# CONTENTS

<table>
<thead>
<tr>
<th>Introduction</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>1</td>
</tr>
<tr>
<td>Forward</td>
<td>2</td>
</tr>
<tr>
<td>What is a pharmaceutical special?</td>
<td>3</td>
</tr>
<tr>
<td>The differences between a licensed medicine and a pharmaceutical special</td>
<td>5</td>
</tr>
<tr>
<td>Processes involved in a medicine’s route to a patient</td>
<td>6</td>
</tr>
<tr>
<td>Professional responsibilities and accountabilities</td>
<td>7</td>
</tr>
<tr>
<td>Guidance for prescribers of pharmaceutical specials</td>
<td>8</td>
</tr>
<tr>
<td>Factors for prescribers to consider when prescribing pharmaceutical specials</td>
<td>9</td>
</tr>
<tr>
<td>Determining the need for a special pharmaceutical medicines</td>
<td>10</td>
</tr>
<tr>
<td>Guidance for pharmacists and dispensers</td>
<td>11</td>
</tr>
<tr>
<td>Sourcing a pharmaceutical special</td>
<td>12</td>
</tr>
<tr>
<td>Expiry dates of pharmaceutical specials</td>
<td>14</td>
</tr>
<tr>
<td>Patient information</td>
<td>14</td>
</tr>
<tr>
<td>Specials Tariff</td>
<td>15</td>
</tr>
<tr>
<td>Specially formulated preservative-free eye drops: prescribing tips</td>
<td>16</td>
</tr>
<tr>
<td>Specials in dermatology</td>
<td>18</td>
</tr>
<tr>
<td>Department of Health top 50 QIPP tips - specials</td>
<td>18</td>
</tr>
<tr>
<td>Melatonin for sleep disorders in children - mid Essex guidelines</td>
<td>18</td>
</tr>
<tr>
<td>Appendix 1: Pharmaceutical issues when crushing, opening or splitting oral dosage forms</td>
<td>19</td>
</tr>
<tr>
<td>Appendix 2: RPS response to members on ‘dealing with specials’</td>
<td>26</td>
</tr>
<tr>
<td>Appendix 3 - An action list for PCT pharmaceutical advisers to manage pharmaceutical specials</td>
<td>33</td>
</tr>
<tr>
<td>Appendix 4: New arrangements for reimbursing specials - Q&amp;A</td>
<td>35</td>
</tr>
<tr>
<td>Appendix 5: Unlicensed specials and imports FAQs</td>
<td>43</td>
</tr>
<tr>
<td>Appendix 6: How to endorse unlicensed medicines</td>
<td>46</td>
</tr>
<tr>
<td>Appendix 7: How and when to endorse unlicensed specials and imports</td>
<td>48</td>
</tr>
</tbody>
</table>
Appendix 8: Actions for PCTs in the East of England following the new ‘Specials’ Tariff 49
Appendix 9: Managing Specials with New Arrangements and Tariff: A Guide for Commissioners 50
Appendix 11: Safe and Appropriate Medicine Use 53
Appendix 12: Patient Information leaflet - Optimising safe & appropriate use 62
Appendix 13: Adult specials patient information leaflet 63
Appendix 14: Child specials Patient information leaflet 65
Appendix 15: Patient information leaflet - intestinal failure 67
Appendix 16: St. Mark’s electrolyte mix solution 68
Appendix 26: Trend of spend on specials since publication of specials toolkit across the East of England 71
Appendix 27: Spend on specials in the East of England SHA compared nationally 72
References 73
Acknowledgments 73
INTRODUCTION

This document is to be used for information by medical healthcare professionals to provide guidance on the nature, prescribing and supply of special medicines. The objective of the document is to highlight their individual responsibilities, the risks involved and to make an overall contribution to preserving the safety of patients.

SCOPE

The material herewith aims to provide information on special medicines within the East of England Strategic Health Authority. The contents reflect reliable research evidence, guidance and best clinical practice. It is free from any commercial conflicts of interest and is intended for use by Medical Healthcare Professionals to support clinical and financial governance. The document is not intended to remove or reduce professional accountability or be an indication of quality standards for the supply of these types of medicines.
In recent years the NHS has seen a dramatic increase in the amount we spend on unlicensed medicines, known as ‘Specials’, receiving much public scrutiny as specific examples have been portrayed in the media. As the financial landscape has changed, the focus on budgetary constraint has become important as has working together to find a solution to this problem.

The recent contractual changes, introducing the ‘Specials Tariff’ will undoubtedly bring new challenges for colleagues working across Community Pharmacy, especially with the extra administration required, but should also provide better accountability and transparency for those who prescribe specials appropriately.

In order to respond to these changes, and offer support to community pharmacists, the east of England’s PrescQIPP and NHS Collaborative Procurement Hub are pleased to release the Specials Toolkit version 3. The updated toolkit, which received a Health Business Award late last year, is constantly evolving to ensure the content is up-to-date and offers a comprehensive one-stop-shop for information from many sources, including good practice, information leaflets and many tools, clearly signposted for easy reference, to support work focusing on specials.

We are regularly seeing great work being done around Specials, not just in the east of England but across the country. I am pleased to introduce the latest version of the Specials Toolkit to support the safe, appropriate and cost effective prescribing, and provision, of specials.

Carol Roberts
Pharmacy and Prescribing Lead for the East of England
NHS Midlands and East
WHAT IS A PHARMACEUTICAL SPECIAL?

The Medicines Act 1968 (http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_1) is the piece of government legislation which controls the use of medicines within the UK. It states that medicines may only be marketed for use in patients if they have been given a licence by the appropriate regulatory body.

To obtain a licence for a medicine, pharmaceutical companies have to demonstrate that the product is both safe and effective. The evidence which is provided to the regulatory body includes the following:

- Effectiveness of the active ingredients
- Expected side effects and frequency
- The physical stability of the preparation
- Any interactions between the ingredients within the product
- Interactions with other medicines
- The bioavailability of the finished product (how much drug is absorbed by the patient)
- The acceptability and safety of the formulation.

The above information is obtained from human trials as well as by demonstrating that the procurement, manufacturing and storage conditions within the manufacturing and distribution elements of the production process are appropriate and safe.

Following this rigorous assessment process every marketed medicinal product in the UK is issued a Marketing Authorisation (MA) number by the regulatory authority the Medicines and Healthcare products Regulatory Authority (MHRA). The MA, previously known as a Product Licence (PL) must be displayed on the pack and provides a guarantee of quality.

Additionally, post marketing surveillance of newly licensed products allows feedback from clinicians and patients about any adverse events from treatment thus identifying less common clinical effects.

As a rule, an unlicensed medicinal product which is a pharmaceutical equivalent of an available licensed medicinal product should not be placed on the market.

A medicinal product should be regarded as a “pharmaceutical equivalent” if:

- It contains the same amount of the same active substance(s), or in the case of liquid dosage forms the same concentration; and
- It is in the same dosage form; and
- It meets the same or comparable standards considered in the light of the clinical needs of the patient at the time of use of the product.

The MHRA website contains further information regarding unlicensed medicines: http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007547.pdf
Occasionally a prescriber will identify that a patient requires a medicine which does not have a licence. For example the patient may be allergic to an additive, require a stronger or weaker form, a different presentation (e.g. a specialist dermatological preparation like menthol in aqueous cream) or a different form such as an unlicensed liquid formulation for a child or to overcome swallowing difficulties.

**NB:** If a medicine or form of a medicine is not listed in the British National Formulary (BNF) then it is likely to be unlicensed.

**The BNF (http://bnf.org/bnf) does list some unlicensed products or uses of medicines but these are clearly identified as unlicensed.**

Products which are unlicensed and are prescribed for individuals are called specials. A pharmaceutical special as defined by law is a medicine made to satisfy an individual patient need. The Medicines Act allows appropriate prescribers to prescribe medicines without a licence providing they are happy to assume full liability for the prescription.

If this is the case, it is allowed under the legal stipulation that the pharmaceutical special medicine made satisfies a patient’s specific requirement.
THE DIFFERENCES BETWEEN A LICENSED MEDICINE AND A PHARMACEUTICAL SPECIAL

Practical and clinical differences

Specials can be made by pharmacists in their dispensaries, by small specialist manufacturers or by large companies who produce specials in a similar fashion to their licensed products. With the exception of pharmacies, special medicines should be manufactured by a supplier who is in possession of a specials manufacturing licence.

This means the facilities of the supplier have reached a minimum standard. It does not mean the product is licensed in any way and is therefore different to a product licence.

Due to a need to adhere to minimal standards only, the amount of information provided with products varies significantly as does the level of stability testing. If the level of testing had been equivalent to a licensed product then the product would be licensed and not a special.

When writing a prescription for a special it is difficult to reassure yourself of the level of quality of the special provided by the supplying pharmacist as it is ultimately their decision as to where they procure the medicine from.

Legal differences

If a prescriber uses a medicine within the terms of the licence e.g. at the stated dose and for the indication specified in the Summary of Product Characteristics (SPC) (the agreed licensing conditions between the regulatory body and the pharmaceutical company) then any adverse side effects are the legal responsibility of the manufacturer. If a patient experiences a side effect (even one not specified in the SPC) then the patient would have grounds to prosecute the manufacturer.

This is not the case for a pharmaceutical 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. Given the uncertainties explained above this should not be underestimated. The prescriber should be able to justify and feel competent in using such medicines.
PROCESSES INVOLVED IN A MEDICINE'S ROUTE TO A PATIENT

1. DRUG DESIGNED OR DISCOVERED
   - Require regulatory licence for manufacturing facility
     - Drug formulated into a medicine
     - Drug formulated into a patient specific medicine
     - Require regulatory licence for clinical trialling
     - Require Product Licence evaluation and approval

2. Medicine distributed
   - Require wholesale dealer’s licence for distribution
   - Pharmacy
   - Contract
   - Cost effective sourcing
   - Professional regulation

3. PATIENT
PROFESSIONAL RESPONSIBILITIES AND ACCOUNTABILITIES

The primary professional responsibility of prescribers and pharmacists is to ensure the safety of the patient. This can best be served by using a licensed medicine where possible (as explained in Guidance Note 14 from the MHRA). Further information can be obtained from the MHRA website: http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedallicence/Medicinesth datonotneedallicence/index.htm

It is a pharmacist’s professional duty to assist prescribers in ensuring that a pharmaceutical special is only used where there is no possible licensed alternative.

It is often possible to use crushed tablets or opened capsules instead of reformulating a medicine with the problems detailed above.

Many Primary Care Trusts in the East of England refer to the reference text of The Handbook of Drug Administration via Enteral Feeding Tubes by White and Bradman, Pharmaceutical Press. This book provides the background knowledge to inform clinical decisions and the accompanying 343 drug monographs contain guidance on the safe administration of specific drugs and formulations.

Contents include:

• Tube flushing
• Restoring and maintaining patency
• Drug therapy review, medication formulation choice
• Unlicensed medication use
• Health and safety interactions.

Additional guidance can also be found on the Calderdale and Huddersfield NHS Trust website: http://www.formulary.cht.nhs.uk/Guidelines/MMC/062b_MedEnt_IndivDrugs.htm

Recently there has been a lot of useful work collated by Waltham Forest NHS Trust on Specials and this work was further developed by Barking and Dagenham NHS Trust. The booklets that were produced are useful references when determining how to use licensed drugs to fulfill an individual patient’s needs instead of a Special. The Barking and Dagenham booklet can be downloaded at the following link: www.barkingdagenham.nhs.uk/Downloads/Health-professionals/Medicines-management/ONEL_specials_information_pack_Jan12.pdf

As described above the prescriber of a pharmaceutical special is expected in law to detail:

1. The exact pharmaceutical need and how that should be addressed (e.g. by stipulating the exact formulation details). In practice they may well not have the expertise to do this.

