use of Specials.

In addition, practical tips to help the prescribers of Specials are included at the end of the document in Box 3 and Appendix 2 contains a short checklist for prescribers to print out and use as a tool when prescribing. The checklist is included in a separate quick reference guide that is included on the RPS Specials webpage: www.rpharms.com/pharmacy-practice-resource/specials.asp

2. WHEN MIGHT A SPECIAL BE APPROPRIATE?

There is a range of diverse clinical situations when Specials may be judged by the prescriber and agreed by the patient or carer to be the most appropriate option for the patient on the basis of available evidence.

SPECIFIC PATIENT GROUPS

In children, Specials may be the only option for the prescriber for some conditions and in some circumstances are routinely prescribed¹⁰. Liquid Specials may be manufactured to achieve the lower doses required, and not just to achieve the optimal form for administration. Overall, the risks of prescribing for children are higher than for adults^{11, 12} and so prescribers need to be vigilant at all times. It is important to ensure that the medicine prescribed and supplied is formulated to ensure a consistently accurate dose can safely be given, and that the practical aspects of supply are addressed.

THERAPEUTIC AREAS

In dermatology and **ophthalmology** where there is a large number of Specials in use, formularies have been produced to improve access to, and inform the prescribing of, Specials^{13, 14}.

PATIENT FACTORS

Patients having medicines administered using an **enteral feeding tube** need alternatives to solid dosage forms. This can also be the case for **patients who experience difficulties with swallowing** for example, older people or those at the end-of-life either at home or in hospices. For patients who require alternatives to solid dosage forms that are not available as a licensed oral liquid a Special is one of a range of options available^{15, 16, 17}.

3. FIVE PRINCIPLES FOR PRESCRIBING SPECIALS

The principles for prescribing Specials are highlighted in Figure 1 and described below. The individual patient's experience is central to every decision that prescribers make when deciding to prescribe.

Under each principle there is a statement in bold that describes the principle itself. This is supported by a series of statements that describe examples of good practice that support the principles application in practice.

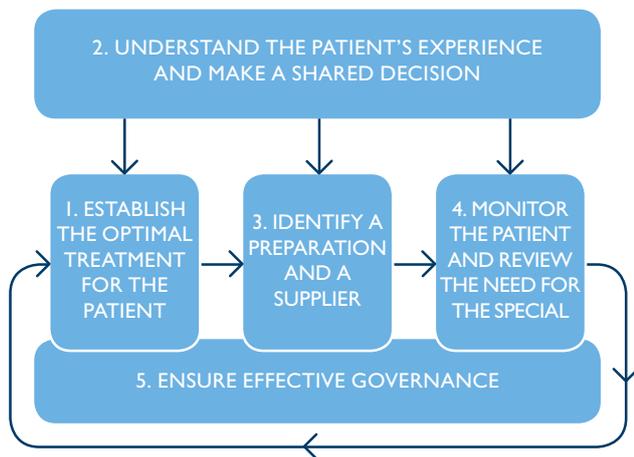


Figure 1: Five principles for the procurement and supply of Specials

For example:

- a different formulation of a licensed medicine may be available (such as dispersible tablets, suppositories, or patches)
- another licensed product in the same therapeutic class may be available in a suitable formulation for the patient
- using a UK licensed medicine outside the terms of its licensed indications.

BOX 1: WHAT DOES NOT CONSTITUTE A SPECIAL CLINICAL NEED?

The MHRA state that supply of unlicensed medicines (including Specials) for reasons of cost, institutional need or convenience is not acceptable and is not a special clinical need.

Examples of inappropriate reasons for supply are given by the MHRA as preference for a non-parallel imported product, cost, more convenient presentation and longer shelf life of the unlicensed product. The MHRA states that none of these reasons are acceptable.

Principle 1. Establish the optimal treatment for the patient

All treatment options are evaluated. Specials should only be prescribed when the patient has a special clinical need that cannot be met by a licensed medicine of established safety, efficacy, and quality; this does not include reasons of cost, convenience or operational need^{2,3} – see Box 1).

- As with all medicines, before initiating or continuing a prescription prescribers need to review the patient's needs.
- If there is a clinical need for a medicine, there may be a range of licensed alternatives to prescribing a Special.

If there is no licensed medicine that meets the patient's clinical need, there may be a range of unlicensed options that can be considered for the patient^{2,18}. These include:

- prescribing a Special, either manufactured in the UK or imported from outside the UK (see Appendix 1);
- preparing a medicine extemporaneously in a registered pharmacy; or
- manipulating a UK licensed product e.g. crushing or dispersing tablets or opening capsules where the formulation allows.

All these options have their own risks, benefits and costs which need to be considered in each individual clinical situation. Local pharmacy teams can provide advice on the various options. See also Section 4. Useful Resources.

CASE STUDY 1

A patient with severe chronic plaque psoriasis on his elbows regularly attended an outpatient dermatology clinic. He had been using coal tar 2% in yellow soft paraffin twice daily to control his symptoms. However at his last appointment he reported that his symptoms were no longer controlled and after discussion with his doctor they agreed to increase the strength of his coal tar preparation.

The doctor initially prescribed coal tar 5% in yellow soft paraffin which could only be supplied as a Special. However after discussion with the pharmacist and the patient they agreed to change the prescription to a licensed preparation – coal tar 6% and lecithin 0.4% cream (brand name Psoriderm 6% cream). As well as being licensed for this indication the formulation was in line with the local formulary and British Association of Dermatologists guidance. It was also likely to be easier for the patient to obtain from a community pharmacy and would provide a consistently formulated product.

KEY LEARNING

This Case Study illustrates the importance of ensuring prescribers consider all options available to their patients before prescribing and supplying a Special. Considering all the available options (with the support of a pharmacy colleague and in consultation with the patient) resulted in a licensed medicine being prescribed rather than a Special.

Principle 2. Understand the patient's experience and make a shared decision

Prescribers discuss the patient's needs, values and preferences to ensure that the implications and practicalities of treatment options are understood^{9, 19}. When a Special is prescribed this is a shared decision and patients are supported to adhere to their medicines^{9, 20}.

- Prescribers use their professional judgment in consultation with the patient (or carer), and where necessary advice from pharmacists and other health and care professionals to guide their prescribing decisions. See Case Study 1.
- Prescribers are aware of whether or not the patient is taking the medicine themselves (or having it administered) and any practical issues that the patient may face with medicines use.
- Prescribers and patients (or carers) understand the practical implications of maintaining an ongoing supply and continuity of treatment. This may require active management and communication between the patient, the pharmacist supplying the Special and the prescriber. See Case Study 2.
- Patients (or carers) know when they have been prescribed a Special and are given appropriate information about what this means for their treatment⁴.
- Patient information leaflets are not routinely available for Specials, and those for imported medicines may not be relevant to the patient or in a language they understand. Where necessary, the prescriber and supplying pharmacist take additional steps to ensure that the patient is informed about the medicine. The Medicines for Children website provides some information leaflets about the use of medicines in children, some of which may be Specials. It also has a leaflet about unlicensed medicines. (www.medicinesforchildren.org.uk).

CASE STUDY 2

A patient with tuberculosis was discharged from hospital on a liquid formulation of ethambutol being taken via an enteral tube. Arrangements were in place for the GP to continue prescribing. When at home, the patient requested another prescription from his GP the day before the supply ran out. The GP issued the prescription which was picked up by the patient's daughter (his carer) the next day. The prescription was then presented to the community pharmacist on Friday afternoon by which time the patient had finished the medicine supplied by the hospital.

Neither the patient nor the carer was aware that the ethambutol was a Special that would not be routinely stocked at his usual community pharmacy. The pharmacist was unable to obtain the ethambutol liquid at short notice so the patient missed one day of treatment, and the patient's daughter had to take time off work to go back to the hospital on Saturday to obtain a supply until the community pharmacist was able to source the product.

Unfortunately the ethambutol liquid prescribed by the GP and supplied by the community pharmacist was a different concentration to the liquid the patient had been using in hospital. Whilst the new concentration was labelled correctly, the patient continued to take the same volume as previously and so received a suboptimal dose of ethambutol until the error was noticed.