2. The pharmacist who orders the medicine has a professional duty to ensure that the product provided to the patient meets the prescriber’s requirements. If these are not implicitly stated then he/she needs to ensure the medicine is fit for the patients use, i.e. the pharmacist is responsible for the formulation, the bioavailability and the stability of the product they supply. It would also be required that this process is documented and can be proven in the form of a Certificate of Analysis which should accompany any special product supplied.

It is also the professional responsibility of the pharmacist to ensure that cost effective medicines are used. The Royal Pharmaceutical Society has issued guidance on this, which can be found in the index of this document as well as on their website: Royal Pharmaceutical Society website: http://www.rpharms.com/home/home.asp
GUIDANCE FOR PRESCRIBERS OF PHARMACEUTICAL SPECIALS

In the UK, an unlicensed medicinal product may only be exempted from the need for a marketing authorisation provided they are fulfilling a special pharmaceutical need and have been supplied in accordance with an unsolicited order, formulated in accordance with the specification of the prescriber and only for use by his individual patient within his direct responsibility.

It is highly desirable that a licensed alternative is used where possible. Pharmacists can assist in this selection process.

To prevent delays at the point of dispensing and supply, it is a good idea for prescribers to contact the community pharmacist (or hospital pharmacy if the item has been supplied from there before) to discuss the details of the patient’s needs and support the achievement of the advice below. At this time any suitable licensed alternative should be discussed.

In many cases it is preferable to give a licensed product via an unlicensed route (e.g. an injection given orally), than to prepare a special formulation. For determining the best option for the patient and any additional drug information can sought from local or regional Hospital Medicines Information services.

The NPC have recently published guidance for prescribing specials called ‘Prescribing Specials: Five guiding principles for prescribers’ and this can be found on their website at the following link: www.npc.nhs.uk/improving_safety/prescribing_specials/resources/5_guiding_principles.pdf
FACTORS FOR PRESCRIBERS TO CONSIDER WHEN PRESCRIBING PHARMACEUTICAL SPECIALS

Prescribing an unlicensed medicine comes with all the inherent risk described above.

• The prescriber must ensure the patient is aware that the medicine is unlicensed. An example Patient Information Leaflet to support this is given in the appendix.

• It is the prescriber's responsibility to decide whether the patient has special pharmaceutical needs which a licensed product cannot meet. As previously mentioned the MHRA guidance note 14 (as detailed in the BNF) requires that a pharmaceutical special medicine should ONLY be used where there is no suitable licensed alternative, e.g. a soluble tablet instead of a liquid medicine.

• The product will not have been assessed by the licensing authority for safety, quality and efficacy.

• The prescriber is directly responsible for the prescribing of these products and will be liable for adverse effects or harm resulting from the use of that product.

• In law the prescriber is supposed to define EXACTLY what the medicine should consist of (the formulation). In practice this seldom (if ever) happens, a pharmacist can assist in this process.

• It may be appropriate to review the need for the patient’s medicine at the time of changing from a licensed to an unlicensed medicine. i.e. could it be discontinued?

• PCTs may have a local formulary for unlicensed medicines. Prescribing within this would to some extent protect the prescriber legally.

• Sourcing pharmaceutical specials from a variety of manufacturers will result in variability in formulation and hence efficacy, bioavailability and excipients. The formulation may actually change from time to time from the same supplier and needs to be checked each and every time.

• A special may have a short expiry date e.g. seven days (see section below). It is advisable to check this at the time of prescribing and thus minimise wastage of unused product by prescribing a suitable amount related to the shelf life of the product.

• Special medicines can be very expensive (several hundred pounds for one bottle) and may not represent a cost effective treatment.

• If the patient has had the special before, information about previous supplies can improve continuity of care (e.g. by questioning the patient or asking to see the product or labelling information).
DETERMINING THE NEED FOR A SPECIAL PHARMACEUTICAL MEDICINES

When deciding whether the patient has special pharmaceutical needs which a licensed medicine cannot meet, consideration should be given to the following:

- The opportunity should be taken to review current medication and assess its continuing need.
- Dermatological pharmaceutical specials with formulations which are more than two years old may have been superseded by commercially available licensed products which were not available at the time of first prescribing.
- Some solid-dose formulations may allow the ‘sprinkling’ of contents onto food.
- Although the crushing or breaking of tablets may be outside of a product’s licensed use, liquid pharmaceutical specials are also unlicensed. An option could be to ask for the tablet to be dissolved in water by writing this requirement onto the prescription directions. This instruction should be added to the label on dispensing.

The UKMI North West Medicines Information centre has produced a medicines Q&A on ‘Therapeutic options for patients unable to take solid oral dosage forms’.

The Q&A suggests a stepwise approach to choose a suitable alternative and is available at: http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Therapeutic-options-for-patients-unable-to-take-solid-oral-dosage-forms/

- Before prescribing an unlicensed liquid medication, consider alternatives such as:
  - Oro-dispersible tablets (e.g. lansoprazole oro-dispersible)
  - Soluble/dispersible tablets (e.g. soluble prednisolone).
- The continuing need for an unlicensed pharmaceutical Special should be regularly reviewed. A swallowing difficulty may have been resolved so the liquid medicines are no longer appropriate and oral licensed medicines safer.
- If patient has a swallowing difficulty confirm with SALT health professional that this difficulty extends to the patient’s medication.

Requests to prescribe unlicensed pharmaceutical specials by a third party, e.g. secondary care, do not diminish the responsibility of the prescriber.
Unlicensed medicines may be obtained from:

- A pharmaceutical manufacturer
- Imported by a specialist importer
- Manufactured by a commercial or hospital MHRA licensed manufacturing unit
- Prepared extemporaneously against a prescription - in many cases it is preferable to give a licensed product via an unlicensed route (e.g. an injection given orally), than to prepare a special formulation.

The safeguards that apply to products with a marketing authorisation should be extended, as far as possible, to unlicensed products. The safety, efficacy, quality and labelling of unlicensed medicines should be assured by means of clear policies on their prescribing, purchase, supply and administration. Extra care is required with unlicensed medicines because less information may be available on the drug and any formulation of the drug. Pharmacy contractors would be expected to have prepared and adhere to an unlicensed medicines policy which addresses these issues. Reference to the local PCT policy on unlicensed medicines may also be necessary.

The manufacturer must have an appropriate licensed facility and regulatory approval covering the production of different forms of special products such as creams, tablets, injections etc.

Some manufacturers ensure pharmaceutical specials are manufactured to the same strict GMP standards as fully licensed products. Ideally the product should be manufactured from raw active ingredients and excipients, following a specially developed formulation to ensure patients receive consistency in their medication, whether it is prescribed or administered in hospitals or in Primary Care.

Pharmaceutical specials manufacturers are not allowed to advertise unlicensed products, because under the Medicines Act it is only possible to advertise licensed medicines. This means that it can be difficult to find information about pharmaceutical specials.

Consideration needs to be taken when switching manufacturers to ensure consistency of clinical outcomes and excipients. This minimises the risk of new side effects and adverse reactions due to different formulations. Ideally there should also be exact reproducibility of products from batch to batch and reasonable shelf lives if the same manufacturer is used.
SOURCING A PHARMACEUTICAL SPECIAL

The following principles should be used in the decision making process for selecting a formulation and a manufacturer of a pharmaceutical special. The process is one of risk assessment where the pharmacist or dispenser should choose the option which reduces the risk of harm to the patient whilst maximising the efficacy of the treatment.

Gradient of risk

The special pharmaceutical need of the patient

The patient may need a pharmaceutical special because of individual sensitivities to excipients, an inability to swallow or a specialised illness. The formulation that is decided on MUST meet these individual pharmaceutical needs.

The quality of the formulation

Pharmacists should specify to the supplier exactly what they require. The formulation should be chosen so that it delivers the following requirements so far as is possible:

- Safety. i.e. none of the excipients constitute a hazard to the patient
- Bioequivalence in terms of efficacy with the alternative licensed medicine or a known bioavailability so the dosage can be adjusted
- A known stability profile for all ingredients within the shelf life attributed to the product
- That the medicine is acceptable to the patient (e.g. texture, taste, absorption characteristics, dose volume)

The quality of the manufacturing process

The manufacturer should be chosen on the basis they:

- Possess a pharmaceutical manufacturing license for the activity they are being asked to undertake.
- Use Good Manufacturing Practice (GMP) processes.
- Label and package the product in accordance with latest guidelines.
• Provide supporting governance documentation of quality (described below).
• Provide a rapid delivery service.

The quality of the product

Pharmacists should not assume any aspect of quality and take all reasonable steps to ensure that the product supplied:

• Is of a suitable standard i.e. checking strength, formulation and excipients.
• Comes with a:
  • Certificate of analysis (COA) - A certificate of analysis should be available for any batch manufactured special and is evidence that critical parameters have been confirmed by retrospective physical, chemical or microbiological assay of a sample of the final product.
  Or a:
  • Certificate of conformity (COC) - A certificate of conformity is a signed statement by the manufacturer that they believe the product complies with the purchaser’s specification.
• Is pharmaceutically appropriate and suitable for the patient.
• Has evidence to support the labeled shelf life of the product.
• Ideally comes with an information leaflet although this is not yet a legal requirement.

Any adverse reactions to the product reported by patients, should be reported to the MHRA via the ‘yellow card scheme’: http://yellowcard.mhra.gov.uk

The cost effectiveness of the medicine

Pharmacists have a professional duty to ensure cost effective utilisation of resources. In this regard they should ensure that the medicine is competitively priced and represents value for money. Ideally this can be achieved by obtaining several quotes and using the one which represents the best quality and cost effectiveness.

Pharmacists should avoid manufacturers offering excessive levels of discount (often linked to high list prices) and order specials direct from manufacturers rather than using intermediaries, where possible, so as to avoid excessive handling costs and mark ups.

Previous supplies

The pharmacist should check if the patient has had the product supplied before (e.g. by questioning the patient or asking to see the product for labeling information). If so, attempts should be made to establish the previous source of the product and continue to access it from the same supplier. This will improve the likelihood of clinical equivalence and continuity of care.
EXPIRY DATES OF PHARMACEUTICAL SPECIALS

Every medication sold over-the-counter, as well as on prescription, has an expiry date - imprinted on the packaging. Generally the expiry is the date before which the medication:

• will have the stated strength
• will provide the desired benefits
• will act safely.

Pharmaceutical specials manufacturers do not necessarily perform stability testing on their products measuring potency and stability over time. The expiry date is therefore reduced to a short period of time compared to a licensed product. This can result in treatment becoming very expensive with high levels of waste over time.

For some drugs (but not necessarily all drugs), using the product after the expiry date can expose the individual to harmful by-products of the medication’s break down.

The pharmacist’s Code of Ethics (in the UK) forbids the use of out of date medicines.

When prescribing a pharmaceutical special there is a possibility that it will have a very short expiry sometimes as low as seven days. Prescribers need to be aware that if this is the case they may need to prescribe four prescriptions for a month’s supply of the pharmaceutical special.

Pharmacists should consider the amount prescribed in the light of expiry date information and contact the prescriber if necessary to:

• Adjust the quantity prescribed should the amount on the prescription lead to wastage
• Minimise the need for patients to request repeat prescriptions less than monthly, arrange for more than one prescription to be written to allow the supply to the patient for several times during a month.