KEY LEARNING

This Case Study illustrates the importance of ensuring that when the responsibility for prescribing and/or supplying a Special is transferred, for example from a hospital setting to primary care, full information about the medicine is also transferred. Consideration should also be given as to whether transferring an unlicensed medicine from hospital to primary care is appropriate. The General Medical Council (GMC) guidance on shared care provides principles for shared care prescribing²¹. When transferring responsibilities for the prescribing and supply of Specials, organisations must have processes in place to support full and timely communication; including for example template letters to be sent to GPs on discharge and/or direct contact with the patient's preferred community pharmacy.

The Case Study also illustrates the need for clear communication with patients and/or carers about the practical differences between licensed medicines and Specials, specifically about timescales necessary for the Special to arrive in the pharmacy and the impact this has on the ordering of repeat prescriptions. The need to consult with patients about any new supply of a Special is also illustrated here with the change in concentration of the ethambutol requiring the patient to take a different volume than they had previously.

Principle 3. Identify medicines and preparations

The risks and benefits of using a Special will differ for different patient groups, different medicines and in individual clinical circumstances. Prescribers need to take into account the safety, efficacy, quality and cost of the different Specials available to patients.

- Unlike licensed medicines, the formulation of a Special cannot be assumed to be consistent. Different supplies of the 'same' Special may have a different formulation, stability and potentially bioavailability. See Appendix 1: Specials FAQs: Are all Specials the same?
- The clinical implications of sourcing decisions will vary between patient groups. For example, in some patient groups, such as young children, transplant patients or patients who are taking medicines with a narrow therapeutic index, formulation and consistency of dose is critical. In these cases, prescribers should be specific about the formulation and work with pharmacists to ensure that an appropriate Special is always supplied. See Case Study 3.
- Local Area Prescribing and Medicines Management Committees (or equivalent Drug and Therapeutics Committees), with local clinical input, can provide a decision-making forum to evaluate usage and develop a local formulary for Specials. In dermatology and ophthalmology rationalised formularies have already been produced by professional bodies to inform the prescribing of Specials^{13, 14}. See Case Study 1.
- For the most commonly prescribed Specials the price paid by the NHS in primary care is listed in the Drug Tariff²². Specials not listed in the Drug Tariff are reimbursed at the invoice price less any discount/rebate. For Specials not listed in the Drug Tariff reimbursement prices can vary depending on the supplier from which the product is sourced.
- Where prescribers are concerned about potential variations in the price of Specials they can discuss this with their pharmacist colleagues (in community pharmacy, primary care organisations or their own practice pharmacists).

CASE STUDY 3

A 4kg neonate was discharged from hospital on phenobarbital 20mg twice a day prescribed as 2ml twice a day of 50mg/5ml unlicensed alcohol-free phenobarbital suspension. When the GP came to prescribe a repeat supply a British Pharmacopoeia (BP) suspension of 15mg/5ml that was in the general practice prescribing system was prescribed as 6.8ml (20mg) twice a day. This was subsequently dispensed by the community pharmacist.

Four days later the child was taken to hospital with lethargy and increased fitting. The 15mg/5ml preparation contained 38% alcohol and the volume of 6.8ml administered to the neonate was similar to an adult having a glass or more of wine with each dose. As a neonate cannot metabolise alcohol as efficiently as an adult this would have resulted in lethargy and decreased seizure threshold which explained the increased fitting.

KEY LEARNING

This Case Study highlights the importance of new prescribers and pharmacists having a full product specification available when a patient transfers from one setting to another. The need for the original prescriber and supplying pharmacist to share this information in a timely way is also highlighted.

Principle 4. Monitor and review

The appropriateness of continued prescribing of a Special is reviewed to ensure that it remains the best option and ongoing supply is justified by the patient's continued special clinical need.

- For patients receiving regular prescriptions for continuing treatment, prescribers periodically review the choice of Special with the patient (and/or carer) to confirm whether there is a more appropriate alternative (see Box 2). For example, if the medication is still required, has a newly licensed medicine become available, is there a licensed medicine in a similar class, or is there an alternative Special? See Case Studies 1 and 4.
- Since the safety, quality and efficacy of Specials will not have been formally assessed by a regulatory body there is less certainty about safety, efficacy and likelihood of adverse events. Where necessary prescribers monitor treatment with Specials more closely. This will depend on individual patient circumstances, for example medicines toxicity and vulnerable patient groups (e.g. babies, children or older people).
- Adverse reactions to the medicine and suspected product defects are reported to the MHRA via the yellow card scheme (<http://yellowcard.mhra.gov.uk> or via the YellowCard app) stating the manufacturer and indicating that the product is unlicensed. Reporting to manufacturers is also encouraged.
- Specials can be expensive. To ensure best value for the NHS, prescribers can work with pharmacists to review usage.