PATIENT INFORMATION

Pharmacists are likely to be the last point of contact with the patient prior to the unlicensed special being administered. It is the responsibility of the pharmacist to ensure they are fully informed about the medicine including its unlicensed status.

Examples of a patient information leaflets that could be used to support this are reproduced in the appendices.
SPECIALS TARIFF

The recent national media focus on specials has resulted in the Department of Health and the Pharmaceutical Services Negotiating Committee (PSNC) introducing, in November 2011, new reimbursement arrangements. The aim of this new ‘Specials tariff’ is to create a more transparent system for reimbursing specials. It is hoped that it will also simplify the arrangements for claiming and payment for sourcing specials.

Unlicensed products included in the Drug Tariff (http://www.ppa.org.uk/ppa/edt_intro.htm) will be listed in Part VIIIB and their prices, which include a margin, are calculated based on sales information provided to the Department of Health from a selection of licensed manufacturers.

The prices and products in Part VIIIB will be subject to two types of review: a quarterly review of prices and a six-monthly review, based on prescribing data, of products included on the list. Initially as it becomes established, review of Part VIIIB will be flexible and where a product becomes licensed outside of these reviews, the Drug Tariff will be updated accordingly.

The new arrangements affect the claiming procedures surrounding specials including: how prescriptions for specials are endorsed, broken bulk claiming, out-of-pocket expense claims, extemporaneous dispensing fees, and Discount not Given (DNG) claims.

As well as the record keeping obligations already in place for specials, pharmacy contractors will also have to keep a record of the prescriber. For specials not listed in Part VIIIB there are additional requirements involving the product’s Certificate of Analysis (COA) / Certificate of Conformity (COC) for the contractor to meet. At the end of every month, the contractor shall send a copy of the COA/COC to the PCT of the prescriber along with details of the prescriber, allowing the PCT to match expenditure to the special supplied.

Various aids have been produced for contractors and PCTs to facilitate the understanding and implementation of these new arrangements and some of them are included in the appendices of this toolkit.
SPECIALLY FORMULATED PRESERVATIVE-FREE EYE DROPS: PRESCRIBING TIPS

The high cost of many specially formulated, preservative-free eye drops continues to be a cause for concern in primary care. Preservative-free eye drops are usually recommended by a specialist and may be required when there is a proven allergy to preservatives such as benzalkonium chloride. Preservative-free eye drops may also be recommended if a product is used very frequently (e.g. more than six applications daily) or if soft contact lenses are worn.

When reviewing the prescribing of preservative-free eye drops, it is important to check whether preservative-free eye drops are clinically required, i.e. does the patient have a genuine allergy to the preservative? In some cases, preservative-free eye drops have been prescribed as a result of selection error on the clinical system rather than for a genuine clinical need.

If the patient does require preservative-free eye drops, there are several options available. The preferred route is to prescribe licensed, single use or unit dose eye drops if these are available. If a licensed product is not available, an unlicensed specially manufactured product may be considered. However, unlicensed specially manufactured eye drops can be extremely expensive, do not have a product license and may often have short expiry dates.

Table 1 below provides details of licensed proprietary alternatives to commonly prescribed unlicensed preservative-free eye drops.

### Commonly prescribed unlicensed preservative free eye drops and licensed alternatives

<table>
<thead>
<tr>
<th>BNF NAME</th>
<th>SUGGESTED LICENSED PROPRIETARY ALTERNATIVE(S)</th>
<th>COMMENTS/ ADDITIONAL INFORMATION (PRICES BASED ON MIMS, FEBRUARY 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypromellose 0.3% preservative-free eye drops</td>
<td>Consider the use of <strong>Hydromoor®</strong> or <strong>Lumecare®</strong> hypromellose 0.3% preservative-free single dose eye drops.</td>
<td><strong>Hydromoor®</strong> eye drops cost £5.75 for 30 x 0.4ml single dose units. Available from Moorfields Pharmaceuticals. <strong>Lumecare® Preservative Free Tear Drops</strong> cost £5.72 for 30 x 0.5ml single dose units.</td>
</tr>
<tr>
<td>Hypromellose 0.25% preservative-free eye drops</td>
<td>No licensed alternative.</td>
<td>Check whether hypromellose 0.25% preservative-free eye drops are required.</td>
</tr>
<tr>
<td>Chloramphenicol 0.5% preservative-free eye drops</td>
<td><strong>Minims® Chloramphenicol</strong> (Chloramphenicol 0.5%)</td>
<td><strong>Minims® Chloramphenicol</strong> cost £9.55 for 20 x 0.5ml single dose units.</td>
</tr>
</tbody>
</table>
### Other considerations

Occasionally, large volumes of preservative-free eye drops (e.g. hyromellose 0.3%) are issued on prescription. In such cases it is necessary to check that the patient is using the eye drops appropriately and to provide the patient with education on the correct use of the eye drops. Referral to an ophthalmologist may also be required if initial attempts to educate the patient prove unsuccessful.

Many unlicensed preservative-free eye drops are possibly being prescribed unintentionally as a result of a selection error on the prescribing system. Prescribers should ensure that the correct preparation is selected on the GP clinical system. Please note that unlicensed special order products may highlight as “nil cost” or alternatively a “cost warning” may appear on the clinical system.

In some instances there may not be an alternative licensed preservative-free special available (e.g. pilocarpine 1% eye drops, vancomycin 5% eye drops etc.) and as a result a specially manufactured, unlicensed product would need to be prescribed. Pharmacists should be encouraged to order these products directly from the manufacturer (e.g. Moorfields Pharmaceuticals) rather than from the wholesaler, as prices
may increase significantly when ordered via wholesalers.

A regular review of epact.net prescribing data is simple to undertake and is recommended on a monthly basis in order to highlight any inappropriate prescriptions, large volumes or high costs of eye drops prescribed as specials.

For practices using ScriptSwitch, recommendations or advice highlighting unlicensed eye drops and possible alternatives can prove particularly helpful in reducing inappropriate prescribing.

**SPECIALS IN DERMATOLOGY**

The British Association of Dermatology compiled a list of preferred unlicensed dermatological preparations in 2008.

This useful list can be found at the following link: http://www.bad.org.uk/Portals/_Bad/Specials/BAD%20Specials%20Booklet.pdf

**DEPARTMENT OF HEALTH TOP 50 QIPP TIPS - SPECIALS**

The Department of Health has recently published a list of 50 efficiency measures for use by SHAs and PCTs as an aid to deliver the QIPP agenda. The examples are from NHS organizations and some pertain to managing specials.

The list can be found at the following link on the Department of Health website: http://www.dh.gov.uk/en/Healthcare/Qualityandproductivity/QIPPworkstreams/DH_115467

**MELATONIN FOR SLEEP DISORDERS IN CHILDREN - MID ESSEX GUIDELINES**

Melatonin is a special that is regularly prescribed and many PCTs have produced guidelines to reduce the level of spend on this drug. There are no licensed melatonin preparations for the treatment of childhood insomnia so the adoption of a policy that specifies the parameters of using and monitoring this medication for this indication increases the safety for the patient.

There are a few policies available online to adapt and use locally. Mid Essex NHS have adopted the North Essex Partnership NHS Foundation Trust (NEPFT) ‘Continuing Care Guidelines & Information for Staff and General Practitioners - Melatonin for Sleep Disorders in Children’.

The guidelines can be found at the following link: www.midessex.nhs.uk/documents/key-documents/medicines%20management/shared%20care%20guidelines/melatonin%20continuing%20care%20guidelines%20nov%202011.pdf
APPENDIX 1: PHARMACEUTICAL ISSUES WHEN CRUSHING, OPENING OR SPLITTING ORAL DOSAGE FORMS

JUNE 2011

Introduction

It is important to recognise the potential consequences of manipulating a medicinal product. Changing the way in which a dosage form is presented can alter its absorption characteristics, result in medicines instability, produce local irritant effects, cause failure to reach the site of action, may produce occupational health and safety issues, and could result in a preparation with an unacceptable taste. Most of these considerations apply equally to Specials (see Footnote), as well as to splitting and crushing of tablets and opening of capsules; there are risks and benefits associated with both. In most circumstances in which no appropriate licensed medicine is available, the prime objective should be to provide patients with a ready-to-use unlicensed medicine. There may, however be circumstances in which this is not the preferred choice.

A recent study\(^1\) found that a tablet splitting device (Pilomat) was able to split a range of tablets more accurately than splitting by hand (for scored tablets), cutting with scissors (for unscored tablets), or using a kitchen knife. Accuracy of splitting is critical if the objective is to give less than a whole tablet dose to a patient but less so if the aim is simply to give the full dose to a patient who cannot swallow the tablet whole. If a situation arises where an oral dosage form has to be spilt, crushed, opened or manipulated in any other way for the benefit of a patient, the resulting preparation should be taken by the patient as soon as possible to reduce the likelihood of degradation and minimise any risks.

There are certain types of dosage form that should never be split or crushed and this document aims to highlight these dosage forms, the science behind why they should remain intact, and the possible sequences of splitting or crushing various dosage forms. This document does not cover the decision making process for deciding whether it is more appropriate to crush, split or open an oral dosage forms, or to use a Special; this can be found in RPS Guidance on Specials (http://www.rpharms.com/best-practice/specials.asp).

When describing the types of dosage forms that should not be crushed, split or opened, and the potential consequences of manipulating a dosage form, a selection of medicines has been listed to illustrate the types of product that have the effect or action under discussion. The medicines included are intended to act as examples and must not be viewed as an exhaustive list. If a pharmacist has any concerns about whether a medicine is suitable for crushing, splitting or opening, advice from the manufacturer of the product should be sought.

Footnote: a Special may be: a) a medicine manufactured by a specials manufacturer holding a Manufacturer’s Specials Licence (MS) in multiple quantities with end product analytical testing, b) a special medicine produced by a specials manufacturer holding an MS as a bespoke medicine without end product analytical testing, or, c) an extemporaneously prepared medicine, which is an unlicensed medicine made in a pharmacy under a pharmacist’s direct supervision.
As with the preparation of Specials, the crushing or splitting of dosage forms will be an unlicensed use of the medicine (unless this form of manipulation is covered by the product’s Marketing Authorisation). This will mean that the pharmacist supplying the medicine may assume additional responsibility and liability for the decision to crush or split the dosage form. Some tablets can also be dispersed in liquids, and, as this is done immediately prior to administration to patients, drug stability is not usually a major issue. However, if only part of the liquid containing the dispersed tablet is to be administered to a patient, problems can arise with drugs that are insoluble in aqueous vehicles. Aggregation, sedimentation and precipitation of insoluble drugs can result in poor accuracy of the dose administrated. Powders or some other dosage forms can be added to beverages and foods although data to support this are lacking, and no single food or beverage will be suitable for all drug substances.

Potential Consequences of Splitting, Crushing and Opening

**Risks to healthcare workers and carers**

Crushing products with carcinogenic (e.g. tamoxifen; methotrexate) or teratogenic (e.g. valganciclovir) potential may expose carers or healthcare professionals to health risks through powder aerosolisation and as such should not be undertaken. Similarly, preparations containing hormones (oral contraceptives; hormonal replacement therapy), corticosteroids (such as dexamethasone) and some other drugs (finasteride; mycophenolate) should not be crushed due to the risks associated with powder aerosolisation. It should be noted that the effects of many other drugs when inhaled are largely unknown.

In addition several drug substances may also cause irritation if the powder is aerosolised and inhaled or comes into contact with the eyes, skin, or other mucous membranes e.g. alendronate, diflunisal, isotretinoin, piroxicam. Ganciclovir is known to be a skin irritant, and exposing the skin to hydroxycarbamide powder can cause serious skin toxicity.