BOX 2: WHEN MIGHT A SPECIAL NO LONGER BE NECESSARY?

- 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 being treated may have resolved or if treating a side effect the medicine causing the original side effect may have been stopped.

CASE STUDY 4

A seventy two year old woman was admitted to hospital for the second time following a fall. Her sitting systolic blood pressure was as low as 50mmHg and she had peripheral neuropathy. Her blood pressure improved with fludrocortisone 100 micrograms but it was still inadequate to support her daily activities. Whilst in hospital, she was started on midodrine 5mg twice daily titrated up to 15mg three times daily. Prior to discharge her blood pressure improved to 135/72 mmHg.

Midodrine is used to treat postural (orthostatic) hypotension but at the time there was no UK marketing authorisation for this or any other indication.

Under a planned shared care arrangement the patient was advised to continue taking midodrine for three months until her next hospital appointment. The hospital informed the patient's GP that she was being discharged on a Special and shared details of the prescription. Prior to discharge the patient was advised that her prescription was for a Special and that she should speak to her community pharmacist about the implications that this might have for the timescales of the further supply.

At the patient's next outpatient appointment the prescriber and the patient decided to continue the midodrine, however a licensed preparation was now available so the prescription was changed to the licensed product.

KEY LEARNING

This Case Study demonstrates that there are situations where a patient's special clinical need cannot be met by an established licensed medicine and so a Special is chosen. In 2013 the National Institute for Health and Care Excellence published an evidence summary to support the use of midodrine²³. The Case Study also illustrates the importance of reviewing and monitoring the patient regularly as in this case a licensed preparation that could meet the patient's special clinical need became available.

Principle 5. Ensure effective prescribing governance

Prescribers understand the rationale for using a Special and the practical implications of prescribing before initiating, transferring, or taking over responsibility for prescribing.

- There can be additional risks and complexities associated with the transfer of prescribing and dispensing responsibilities for Specials and overall there is likely to be less professional familiarity with these products.
- When a secondary or tertiary care prescriber requests a primary care prescriber to continue (or initiate) a Special, they ensure that the rationale, formulation, expected duration of treatment and ongoing monitoring requirements for the Special are documented and communicated to the new prescriber. When taking over the prescribing of a Special the prescriber ensures that they are aware of the clinical need for, and implications of, continuing to prescribe the Special⁹. See Case Studies 2 and 3.
- Where consistency of formulation is particularly important, secondary or tertiary care prescribers ensure that details of the formulation are communicated to the primary care prescriber, who can liaise with community pharmacy colleagues to ensure a consistent supply. See Case Study 3.
- Prescribers record the Special prescribed and, where not following common practice, the reason for choosing this medicine in the patient's notes⁴.
- The requirements set out in national, and local guidance, are taken into account before a Special is prescribed.

BOX 3: TIPS TO HELP PRESCRIBERS WITH IDENTIFYING AND PRESCRIBING SPECIALS

Specials can be difficult to identify at the point of prescribing however some products commonly formulated as Specials include, dermatology products, preservative-free eye drops and liquid preparations (e.g. for children or for people with PEG or nasogastric tubes).

Any pharmacist supplying a Special should ensure that the prescriber is fully aware of the unlicensed status of the medicine². Therefore pharmacists and prescribers (in any care setting) can agree how local communication will work best to support the prescriber.

Healthcare providers (such as Health Boards, NHS Hospital Trusts, Clinical Commissioning Groups and independent hospitals) may have policies on, and oversight of, the commissioning and use of Specials that support prescribers (see also Section 4. Useful Resources). Some organisations also employ pharmacists who can provide support locally although this varies.

Pharmacists working in general practices are well placed to oversee the processes used by the practice to manage the prescribing of Specials. This could include:

- ensuring that full information is communicated to the practice for hospital initiated Specials and where relevant shared care processes are in place
- liaising with local community pharmacists to ensure that a timely, safe and effective Special is supplied to the patient.