**Drug Instability**

Crushing an oral solid dosage form may have a negative impact on the stability of the drug substance. If an enteric coating, which protects a drug from the acidic environment in the stomach, is removed by crushing the tablet, the in vivo drug degradation will increase, with less drug available to produce the desired clinical effect.

Coatings are also added to oral solid dosage forms to protect the drug from the effects of light. Nifedipine is an example of a drug that is highly light sensitive after tablets have been crushed.

**Changes in Pharmacokinetics and Bioavailability**

Splitting or crushing oral dosage forms may produce changes in the drug pharmacokinetics and bioavailability resulting in underdosing or adverse effects. Such changes may be particularly important for drugs that have narrow therapeutic windows e.g. phenytoin, digoxin, carbamazepine, theophylline, or sodium valproate.

**Drug Irritation**

Many drugs have irritant actions and are formulated or coated to minimise the risk to patients. Some medications may cause oesophageal or stomach irritation or ulceration if tablets are crushed or capsules opened (e.g. nitrofurantoin, potassium chloride, alendronate, diclofenac).

**Bitter Tasting Drugs**

For drugs which have a particularly bitter taste, a coating (sugar/film) is often used to help mask the taste of the active substance. A sugar coating provides a thick hard coat to a tablet and is traditionally used to mask the taste of particularly unpleasant tasting drugs such as ibuprofen or quinine. Film coating produces a much
thinner layer on tablets but this is still capable of masking the unpleasant taste of drugs. Other examples of bitter or unpleasant tasting drugs include cefuroxime axetil, ciprofloxacin, docosate, pseudoephedrine and praziquantel. Crushing tablets containing bitter or unpleasant tasting drug substances may produce a preparation which is unpleasant to taste and which a patient may refuse to take unless the taste can be masked using a suitable food or liquid.

Other Effects

Sertraline is known to have an anaesthetic effect on the tongue; patients may become aware of this effect if a formulation of sertraline is given in a powdered form.7

Requirement for Patient Monitoring

Patient monitoring should be undertaken when some products are crushed. Blood pressure monitoring has been advised when crushed preparations of alfuzosin, carvedilol, nifedipine, or ramipril are administered due to the risk of hypotensive effects.7 If oral dosage forms of glibenclamide, gliclazide, or metformin are crushed or opened, monitoring of blood glucose levels has been suggested.7

Dosage Form Effects

Extended Release Preparations

Extended-release products are formulated to release the drug over an extended period of time, generally over 12 to 24 hours. The aim of an extended-release preparation is to produce a constant plasma drug concentration, although in practice there are small rises and falls in drug concentration over the period that the drug is released. Extended-release formulations often have one of the following abbreviations after the product name CR, ER, LA, SR, XL or XR.

Several different methods can be used to modify the rate of release of a drug from an oral dosage form including the following:

- Modifying the pharmaceutical form - by increasing the drug particle size or forming insoluble crystals leads to a reduced rate of drug release e.g. Tegretol Retard, Adalat Retard.

- Coating pellets – coating drug pellets with a slowly dissolving polymer of varying thickness can vary the drug release rate. The pellets can either be compressed into a tablet or put in gelatin capsules e.g. Slo-Phyllin, Inderal-LA.

- Insoluble matrix – drug is dispersed within an insoluble matrix and as fluid enters the matrix, the drug is dissolved and slowly diffuses out e.g. Slow-K, Imdur Durules.

- Eroding matrix – the drug is dispersed within a soluble matrix and as the matrix is slowly eroded the drug is released e.g. MST Continus, Phyllocontin Continus.

- Osmotic pump – the drug and an osmotic agent are enclosed in a semi-permeable membrane; water is drawn into the matrix and the dissolved drug is released in a controlled manner through a laser drilled hole e.g. Adalat LA.

Crushing an extended-release preparation may change the drug release characteristics, with the potential for an unintended large bolus dose being delivered rather than controlled release over the intended timescale. The consequence of this would be for a potentially toxic dose of medication to be delivered following administration with an increased risk of adverse effects. While there is the risk of initial overdosing of drug, there will be under dosing at later times which could result in a lack of clinical efficacy.8,9

A case has been reported in which a crushed extended-release nifedipine tablet contributed to a patient fatality10; the administration of a crushed nifedipine XL tablet resulted in severe hypotension and the
concurrent administration of labetalol prevented a compensatory heart rate increase in the patient.

Crushing sustained-release isosorbide mononitrate tablets and administration through a percutaneous endogastric tube to a 78 year old patient produced recurring chest pain and nausea, with an ECG confirming ischaemic changes; symptoms resolved when therapy was changed to a short acting nitrate administered three times daily.

With some capsule formulations where the controlled release properties are built into individual pellets contained in the capsule, it may be possible to open the capsule and use the contents provided the pellets are not crushed.

**Enteric Coated Preparations**

Enteric coatings on tablets are produced by coating the tablet with polymers that remain intact in the stomach but dissolve and release the drug from the dosage form in the more alkaline pH of the small intestine. Enteric coatings are applied to tablets to delay the release of drugs that are inactivated by the stomach contents (pancreatin; erythromycin; omeprazole), to prevent stomach irritation (aspirin; diclofenac; naproxen; corticosteroids), or to delay the onset of action to a specific site within the gastrointestinal tract (sulphasalazine in the treatment of Crohn’s disease).

Crushing enteric coated tablets may result in the drug being released too early, destroyed by stomach acid, or irritating the stomach lining. In general, manipulation of enteric coated and extended-release formulations is not, therefore, recommended. However, it is accepted a few extended-release preparations may be manipulated, but this should only be done on the recommendation of the product manufacture.

**Other Types of Dosage Forms**

Sublingual and buccal tablets allow a drug substance to be directly absorbed across the mucosal membrane leading to rapid rises in the drug concentration in the blood; this method of delivery also avoids first pass metabolism in the liver. Lozenges are large tablets that are intended to stay in the mouth for periods of 10 to 15 minutes while they dissolve and have a local action in the mouth.

If these types of dosage form are crushed, the pharmacokinetics and bioavailability of buccal and sublingual products will be altered, and the local action of lozenges will be affected. However, in practice, there is unlikely to be any circumstance where it will be necessary to crush these types of dosage form.

An indication of which oral dosage forms should not be crushed and the reasons for this can be found at the following sites which list American products (http://www.ismp.org/tools/donotcrush.pdf; http://www.rphworld.com/viewlink-23475.html), and the ways in which pharmacists can help optimise the treatment of patients, and in particular children, who have swallowing difficulties has recently been described.

**When May it be Appropriate to Consider Crushing, Opening or Splitting?**

If a decision is taken that the most appropriate way to address an individual patients needs is to manipulate a preparation, it may be possible to crush, open, or split uncoated tablets, film coated tablets, sugar coated tablets or immediate-release capsules provided that consideration is given to any cytotoxic, teratogenic, stability, irritancy and bitterness issues associated with the dosage form. If a tablet is sugar- or film-coated, the reason for the coating should be determined before the tablet is crushed.

If crushing of tablets or the opening of capsules is to be considered, useful information on whether this form of manipulation is appropriate for a drug product can be found in the Handbook of Drug Administration via Enteral Feeding Tubes, and at the website created by Colchester Medicines Information at Colchester Hospital University NHS Foundation Trust. While these sources provide guidance on whether a dosage
form can be manipulated, there is an absence of data to indicate how this manipulation may affect the bioavailability of the product, or if the manipulated product remains bioequivalent with the original dosage form.

Methods that have been used to crush tablets include using a mortar and pestle, one of the commercially available devices designed to crush tablets, or a tablet crushing syringe. It should be recognised that there is the possibility of powder loss in using some of these methods; about 25% of aspirin was lost when a mortar and pestle was used to crush tablets prior to suspending the powder in water.15

It has been reported that crushing film coated telithromycin tablets and administering them with a nutritional supplement drink was found to be bioequivalent to ingesting whole tablets.16

When splitting tablets, either by hand or using a splitting device, it is not uncommon to obtain two tablet pieces that are not the same size, and whose weight can vary by 15% to 20% of the theoretical weight i.e. half the weight of the intact tablet.17-19 This may be highly significant if only a part of the tablet dose is to be administered, but may be insignificant if the aim is simply to help a patient who can’t swallow a tablet whole. Dose variation is greater for non-scored tablets than scored tablets.20

It should be borne in mind that there is the possibility of a reduced or absent clinical effect when the smaller portion of a split tablet is administered. When unscored cyclobenzaprine 10mg tablets were split using a kitchen knife and a tablet splitter, it was found that the variation in weight of the two tablet pieces obtained was less with the tablet splitter than the kitchen knife; variations of up to about 30% of the theoretical weight were obtained with the tablet splitter while variations of up to 50% were noted with the kitchen knife. Interestingly, the smaller of the two tablets pieces could contain as little as 2.49 mg cyclobenzaprine when tablets were split with a kitchen knife; the authors noted that the efficacy of cyclobenzaprine 2.5 mg has been shown to be no different from placebo.21

There is relatively little published information on the clinical effects resulting from the administration of split tablets to patients. Two studies have investigated the effect of splitting tablets containing statins on in vivo markers; in one study, splitting tablets had no significant effect on total cholesterol and LDL cholesterol,22 while the other study reported that tablet splitting produced no difference in total cholesterol and triglycerides.23

References


3. Wright W. Tablet crushing is a widespread practice but it is not safe and may not be legal. Pharmaceutical Journal 2002; 269: 132.


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**Andrew Lowey** (Clinical Pharmacy Manager, Leeds Teaching Hospitals NHS Trust, Leeds)

**Tony Nunn** (Associate Director, NIHR Medicines for Children Research Network, University of Liverpool, and Industry Professor, School of Pharmacy and Biomedical Sciences, Liverpool John Moores University)
Dealing with specials

Responding to members’ requests the Society presents practical guidance for pharmacists on professional responsibilities when dealing with the supply of specials

As a pharmacist, you’ve worked incredibly hard to get where you are today.
As a professional, your patients place their trust in your expertise and care.
Your new Society will champion your vital role in improving the health of the nation. Providing accessible healthcare advice, supplying medicines or managing long term conditions; the public and other healthcare professionals need to better appreciate and value the services you provide.
We will work with you, our members, to ensure you are recognised for the great work you do.
And the commitment you show to the profession, and to your own development, as a member of the new Society, will entitle you to use the professional designation of MRPharmS or FRPharmS.
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GOOD PRACTICE GUIDANCE ON:
THE PROCUREMENT AND SUPPLY OF PHARMACEUTICAL SPECIALS

Background
Pharmacists throughout the whole of the supply chain have a responsibility for procuring and supplying specials in a professional manner. We are aware that the supply chain encompasses manufacturing, prescribing, procuring and dispensing of specials. This guidance only addresses part of that whole process. Other parts need to be considered by other organisations.

Over the last few years pharmacists have increasingly bought in specials rather than prepare products extemporaneously within the pharmacy setting. This practice has arisen from a need to ensure quality in the manufacturing process and to enhance patient safety.

This guidance provides good practice advice on the key professional responsibilities for pharmacists when dealing with the supply of specials.

There are patients who do benefit from receiving a special and this guidance will help pharmacists in providing the appropriate product and advice for their patients.

n.b: this guidance is specific to the use of specials. It does NOT apply to licensed products used outside the clinical indications of their licence i.e. “off-label” use.*

Community, hospital, primary care and industrial pharmacists are encouraged to engage with one another and with prescribers to discuss the issue of specials. This can lead to a more efficient procurement of specials within the locality.