At the point of prescribing, clinical systems can be used to highlight that a Special is being selected. In addition some prescribing decision support tools may be used to suggest alternatives to Specials where appropriate. Prescribers should check how their own local systems work.

As well as clinical systems, reference sources may indicate whether a product is a Special. For example, some preparations in the *BNF* and *BNF for Children* indicate whether the preparation needs to be obtained through a 'special-order' manufacturer, or a specialist importing company.

4. REFERENCES AND USEFUL RESOURCES

REFERENCES

1. Royal Pharmaceutical Society. Professional guidance for the Procurement and Supply of Specials. 2015. www.rpharms.com/support-pdfs/rps---specials-professional-guidance.pdf
2. Medicines and Healthcare products Regulatory Agency. Guidance Note 14: The supply of unlicensed medicinal products ("specials"). www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf
3. MHRA Inspectorate. Supply of unlicensed medicines when an equivalent licensed product becomes available. October 2015. <https://mhrainspectorate.blog.gov.uk/2015/10/09/supply-of-unlicensed-medicines-when-an-equivalent-licensed-product-becomes-available/>
4. General Medical Council. Prescribing guidance: Prescribing unlicensed medicines. 2013. www.gmc-uk.org/guidance/ethical_guidance/I4327.asp
5. Jackson, Lowey A. Handbook of Extemporaneous Preparation. A guide to pharmaceutical compounding. May 2010. Pharmaceutical Press; London
6. General Medical Council. Good practice in prescribing and managing medicines and devices. 2013. www.gmc-uk.org/Prescribing_guidance.pdf_59055247.pdf
7. NHS England Patient Safety Alert NHS/PSA/W/2014/014 www.england.nhs.uk/wp-content/uploads/2014/08/psa-imp-saf-of-discharge.pdf
8. Royal Pharmaceutical Society. Keeping patients safe when they transfer between care providers – getting the medicines right. 2012. www.rpharms.com/previous-projects/getting-the-medicines-right.asp
9. National Institute for Health and Care Excellence. Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes. March 2015. www.nice.org.uk/guidance/ng5
10. British National Formulary for Children. www.evidence.nhs.uk/formulary/bnfc/current
11. Wong IC, Ghaleb MA, Franklin BD, et al. Incidence and nature of dosing errors in paediatric medications. *Drug Safety* 2004; 27(9):661-70
12. Conroy S, Sweis D, Planner C, et al. Interventions to reduce dosing errors in children. *Drug Safety* 2007; 30(12):1111-1125
13. UK Ophthalmic Pharmacy Group and Royal College of Ophthalmologists. Ophthalmic special order products, general principles. Updated six monthly. www.rcophth.ac.uk/2015/11/ophthalmic-special-order-pharmacy-products-guidance-updated/
14. Specials Recommended by the British Association of Dermatologists for Skin Disease. 2015. www.bad.org.uk/shared/get-file.ashx?itemtype=document&id=1848
15. Betsi Cadwaladr University Health Board (Eastern Division) (Previously North East Wales NHS Trust). The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties. Smyth J Ed. 3rd ed. 2015. The online version of the NEWT guidelines can be found at www.newtguidelines.com/index.html
16. UK Medicines Information. What are the therapeutic options for patients unable to take solid oral dosage forms? 2013. www.medicinesresources.nhs.uk/GetDocument.aspx?pagelD=781926
17. Bradnam R, White V. Handbook of Drug Administration via Enteral feeding Tubes. Pharmaceutical Press. 2007.
18. Medicines and Healthcare products Regulatory Authority. Off-label or unlicensed use of medicines: prescriber's responsibilities. April 2009. www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities
19. National Institute for Health and Care Excellence. Patient experience in adult NHS services: improving experience of care for people using adult NHS services. 2012.