Pharmacists also need to raise awareness of prescribers to the issue of specials as they themselves are not always aware they are prescribing a special and therefore will not be aware that as a bespoke special it is likely to be more expensive to procure than a licensed product.

The Society would like to thank the contributors from Hospital, Primary Care and Community practice, specials Manufacturers, NHS Quality Assurance and PSNC for their help in developing this guidance.

Content
The document is divided into 8 sections:
1. Purpose of this document
2. General Information about specials
3. Key Professional Responsibilities
4. Assessing Clinical Need
5. Choosing a Suitable Product
6. Choosing a Suitable Supplier and Placing an Order
7. Good Record Keeping
8. Useful Resources
9. Glossary of terms and abbreviations
10. Annex A – Hierarchy of risk
11. Annex B – Decision aid flowchart

If you have any enquiries about this guidance, please contact the Information and Advisory Service at RPSGB on 0207 572 2302

1. Purpose
This document aims to:
- Provide ‘good practice guidance’ on the key professional responsibilities for pharmacists when dealing with the supply of specials.
- Encourage pharmacists working in Primary Care Organisations and community pharmacy to work collaboratively with each other and with GPs to update and inform on prescribing policy and support joint working.
- Help support clinical governance in pharmacy.

2. General Information about specials (also see Glossary of Terms and Abbreviations)
- The term specials has a number of meanings. In the context of this guidance it can be taken to include:
  - A medicine manufactured by a specials manufacturer holding a Manufacturer’s specials Licence (MS) in multiple quantities with end product analytical testing
  - A special medicine produced by a specials manufacturer holding a MS as a bespoke medicine without end product analytical testing
  - Extemporaneously prepared medicines – unlicensed medicines made in a pharmacy under a pharmacist’s direct supervision
- Every medicinal product marketed in the UK is issued a Marketing Authorisation (MA) number by the regulatory authority, the Medicines and Healthcare products Regulatory Authority (MHRA) or by the European Medicines Agency (EMEA). The MA, previously known as a Product Licence (PL), or ECE/authorisation, guarantees that the quality, safety and efficacy of a medicine has been rigorously assessed, and must be displayed on the pack.
- To manufacture specials in the UK, an

3. Key Professional Responsibilities

CODE OF ETHICS:

1. MAKE THE CARE OF PATIENTS YOUR FIRST CONCERN
1.5 Seek to ensure safe and timely access to medicines and take steps to be satisfied of the clinical appropriateness of medicines supplied to individual patients.
1.7 Be satisfied as to the integrity and quality of products to be supplied to patients.
2. EXERCISE YOUR PROFESSIONAL JUDGEMENT IN THE INTERESTS OF PATIENTS AND THE PUBLIC
2.3 Make best use of the resources available to you Professional Standards and Guidance for the Sale and Supply of Medicines
3. SUPPLY OF PRESCRIBED MEDICINES
Patients are entitled to expect the dispensing service provided to be accurate, accessible and reasonably prompt. Appropriate standard operating procedures must be in place for the dispensing services you provide, or are responsible for and you must ensure that:
GOOD PRACTICE GUIDANCE ON: THE PROCUREMENT AND SUPPLY OF PHARMACEUTICAL SPECIALS

Background
Pharmacy throughout the whole of the supply chain have a responsibility for procuring and supplying specials in a professional manner. We are aware that the supply chain encompasses manufacturing, prescribing, procuring and dispensing of specials. This guidance only addresses part of the whole process. Other parts need to be considered by other organisations.

Over the last few years pharmacists have increasingly bought in specials rather than prepare products extemporaneously within the pharmacy setting. This practice has arisen from a need to ensure quality in the manufacturing process and to enhance patient safety.

This guidance provides good practice advice on the key professional responsibilities for pharmacists when dealing with the supply of specials. It also encourages pharmacies to provide joint working with other health professionals and support in making appropriate choices for their patients.

This document is aimed at those organisations who receive a special and this guidance will help pharmacists in providing the appropriate product and advice for their patients.

1. Purpose
This document aims to:

• Provide ‘good practice guidance’ on the key professional responsibilities for pharmacists when dealing with the supply of specials.

• Encourage pharmacies to provide joint working with other health professionals and support in making appropriate choices for their patients.

• Support pharmacists when providing advice about or recommending specials.

2. General Information about specials (also see Glossary of Terms and Abbreviations)

3. Key Professional Responsibilities (Code of Ethics)

1. MAKE THE CARE OF PATIENTS YOUR FIRST CONCERN
2. SEEK TO ENSURE SAFE AND TIMELY ACCESS TO MEDICINES
3. MAKE SURE YOUR PRACTICE MEETS THE PATIENT'S CLINICAL NEEDS
4. EXERCISE YOUR PROFESSIONAL JUDGEMENT IN THE INTERESTS OF PATIENTS AND THE PUBLIC
5. MAKE THE BEST USE OF THE RESOURCES AVAILABLE TO YOU
6. PATIENT SAFETY
7. PATIENT ACCURACY
8. PATIENT INFORMATION
9. PATIENT RECORDS
10. PATIENT CONFIDENTIALITY
11. PATIENT RESPONSIBILITY

4. Choosing a Suitable Product

5. Choosing a Suitable Supplier and Placing an Order

6. Good Record Keeping

7. Useful Resources

8. Glossary of terms and abbreviations


10. Annex B – Decision aid Rowchart

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Pharmacists also need to raise awareness of prescribers to the issue of specials as they themselves are not always aware they are prescribing a special and therefore will not be aware that a bespoke special is it likely to be more expensive to procure than a licensed product.

Keeping the patient’s needs for the medicine and taking steps to be assured of quality, safety and reliability is of the appropriate quality and clinically appropriate for their condition and their circumstances, with minimal clinical risk.

They understand their professional responsibilities when supplying specials i.e. ensure the patient receives a medicine of the appropriate quality.

They minimise risk to patients and themselves: the expectation is that pharmacists will supply an unlicensed product only by exception and with the full knowledge of the prescriber and the patient.

A pharmacist shares with the prescriber, accountability for supplying a Special to a patient. They must be able to demonstrate that they have acted with due diligence in regards to patient safety, and that they have taken all reasonable steps to ensure:

• Procurement from an appropriate source

• The product is of appropriate quality

• That the product meets the particular clinical needs of the patient: this may require dialogue with the manufacturer, and if relevant the hospital pharmacy, about formulation, strengths etc.

• That relevant records are kept

3.2 Every prescription is clinically assessed by a pharmacist to determine its suitability for the patient.

3.7 A product with a marketing authorisation is supplied where such a product exists in a suitable formulation and in an unlicensed preference to an unlicensed product or food supplement.

1.1.1 Reimbursement claims for NHS or other professional services are honest and accurate.

To meet these standards all pharmacists have a professional responsibility to ensure that:

• Patients receive medication that is safe, effective, appropriate for their condition and their circumstances, with minimal clinical risk.

• A special is supplied (if you are a pharmacist prescriber) supplied (if you are dispensing it) only when there is no available licensed medicine which fully meets the patient’s clinical needs.

• A pharmacist is aware of the microsomal enzyme inducers and inhibitors.

• A pharmacist is aware that a medicine with this stability of the products containing this medicine in neonatal and paediatric age.
the following points around quality should be supplied to the patient remains exempt or under a MS, the pharmacist who makes a special is made under section 10 of the Data Protection Act and contains a route (other than a pharmacist) to show the heading 'special' on the dispensing label. Whether a special is made under section 10 of the Data Protection Act and contains a route (other than a pharmacist) to show the heading 'special' on the dispensing label.

Safety and Quality considerations

Whether a special is made under section 10 exemption or under a MS, the pharmacist who supplies the product to the patient remains accountable for its quality and should take all reasonable steps to assure it. Where a decision is taken to supply a special, the following points around quality should be considered:

- Pharmacist should agree with the supplier what they require, which includes strength, formulation and excipients, where relevant, such as requirements for sugar-free or alcohol-free formulations. This will be based on the pharmacist’s understanding of the clinical needs of the patient.
- Where feasible the agreed formulation should be confirmed to the manufacturer in a written order.
- Pharmacist should not assume any aspect of quality and take all reasonable steps to ensure that the product supplied is of a suitable standard.
- Comes with a certificate of analysis or a certificate of conformity to show it has been produced in batches a certificate of conformity confirms that, in conformance with its release specification i.e. that it is of the specification against which the tests were performed.
- A Certificate of Analysis should state:
  - The laboratory/organisation issuing it
  - Be authorised by an appropriately qualified person with signature
  - Be specific to the batch concerned (state the batch number which matches that of the medicine supplied)
- Clearly indicate who performed the tests and the date
- State the specification against which the tests were performed
- State the test results (actual result or ‘complies’)
- A Certificate of Conformity states that the batch of medicine supplied matches that of the medicine supplied.
- The Laboratory/organisation issuing it
- Be authorised by an appropriately qualified person with signature
- Be specific to the batch concerned (state the batch number which matches that of the medicine supplied)
- Clearly indicate who performed the tests and the date
- State the specification against which the tests were performed
- The Laboratory/organisation issuing it
- Be authorised by an appropriately qualified person with signature
- Be specific to the batch concerned (state the batch number which matches that of the medicine supplied)
- Clearly indicate who performed the tests and the date
- State the specification against which the tests were performed
- State the test results (actual result or ‘complies’)

7. Good Record Keeping

The MHRA has specific requirements around record keeping for all specials, including these that are imported. In addition, pharmacists should also comply with the RPSGB guideline on record keeping for unlicensed medicines (http://www.rpsgb.org/pdfs/factsheet5.pdf).

It is recommended to maintain the following records:

- **TO BE KEPT FOR A MINIMUM OF 5 YEARS**
  - A record of the purchase and supply of a special and the specification of the product agreed with the supplier (see safety and quality considerations) should be documented and kept on file in the pharmacy for at least five years.
  - Documentation to verify the specifications i.e. certificate of analysis or a certificate of conformity from the manufacturer, should be obtained on delivery and must include the batch number and expiry details of the product, kept on file in the pharmacy.
  - Patient details, such as name and address linked to the special should also be maintained to provide an adequate audit trail.
  - The source of the product i.e. manufacturer details.
  - The quantity of each sale or supply.
  - The batch number and expiry date of the product (listed on certificate of analysis or a certificate of conformity).
  - If the product is in response to a prescription, the records must also include the patient details, prescription details and the date of dispensing.
  - The date the product was supplied (as may differ from the date of manufacture).

*The MHRA requires a minimum of 5 years, but in some circumstances it may be advisable to retain documents for longer periods.*

**No洛杉矶 some specials such as fluids that are used as standard supplies and are therefore used as general stock. The Trust recommends retaining a copy of the order issued to the supplier in one of these cases.**

8. Useful Resources

There are several documents which impact on the procurement and supply of specials, as referenced in the text:

- RPSGB Legal and Ethical Advisory Service Fact Sheet 1: The use of Unlicensed Medicines in Pharmacy (http://www.rpsgb.org/pdfs/factsheet5.pdf)
- This document summarises the legislation and best practices when issuing unlicensed medicines.
- MHRA Guidance Note 14: The supply of unlicensed relevant medicinal products for individual patients (http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007547.pdf)
- Recommendations for the Retention of Pharmacy Records: Hospital Pharmacist 2008; 15: 254 (full text accessible via PJ Online)
- Guidance for the purchase and supply of unlicensed medicinal products: Notes for Prescribers and Pharmacists. (http://www. partial.nhls.nhs.uk/ade/default.aspx) You need to be a member of the National Electronic Library for Medicines (NLMV) to view this document.
- The Association of Commercial special Manufacturers website which provides information on their code of conduct and general information on unlicensed medicines, as well as links to member organisations. The address is www.acsm.org.uk
Safety and Quality considerations

Whether a special is made under section 10 exemption or under a MS, the pharmacist who supplies the product to the patient remains accountable for its quality and should take all reasonable steps to assure it. Where a decision is taken to supply a special, the following points around quality should be considered:

- Pharmacists should agree with the supplier what they require, which includes strength, formulation and excipients, where relevant, such as requirements for sugar-free or alcohol-free formulations. This will be based on the pharmacist’s understanding of the clinical needs of the patient.

- Where feasible the agreed formulation should be confirmed to the manufacturer in a written order.

- Pharmacists should not assume any aspect of quality and take all reasonable steps to ensure that the product supplied:
  - Is of a suitable standard.
  - Comes with a certificate of analysis or a certificate of conformity.
  - Is pharmacologically appropriate and suitable for the patient (e.g. check strength, formulation and excipient details on the label).
  - An MHRA licensed specials supplier is preferred and details of registered licensed manufacturing sites can be found at www.mhra.gov.uk/PharmacueticalIndustry/ ManufacturingandWholesaling/index.htm.

Details of NHS hospital manufacturing departments are listed in the BNF.

- Preference should be given to suppliers with a history of satisfactory service to the pharmacy, although new providers and those who are in agreement with good feedback from other pharmacies should also be considered, especially if this could secure improvements. A supply chain involving more than three parties is potentially associated with additional risk and cost.

- When dispensing a repeat supply rather than a new treatment, it is advisable to use the same supplier if possible, to ensure product consistency, see Case Study 3

- Regularly check that your chosen supplier is offering the best overall service, taking into account quality, promptness of supply and value for money.

- Responsible Pharmacists can amend or change existing SOPs if they believe that the SOP in its current format does not support best practice as described in this guidance.

Example case study

A child with epilepsy was prescribed clonazepam tablets, which are licensed for epilepsy for children aged 3 years and older. The mother reported that the child was struggling to swallow the tablets and the GP decided that it was necessary to prescribe a liquid preparation. The BNF for Children confirmed that no licensed liquid was available, so the GP spelt out a prescription for the appropriate concentration and strength of liquid clonazepam. The community pharmacist subsequently dispensed this clonazepam as an extra-pyramidal medicine. The mother returned a week later reporting that the child had increased fitting. Although the GP prescribed clonazepam liquid at the appropriate dose and strength and the pharmacist dispensed the correct medicine, clonazepam is very hard to suspend. This means that unless the product is developed as a sterile liquid, it has an appropriate formula and production method, and the bottle is shaken well before dosing, the amount of active ingredient that the child will receive in each dose will vary enormously. Indeed, in some bottle, clonazepam is so mixed on the bottom of the bottle that the strength of the suspension is only 20% of that expected, even after vigorous shaking. While it is hard for the GP to avoid such a problem, advice could be sought from the original prescriber or pharmacist to ensure that the child receives the most appropriate unlicensed medicine. They should also be prepared to closely monitor the patient and warn patients/carers that symptom control may vary when swapping between products that are not licensed. Changing preparations may impact on symptom control and result in adverse events.

Good Record Keeping

The MHRA has specific requirements around record keeping for all specials, including those that are imported. In addition, pharmacists should also comply with the RPSGB guidelines on record keeping for unlicensed medicines (http://www.rpsgb.org/pdfs/factsheet5.pdf).

It is recommended to maintain the following records:

**TO BE KEPT FOR A MINIMUM OF 5 YEARS**

- A record of the purchase of a special and the specification of the product agreed with the supplier (see safety and quality considerations) should be documented and kept on file in the pharmacy for at least five years.

- Documentation to verify the specifications i.e. certificate of analysis or a certificate of conformity from the manufacturer, should be obtained on delivery and must include the batch number and expiry details of the product, kept on file in the pharmacy.

- Patient details, such as name and address linked to the special should also be maintained to provide an adequate audit trail.

- The source of the product i.e. manufacturer details.

- The quantity of each sale or supply.

- The batch number and expiry date of the product (listed on certificate of analysis or a certificate of conformity).

- If the product is in response to a prescription, the records must also include the patient’s details, prescription details and the date of dispensing.

- The date the product was supplied (as may differ from the date of manufacture).

**Note:** The MHRA requires a minimum of 5 years, but in practice pharmacies are accountable for the quality, and traceability under the Consumer Protection Act may be brought after many years, pharmacists could decide to make records for longer periods.

**Note:** In addition, some specials such as fluids are used as standard supplies and are therefore stock at ward level. The Trust may retain copies for up to six months of one of these particular specials as long as appropriate governance is in place, there may be exceptions to the requirements in the table above.

**Practice Tip**

Pharmacists are recommended to have a validated and operational Standard Operating Procedure (SOP) in place detailing the steps involved in the ordering of specials including risk assessments of the different options available.

When developing an SOP the following should be considered:

- An SOP for ordering specials demonstrates that the pharmacist has understood the need to follow a process for this and how this can be achieved.

- A written order listing the formula of the product required demonstrates that the pharmacist has understood exactly what is required and communicated that accurately to the supplier.

- For products produced in batches a certificate of analysis confirms that levels of active ingredients have been retrospectively confirmed by testing a sample of the final product.

- For products produced individually, as a one-off, a certificate of conformity confirms that, to the best of the knowledge of the signatory, the final product conforms to the specifications supplied by the pharmacist.

- An MHRA licensed specials supplier is preferred and details of registered licensed manufacturing sites can be found at www.mhra.gov.uk/PharmacueticalIndustry/ManufacturingandWholesaling/index.htm.

- A certificate of conformity from the manufacturer to have evidence to support the quality of a product if the purchaser knows what the release specification of the product in question actually is – see MA above.

- The Marketing Authorisation (MA) defines the therapeutic or diagnostic use, dosage and administration, the specification against which the tests were performed, the certificate of analysis and the date of manufacture of the medicine. The MA provides the authority granted under the Medicines and the FBA for the NA holder to promote or sell the product for these purposes. The permitted clinical indications stated in the MA are based on the data submitted by the MA holder during the licensing process. As such the safety, quality and efficacy of the medicine for use as stated within the MA is in the hands of the person performing the tests who is indicated on the certificate of analysis. The MA holder must have evidence to prove that the tests have been performed under a certificate of conformity approved by the regulating body (the MHRA in the UK or the EMEA in Europe). The MA was formally known as the product licence before harmonisation of the Medicines with EU law.

- A special medicine produced by a special manufacturer holding a MS is a bespoke medicine without end product analytical testing.

- A certificate of analysis from the manufacturer including a list of the ingredients, indicating who performed the tests and the date the tests were performed, as well as specifying which batch was tested.

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Certificate of Conformity

- A certificate of conformity from the manufacturer to have evidence to support the quality of a product if the purchaser knows what the release specification of the product in question actually is – see MA above.

- The Association of Commercial Specials Manufacturers website which provides information on their code of conduct and general information on unlicensed medicines, as well as links to member organisations. The website is www.acsm-uk.com.


8. Useful Resources

There are several documents which impact on the procurement and supply of specials, as referenced in the text:

- RPSGB Legal and Ethical Advisory Service Fact Sheet 5: The use of Unlicensed Medicines in Pharmacy (http://www.rpsgb.org/pdfs/factsheet5.pdf)

- This document summarises the legislation and best practices when issuing unlicensed medicines.


- You need to be a member of the National Electronic Library for Medicines (NLMV) to view this document.


The Association of Commercial Specials Manufacturers website which provides information on their code of conduct and general information on unlicensed medicines, as well as links to member organisations. The address is www.acsm-uk.com.

Hierarchy of risk on basis of product origin
(adapted from MHRA guidance)

UK-licensed medicine
Off label use of a UK-licensed medicine
An imported product licensed in the country of origin
A UK manufactured special made in MHRA licensed facilities
An extemporaneously dispensed medicine
An imported product not licensed in the country of origin
A non-UK-made unlicensed medicine or food supplement

Preferred choice

Lowest net risk

Last choice

Highest net risk

N.B. This hierarchy diagram was updated in June 2011. Please read the text on following page.

Hierarchy may differ in particular patient groups such as neonates

Decision aid/flowchart
Supplying a special: decision guide

Prescription received

Confirm patient's special clinical need
Can it only be met by the use of an unlicensed medicine?

No

You should supply a licensed product: discuss with prescriber

Use original supplier?

Yes: Email or fax repeat order, specifying full formulation, to original supplier

No: discuss product with potential suppliers

Yes

Confirm all formulation details of product previously supplied

Is this a new prescription?

No

Yes

Clarify the patient’s requirements and identify a suitable product

Agree formulation with appropriate potential supplier(s)

Email or fax order, specifying full formulation to chosen supplier

Other matters outside the terms of this guidance
The guidance above is intended to ensure that specials are only used when there is no available, clinically appropriate, licensed medicine. All pharmacists are encouraged to ensure that the NHS secures good value from its expenditure, and pharmacists should bear this in mind in procurement of specials.
In response to comments received about the Society’s Good Practice Guidance on the Procurement and Supply of Pharmaceutical Specials, published in June 2010, we have clarified the advice it includes about crushing tablets and opening capsules. Reference to this option has been deleted from the hierarchy of risk which now relates only to choice of medicinal product. The circumstances in which it may be in the patient’s best interests to choose a licensed product but to recommend administration by “off-label” means, such as crushing a tablet, is discussed separately as follows:

“When considering how best to supply essential medicines for a patient unable to swallow tablets or capsules, pharmacists should use their professional judgement to choose the most appropriate product for an individual patient, taking into account the views of the prescriber as well as the clinical needs of the patient, their wishes and capabilities and those of their carers, where relevant. There may be some circumstances where crushing is clearly the preferred option such as when a stable oral liquid product can’t be formulated or made available when required, or if the patient finds an oral liquid unacceptable. Fine-bore tubes may be easily blocked by viscous liquids and tablet particles. Where this is a potential issue, pharmacists are recommended to consult specialist references such as the Handbook of Drug Administration via Enteral Feeding Tubes (Pharmaceutical Press). It is important for pharmacists to be aware that there are risks & responsibilities associated with the dispensing of Specials as well as with recommending crushing/splitting tablets or opening capsules. Pharmacists should use their professional judgement to make a decision in the best interests of each patient, to optimise treatment and to minimise the risk of harm.”

Where to go for further information
RPS Support: 0845 257 2570
Email: support@rpharms.com
Website: www.rpharms.com/best-practice/specials.asp

Supporting guidance

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APPENDIX 3 - AN ACTION LIST FOR PCT PHARMACEUTICAL ADVISERS TO MANAGE PHARMACEUTICAL SPECIALS

Introduction

There has been considerable concern about the market for pharmaceutical specials in primary care where costs of both individual items and budgets have grown very quickly. This practical set of actions offers pharmacy managers working in PCTs a range of options they may wish to consider in attempting to manage this market in their locality. No one option will deliver complete control but a range may have an effect.

The options have been split into collecting and collating information, in attempting to control demand for pharmaceutical specials or to control the supply.

DEMAND SIDE MEASURES

The overall guidance document on the East of England Procurement Hub website (http://www.eoecph.nhs.uk/)

• Containment of commercial companies activities
• Incentive scheme for GPs
• Authorisation schemes
• KPI for practices
• Practice visits
• Local enhanced scheme with community
• Post payment verification
• Specials focus team
• End of life guidelines
• Medicines Information facility.