20. National Institute for Health and Clinical Excellence. Medicines adherence. Involving patients in decisions about prescribed medicines and supporting adherence. NICE Clinical Guideline 76. 2009. www.nice.org.uk/CG76

21. General Medical Council. Prescribing and managing medicines and devices. Prescribing Guidance: Shared care. www.gmc-uk.org/guidance/ethical_guidance/14321.asp

22. For England and Wales: NHS Business Services Authority. Drug Tariff. April 2016. www.nhsbsa.nhs.uk/PrescriptionServices.aspx

For Scotland refer to: www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/Drugs-and-Preparations-with-Tariff-Prices.asp

23. National Institute for Health and Care Excellence. Orthostatic hypotension due to autonomic dysfunction: midodrine. October 2015. www.nice.org.uk/advice/esnm61/chapter/Key-points-from-the-evidence

USEFUL RESOURCES

- The National Institute for Health and Care Excellence publishes evidence summaries for some off-label or unlicensed medicines. www.nice.org.uk/about/what-we-do/our-programmes/nice-advice/evidence-summaries-unlicensed-or-off-label-medicines
- NHS Greater Glasgow and Clyde Guidance on the Use of Specials in Primary Care. 2015. http://www.ggcprescribing.org.uk/media/uploads/prescribing_resources/specials_guidance_v3__dec_15.pdf
- NHS Greater Glasgow and Clyde. Specials A-Z. 2015. http://www.ggcprescribing.org.uk/media/uploads/prescribing_resources/specials_a_z_ggc_march_16_cp.pdf
- Prescqipp. Specials Prescribing Optimisation Tool (SPOT). <https://www.prescqipp.info/specials-prescribing-optimisation-tool/send/171-specials-prescribing-optimisation-tool/1910-spot-specials-prescribing-optimisation-tool-list>
- East of England NHS Collaborative Procurement Hub and NHS East of England. Information and guidance on the prescribing and use of unlicensed pharmaceutical specials. <http://www.eoecph.nhs.uk/Files/Project%20Summaries/Prescribing%20toolkit%20-%20updated%20Feb%202012.pdf>
- UK Medicines Information. What are the therapeutic options for patients unable to take solid oral dosage forms? 2013. www.medicinesresources.nhs.uk/GetDocument.aspx?pagelD=781926
- Liverpool Women's, Alder Hey Children's, John Moores University. Manipulation of drugs required in children. A Guide for health professionals. www.alderhey.nhs.uk/wp-content/uploads/MODRIC_Guideline_FULL-DOCUMENT.pdf
- Nursing and Midwifery Council. The Code: Professional standards of practice and behaviour for nurses and midwives. 2015. www.nmc.org.uk/standards/code/
- Nursing and Midwifery Council. Standards for medicines management. 2007. www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/

APPENDIX I: SPECIALS FAQs

QUESTION	ANSWER
Why are medicines licensed in the UK?	Medicines can only be marketed in the UK if licensed by the appropriate regulatory body. The regulatory body ensures a rigorous assessment of the safety, quality and efficacy of a medicinal product prior to granting a Marketing Authorisation (formerly called a Product Licence, hence the term licensed medicines).
Do all medicines prescribed in the UK need to be licensed?	No. There are clinical situations where the use of unlicensed medicines may be judged by the prescriber and agreed with the patient or carer to be the most appropriate option for the patient on the basis of available evidence. Healthcare professionals may regard it necessary to prescribe, or advise on the use of an unlicensed medicine. This may be when no licensed suitable alternative is available, or when a licensed medicine is used outside the terms defined by the licence.
What are the Specials referred to in this document?	Specials are unlicensed medicines (either imported or made under a UK Specials manufacturing licence) prescribed to meet the special clinical needs of an individual patient on the direct personal responsibility of the prescriber.
What is the difference between a Special and an off-label medicine?	A licensed medicine can be prescribed for use outside the terms of its Marketing Authorisation. Using a licensed medicine like this is referred to as 'off-label' use. A Special however is a medicine without a Marketing Authorisation which is manufactured to meet a patient's special clinical need.
How are Specials regulated?	Specials can be made in the UK by the holder of a Manufacturer's (Specials) Licence (MS Licence), issued by the MHRA, to manufacture and supply unlicensed medicines. Specials can also be imported from within the European Economic Area (EEA) by the holder of a Wholesale Dealer Licence, and from outside the EEA by the holder of an MS Licence.
Are all Specials the same?	No. Specials that are licensed in the EEA or in a country with which the EU holds a Mutual Recognition Agreement can be considered to be of equivalent pharmaceutical quality to UK licensed medicines. Specials that are licensed in other countries may be of equivalent pharmaceutical quality, but additional assurance of quality is usually required. Specials manufactured in the UK by a holder of a MS Licence are made according to a specification agreed between the purchaser and the manufacturer. They may be individual items or may be made in batches. The manufacturer may test the medicines before release for sale, and should be able to provide evidence that the medicine meets its specification. However the MHRA makes no formal assessment of the quality, safety or efficacy of the medicine. All UK manufactured Specials must bear the MS licence number.
How can a prescriber be sure about the quality of Specials?	Pharmacists (and their teams) should agree with suppliers what evidence is required to give assurance that the Special meets the purchasing specification and prescribing requirements. This may include Certificates of Analysis or Conformity to specification for UK manufactured Specials and may include Summaries of Product Characteristics and Patient Information Leaflets for imported Specials. The pharmacist dispensing the Special should request this documentation.
Where can a prescriber get more information about the manufacture of Specials?	NHS hospital pharmacy manufacturing units listed in the British National Formulary: www.evidence.nhs.uk/formulary/bnf/current The Association of Pharmaceutical Specials Manufacturers: www.apsm-uk.com/ Jackson M, Lowey A. Handbook of extemporaneous preparation. Pharmaceutical Press 2010. www.pharmpress.com/product/9780853699019/handbook-extemporaneous-preparation NHS Pro-File (access restricted to NHS employed staff): www.pro-file.nhs.uk/