SUPPLY SIDE MEASURES

• Request community pharmacists use cost effective suppliers
• Best value list
• Arrangements with secondary care.

PROFESSIONAL GUIDANCE

• Royal Pharmaceutical Society best practice guidance
• Training on unlicensed medicines for pharmacists.

COLLECTING INFORMATION

This subject describes the collecting of data with the use of the ePACT software and is covered later in this specials guidance. Eclipse software can also be used for this purpose and a guide is also included in this document.
DEMAND SIDE MEASURES

This action list sits within the overall education package and has been developed by a group of pharmacy specialists in the East of England. It is hosted on the East of England Procurement Hub website (http://www.eoecph.nhs.uk/) and is aimed at prescribers, pharmacists and care home staff.

• Consider advising nursing homes not to allow commercial pharmaceutical companies to provide education programmes into homes.

• Add an incentive scheme for GPs. Current examples:
  • Number of specials prescribed not authorised by PCT. (Several PCTs have authorisation schemes)
  • Number of specials prescribed per 1000 patients
  • PCT could develop a KPI for practices (e.g. Cost per 1000 patients). For example NIC/ASTROPU

• Make discussion of specials part of practice visits. Consider the following:
  • Compare practice with RPSGB guidelines specifically SOPs and evidence of risk assessments undertaken.
  • Ensure pharmacist understand the professional responsibilities and risks associated with these medicines.
  • Check that quotes are obtained from at least three specials manufacturers
  • Compare prices with hub indicative list
  • Check that Certificate of Analysis or Conformity is being requested and retained.
  • Ensure the PSNC statement on specials is understood and followed.

• Set up a Local Enhanced Scheme with community pharmacists to review prescriptions for specials and to use a cost effective supplier

• Post Payment Verification - If the returns from the PPD are scrutinised it is possible to identify high cost items. In these cases it is possible to ask the community pharmacist involved for proof of the costs incurred. This can lead to errors being corrected and in repayments in many cases.

• Implement end of life guidelines to stop unnecessary prescribing of these agents.

• A project is underway in Suffolk to evaluate the effect of a medicines information resource, made available to community pharmacists to enable evidence based advice about alternatives to unlicensed medicines (e.g. alternative forms or crushing tablets). It may be cost effective to expand this (or the FAQs developed) across the whole region.

Supply Side Measures

• Request community pharmacists use cost effective suppliers. Whilst this will very quickly become dated it illustrates market variability and provides some sort of benchmark.

• Set up best practice arrangements for secondary care to continue to prescribe specials, manufacture in technical services, and dispense with courier service. Trusts to charge realistic rate to PCTs to cover this.

Professional Guidance

The Royal Pharmaceutical Society of Great Britain is considering a paper on best practice guidelines. This paper details the professional responsibilities of the pharmacist in providing the patient with the medicine (either an unlicensed product or a licensed alternative) best suited to the clinical need of the patient and which presents them with the lowest clinical risk.
APPENDIX 4: NEW ARRANGEMENTS FOR REIMBURSING SPECIALS - Q&A

The following Q&A is available on the NHS Business Services Authority website (accessed 08/03/2012) http://www.nhsbsa.nhs.uk/documents/prescriptionservices/20111011_specials_tariff_q_and_a.pdf

What are the new arrangements for reimbursing specials?

DH has worked closely with the PSNC to introduce new reimbursement arrangements for specials, which will come into effect from 1 November 2011. As part of the new arrangements, a number of specials will be listed in the Drug Tariff. The initial list, which will form a new part of the Drug Tariff (Part VIIIB) will be relatively small but will capture the majority of high cost, high volume specials prescribed. The list and the reimbursement prices of the products listed will be reviewed regularly and the list will be expanded, as appropriate.

For those specials not listed in Part VIIIB, payment will depend on how the product is sourced. A new fee for products made under the Section 10 exemption and new arrangements for out of pocket expenses will apply.

Why are the DH introducing new arrangements for reimbursing specials?

The aim of the new arrangements is to create a more transparent system for reimbursing specials, linking the cost of reimbursement to the cost of the product, while providing value for money for the NHS. Having a Drug Tariff price will create an incentive for pharmacy contractors to procure in a manner that is cost-effective for the NHS. Further, the new arrangements will simplify the arrangements for claiming and payment for sourcing specials.

Is the aim of the new arrangements to stop pharmacies from making lots of excess profit on the purchase of specials?

The aims of the new arrangements are outlined above. The funding arrangements for community pharmacy contractual framework (CPCF) recognise that community pharmacy contractors retain a margin on the products they supply against NHS prescriptions.

Each year, in conjunction with the PSNC, the Department holds a margin survey to investigate how much medicine margin the average pharmacy contractor has retained in the previous year. Taking account of the results of the margin survey, the prices of the generic products in Category M are adjusted to ensure that the target amount of retained margin is available. Currently, the target amount of retained margin is set at £500m per annum. Margin retained from procuring specials is considered as part of these CPCF funding arrangements.

When will the Part VIIIB price be paid for a special?

Under the new arrangements, pharmacy contractors will be paid the Part VIIIB price for any product listed in this Part, regardless of how they sourced the product.

Where there is not a significant price difference between the different formulations, the Part VIIIB listing will incorporate as many formulations as possible under the umbrella of a single drug name, e.g. where amlodipine 5mg/5ml solution is listed; this will incorporate the standard formulation along with sugar free, colour free, lactose free. A formulation will be considered a ‘standard’ where the prescriber has not specified a formulation above stating solution or suspension.

However, where there is a significant price difference between the formulations, the formulations may either be listed separately (solution versus suspension) or treated as a non-Part VIII product.
There may be instances where a drug has both licensed and unlicensed formulations available and as a result one formulation will be listed in Part VIIIB and others in Part VIII or IX. For example, sodium chloride eye drops is listed in Part IXA as an appliance but the preservative free formulation is listed in Part VIIIB. In this instance, the pharmacy contractor will be paid the Part IX price unless the preservative free formulation is specifically prescribed.

How will products not listed in Part VIIIB be reimbursed?

Due to the number of specials potentially available, it is not possible to list all the specials available to prescribe. Therefore, new arrangements have been introduced to reimburse those products not listed.

Payment will depend on how the product was manufactured.

1. Where the product is manufactured by a manufacturer licensed by the MHRA and operating under their specials licence, the pharmacy contractor will be paid the price that they pay (invoice price minus any discount/rebates given) for the product.

2. Where it is manufactured under the section 10 exemption (by the pharmacy contractor or a 3rd party), the pharmacy contractor will be paid the cost of the ingredients in the product.

Apart from the cost of the product, what other payments will be made?

Regardless of whether a product is listed in Part VIIIB or not, contractors will be eligible to an additional payment, which will depend on how the product was sourced.

- Where the product has been prepared by a manufacturer operating under a Specials Licence issued by the MHRA – a payment of £20 to contribute to out of pocket expenses e.g. carriage. This payment must be claimed by endorsing SP on the prescription. The usual way of claiming out of pocket expenses (via the FP34C) must not be used.

- Where the product is prepared under the Section 10 exemption (by the contractor or a 3rd party), a £20 extemporaneous dispensing fee will be paid to recognise the cost of preparing the product or the cost of sourcing the product from a supplier who has produced the product under the Section 10 exemption. This payment must be claimed by endorsing ED on the prescription.

The professional fee will be paid for every special supplied and other fees e.g. CD or expensive item fees will be paid as appropriate.

How have the Part VIIIB prices been calculated?

A system similar to that used for the calculation of the price of category M generics has been employed, using sales and volume data from suppliers. Under a memorandum of understanding (MOU), a selection of licensed specials manufacturers have provided sales information to DH, which has been used to set a reimbursement price that includes margin.

When setting the value of the payment for out of pocket expenses (e.g. carriage, wholesalers charges), the DH used information supplied by specials manufacturers concerning the cost of carriage for a wide range of specials e.g. liquid specials, controlled drugs and fridge lines. Emergency supply and location were also considered.

When considering the value of the payment for products prepared under the Section 10 exemption, the time and equipment needed to extemporaneously prepare a product was assessed.

The prescriber has prescribed a ‘liquid’ – what will I be paid?
Where a drug is listed in Part VIIIB as both a solution and suspension e.g. Amitriptyline 10mg/5ml, pharmacy contractors will need to clarify which formulation the prescriber wanted the patient to receive. To ensure prompt and accurate payment, the pharmacy contractor should endorse the prescription with the formulation provided.

Where only one formulation has been listed in Part VIIIB, e.g. Bendroflumethiazide 2.5mg/5ml oral suspension, the pharmacy contractor will need to clarify what the prescriber wanted the patient to receive. Depending on whether they supplied the product listed in Part VIIIB or supply a non Part VIII special, the pharmacy contractor will need to endorse as appropriate to ensure accurate and prompt payment.

**What are the endorsement requirements for specials?**

Endorsement requirements outlined in Part II Clause 9 of the Drug Tariff applies when endorsing specials. For products listed in Part VIIIB, typically the contractor will only need to indicate whether they are claiming the £20 payment for out of pocket expenses (by endorsing SP) or claiming the extemporaneous dispensing fee (by endorsing ED).

However, for products not listed in Part VIIIB, contractors must endorse the prescription according to how the special was sourced.

1. Where the special is manufactured under a specials licence by a manufacturer holding a Specials Licence issued by the MHRA, the contractor must endorse the:
   - Invoice price less discount/rebates (the amount actually paid for the product
   - Manufacturer's licence number
   - Batch number of the product.

2. Where the special has been prepared under the Section 10 exemption from the Medicines Act 1968, by the contractor or by a third party, the contractor shall endorse the names, quantities and cost of the ingredients used in preparing the special.

Where any of the above information is missing, the prescription form will be returned to the contractor for clarification and may delay payment.

**How often will the Specials Tariff be updated?**

In general, there will be two types of review. There will be a:

- Rolling quarterly review. This review will reassess prices only and prices will be updated as appropriate.
- Six monthly review in which prescribing data will be examined to allow products to enter and exit the list. The aim is to produce a list that can be easily updated to incorporate changes in prescribing habits.

Flexibility concerning these reviews will be required, especially in the initial period as Part VIIIB becomes established. Furthermore, where a special becomes available as a licensed product outside of these reviews, the Drug Tariff will be updated to reflect the introduction of the licensed product.

**My usual supplier sells the special I require at a price higher than the Drug Tariff; can I claim the extra cost?**
No. Pharmacy contractors are expected to shop around and negotiate lower prices in a similar way they do for generics.

I have contacted a number of manufacturers and I cannot source the product below the Drug Tariff price – what should I do?

Unless there are exceptional circumstances pharmacy contractors should be able to purchase the products in Part VIIIB below the Tariff price. Pharmacy contractors will need to ensure they have considered a range of suppliers and where they are still having difficulties, pharmacy contractors should contact PSNC. The PSNC will monitor the situation and will consider whether it is appropriate to apply to the DH for an NCSO concession.

Where an NCSO concession is granted, pharmacy contractors will be able to source the product from wherever it is available and be paid the cost of product they have procured. To ensure they are paid this cost, they must endorse in line with Part II Clause 9C of the Drug Tariff.

What will happen to Part VIII Category E products?

With the introduction of Part VIIIB, category E will be deleted from the Tariff from November. The ingredients of products listed in category E will also be deleted, as appropriate.

How will I know if my supplier is an MHRA licensed manufacturer or operating under the manufacturing part of the Section 10 exemption from the Medicines Act?