APPENDIX 2: PRESCRIBING SPECIALS: A CHECKLIST FOR PRESCRIBERS

Ask pharmacy colleagues for advice and support when prescribing Specials. Use this short checklist to help guide your prescribing decisions.

1. ESTABLISH A CLINICAL NEED

Prescribers should be vigilant when prescribing a Special, or asking another professional to administer one. Specials should only be prescribed when the patient has a special clinical need which cannot be met by a licensed medicine of established safety, quality and efficacy.

Does the patient need a medicine? Is it essential for this patient?

Is there a licensed preparation which could meet the patient's needs, for example soluble tablets, liquid formulations, or patches?

What are all the unlicensed alternatives?
Is local guidance available?

2. UNDERSTAND THE PATIENT'S EXPERIENCE AND MAKE A SHARED DECISION

Prescribers discuss the patient's needs, values and preferences to ensure that the implications and practicalities of treatment options are understood. When a Special is prescribed this is a shared decision and patients are supported to adhere to their medicines.

What are the practical implications of prescribing?
What is the shelf-life? How often will prescriptions be needed? How long does it take to obtain the Special?
Do you need to consult with pharmacy colleagues?

Will the patient be taking or using the medicine themselves? Will it be administered by someone else? How? Are there any implications for the choice of product?

3. IDENTIFY MEDICINES AND PREPARATIONS

The risks and benefits of taking or using a Special will differ for different patient groups, different medicines and in individual clinical circumstances. Prescribers need to take into account the safety, efficacy, quality and cost of the different Specials available to patients.

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?
Do you need to discuss formulation and suppliers with a pharmacist?

Given the patient's clinical needs, what is the most appropriate Special? Will the Special be supplied from a community pharmacy or a hospital? Is there any local or national guidance (e.g. specialist or local formularies)? Do you need to discuss alternatives with your local pharmacist?

4. MONITOR AND REVIEW

Prescribers have systems in place to ensure the need for the Special is regularly reviewed, both in terms of the patient's continued clinical need for a Special and in the context of the need for a medicine overall.

How often will the patient be reviewed? Who will undertake the review?

5. ENSURE EFFECTIVE PRESCRIBING GOVERNANCE

Prescribers understand the rationale for using a Special and the practical implications of prescribing before initiating, transferring, or taking over responsibility for prescribing.

If initiating prescribing, how long is the patient expected to need this medicine?

If asking someone to continue prescribing, have you communicated all necessary information to them?
Do you need to involve pharmacy colleagues?

If continuing the prescribing of a Special, do prescribers know the formulation and source of the initial supply?
Is there a need to ensure consistency of dose by specifying the formulation?

APPENDIX 3: ACKNOWLEDGEMENTS

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All members of the Specials Expert Advisory Group completed a conflict of interest declaration. No conflict of interests were declared.

Further information on the processes governing the development of RPS Professional Standards and Guidance can be found on the RPS website: www.rpharms.com.

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