It is for each pharmacy contractor to determine whether their supplier has a specials licence issued by the MHRA. They may ask their supplier when placing the order; however, the following websites may also be useful:

- http://www.acsm.uk.com

How will I know if a licensed manufacturer has prepared the product under their licence or under the Section 10 exemption?

The British Pharmacopoeia outlines the requirements for the labelling of medicinal products including manufacturer’s ML number (where appropriate) and manufacturers name and address. As a result, specials manufacturers must print their name, address and licence number on the product label where they have manufactured it under their MHRA specials licence. As those companies or pharmacies manufacturing solely under the section 10 exemption will not have a licence number, they are required to print their name and address only.

In January 2008, the MHRA issued the guidance note 14, “the supply of unlicensed relevant medicinal products for individual patients”, which also states that where a specials manufacturer is also a registered pharmacy supplying products prepared under the Section 10 exemption, the labels of these products should not make reference to the manufacturer’s licence or number.

Contractors may also wish to consider other professional guidance when deciding how to source their specials


I normally source my specials from a manufacturer holding a specials manufacturing licence – how will I be paid for my specials?
Where the product is listed in Part VIIIB, the pharmacy contractor will be paid this price regardless of how they sourced the product – from a specials manufacturer or prepared under the Section 10 exemption of the Medicines Act 1968 (by the pharmacy contractor or by a third party).

Where a special not listed Part VIIIB has been manufactured under a specials manufacturing licence, the pharmacy contractor will be paid the supplier’s invoice price less discount (the supplier may be the manufacturer or a 3rd party e.g. a wholesaler). To ensure accurate and prompt payment, the pharmacy contractor will need to know what they have paid for the product - invoice price less all discounts and rebates.

However, there are times where a specials manufacturer prepares specials under the Section 10 exemption. In these circumstances, the contractor will be paid the cost of the ingredients used to prepare the product.

To claim the appropriate additional payment, the contractor must endorse SP if the product was manufactured under the manufacturer’s Specials Licence and ED if it has been prepared under the Section 10 exemption.

**I normally source my specials from a manufacturer operating under the Section 10 exemption – how will I be paid for my specials?**

Where the product is listed in Part VIIIB, the pharmacy contractor will be paid the Part VIIIB price regardless of how the product was sourced.

Where a special is not listed in Part VIIIB and has been prepared under the Section 10 exemption (by the pharmacy contractor or a third party), the pharmacy contractor will be paid the cost of the ingredients used in preparing the product. To ensure accurate and prompt payment, the pharmacy contractor will need to endorse the ingredients used in preparing the product along with the quantity and cost of each ingredient used.

To claim the appropriate additional payment, the contractor must endorse ED as the product has been prepared under the Section 10 exemption.

**I normally source my specials through a wholesaler – how will I be paid for my specials?**

Where the product is listed in Part VIIIB, the pharmacy contractor will be paid the Part VIIIB price regardless of how they sourced the product.

For products not listed in Part VIIIB the pharmacy contractor will be paid depending on whether the product is manufactured by a specials manufacturer operating under their specials licence or under the Section 10 exemption (as outlined previously). The pharmacy contractor will therefore need to establish how the product has been prepared.

Along with payment for the product, the contractor will also be paid the appropriate additional payment depending on whether the product was manufactured by a MHRA licensed specials manufacturer under their licence (they must endorse SP) or manufactured under the Section 10 exemption by the contractor or by a 3rd party (they must endorse ED).

**I have extemporaneously dispensed a product for my patient – how will I be paid?**

As outlined above, where the product is listed in Part VIIIB, the pharmacy contractor will be paid the Part VIIIB price regardless of how they sourced the product.

Where a special is not listed in Part VIIIB and has been prepared under the Section 10 exemption by the pharmacy contractor, the pharmacy contractor will be paid the cost of the ingredients used in preparing the product. To ensure accurate and prompt payment, the pharmacy contractor will need to endorse the
ingredients used in preparing the product and the quantity of each ingredient used.

To claim the appropriate additional payment, the contractor must endorse ED as the product has been prepared under the Section 10 exemption.

**Will broken bulk be allowed on specials?**

That will depend on how the pharmacy contractor has sourced the product. When setting the reimbursement prices of products listed in Part VIIIB, available pack sizes were taken into account and the minimum quantity is based on the smallest available pack size produced. As a result, broken bulk cannot be claimed on products listed in Part VIIIB.

However, where a product has been extemporaneously prepared by the pharmacy contractor, broken bulk will be allowed on the ingredients used to prepare the product. This recognises that the pharmacy contractor may not have the opportunity to use the remainder of the open container used to prepare the special.

**Will out of pocket expenses be allowed on specials?**

Yes but as outlined above, pharmacy contractors will not claim their out of pocket expenses in the same way that they have traditionally claimed these expenses. As outlined previously, under the new arrangements, pharmacy contractors will be paid a flat payment, initially set at £20 for each prescription for a special that was manufactured by a specials manufacturers operating under an MHRA specials licence. This is to contribute to any expense incurred when sourcing the product from a third party e.g. carriage. Pharmacy contractors must endorse SP on the prescription form to reflect that they are claiming this payment.

Pharmacy contractors **MUST NOT** include these in their out of pocket expenses totals on their submission form they send with their prescriptions (FP34C) to the NHSBSA at the end of each month, as there may be a risk of payment being claimed that is not due (i.e. fraud) where this occurs.

**If I am charged more than £20 as an out of pocket expense, can I claim the additional expense?**

No. The value of this fee recognises that there will be times where pharmacy contractors will have paid less than the value of the payment in procuring the product but also times where they will have paid more. Overall, it should balance out.

**I extemporaneously prepare some of my orders for specials – is there an extemporaneous dispensing fee?**

Yes. With the introduction of these arrangements, the extemporaneous dispensing fee has been changed to reflect the work involved in extemporaneously dispensing a product. There will be a flat payment of £20 paid where a product has been prepared under the Section 10 exemption (by the contractor or a 3rd party). Pharmacy contractors must endorse ED on the prescription form to reflect that they are claiming this payment.

**The value of the out of pocket expenses payment and extemporaneous dispensing payment are the same – why do I have to endorse them differently?**

Pharmacy contractors are required to supply any information that may be required to calculate prices, payments, fees or allowances payable to pharmacy contractors.

By coincidence the initial value of both payments have been set at the same value. However, this may change at a later date when the payments are reviewed. Pharmacy contractors must endorse accurately to ensure prompt and accurate payment.
Will I still be able to claim Discount not Given (DNG) on my specials?

That will depend on whether the product is listed in Part VIIIIB or not. Where a product is listed in Part VIIIIB, DNG will not be available, as margin has been added to the reimbursement prices of products listed.

However, where a product is not listed in Part VIIIIB, pharmacy contractors will endorse the prescription with the invoice price less discount/rebate (the cost actually paid by the pharmacy contractor). In these cases, contractors will not need to endorse ‘DNG’ but discount will not be deducted. Special care should be taken when endorsing the price paid to ensure that the net price paid is endorsed and not the full invoice price. There may be a risk of payment being claimed that is not due (i.e. fraud) where not all discount has been reflected in the amount endorsed.

What records do I need to maintain under the new arrangements?

Under the current requirement on record keeping, there are obligations already in place requiring the pharmacy contractor to:

a. Keep the following records for 5 years:
   - The source of the product
   - The person to whom and the date on which the product was sold or supplied
   - The quantity of each sale or supply
   - The batch number of the product.

b. Make available these records for inspection by the Licensing Authority.

In addition to the above, pharmacy contractors shall keep a record of the prescriber details, which would be available for inspection by the PCT of the prescriber and/or pharmacy contractor, allowing the PCT to match expenditure to the product supplied.

For specials not listed in Part VIIIIB, the contractor or his representative will stamp, date, initial and endorse the Certificate of Analysis (COA)/ Certificate of Conformity (COC) with the price paid and prescriber’s details. At the end of each month, the contractor shall send a copy of the COA/COC to the PCT of the prescriber along with details of the prescriber, allowing the PCT to match expenditure to the special supplied.

As a PCT, we have introduced our own local specials arrangements - can we continue to use them?

The Department would recommend that any PCT undertaking arrangements separate to the new arrangements should consult their legal teams to ensure they are operating within the law. The only remuneration arrangements for pharmaceutical services that PCTs have the power to determine locally are remuneration for enhanced services and some remuneration for local pharmaceutical services.

Are imported products included in the new arrangements?

Yes. Under the new arrangements, pharmacy contractors will be paid the Part VIIIIB price for any product

1 MHRA Guidance Note No.14: the supply of unlicensed relevant medicinal products for individual patients
listed in this Part, regardless of how they sourced the product (from their usual wholesaler or from a 
specialist supplier).

Where an imported product is not listed in Part VIIIB, the pharmacy contractor will be paid the supplier’s 
invoice price less discount (the supplier may be a wholesaler). To ensure accurate and prompt payment, the 
pharmacy contractor will need to know what they have paid for the product - invoice price less all discounts 
and rebates.

For imported products, pharmacy contractors can only claim the additional £20 payment which contributes to 
the out of pocket expenses incurred in sourcing the product e.g. carriage. This payment must be claimed by 
endorsing SP on the prescription. The usual way of claiming out of pocket expenses (via the FP34C) must 
not be used.

**What are the endorsement requirements for imported products?**

Endorsement requirements outlined in Part II Clause 9 of the Drug Tariff applies when endorsing imported 
products. For products listed in Part VIIIB, typically the contractor will only need to indicate that they are 
claiming the £20 payment for out of pocket expenses (by endorsing SP).

However, for products not listed in Part VIIIB, contractors must endorse the following:

- Invoice price less discount/rebates (the amount actually paid for the product)
- Importer’s licence number (issued by the MHRA)
- Batch number of the product (if available).
APPENDIX 5: UNLICENSED SPECIALS AND IMPORTS FAQS

The Drug Tariff gives this definition of a special:

“Specials are unlicensed medicinal products manufactured in the UK for human use which have been specially prepared to meet a prescription ordered for individual patients without the need for the manufacturer to hold a marketing authorisation for the medicinal product concerned.”

a) What happens if I receive a prescription for an unlicensed special at the end of October and order it, but then don’t actually receive the product until November?

From 1st November 2011 contractors dispensing prescriptions for unlicensed specials and imports will be reimbursed under the new arrangements and products listed in Part VIIIB will be reimbursed at the fixed Drug Tariff price. Contractors should therefore be careful that any prescriptions received in October are submitted promptly for payment with October’s prescriptions, to avoid the risk of items being reimbursed at the November Drug Tariff price, which may be lower than the price they have been charged in October. If necessary contractors should contact their specials manufacturer by telephone to ascertain the invoice price for items ordered in October, if the invoice has not been received by the time the October prescription bundles are being prepared for dispatch to NHS Prescription Services.

b) What is happening with imported products?

Imported products will also be included in these new rules surrounding unlicensed specials.

c) How are the basic prices in Part VIIIB applied for reimbursement?

For Part VIIIB products, the minimum reimbursement a pharmacy contractor will receive is the list price for the pack size given. If the quantity on a prescription is more than the Part VIIIB listed pack size, reimbursement will be paid on the listed pack size plus the 1ml or 1g list price for every additional 1ml or 1g prescribed.

For example, a prescription for 200ml of an unlicensed special with a Part VIIIB listed pack size of 100ml, the price will be calculated as $1 \times 100\text{ml} + 100 \times 1\text{ml}$.

d) I normally source my specials through a wholesaler – how will I be paid for (and how should I endorse) my specials?

If you source a product through your wholesaler’s ‘special obtains’ department, it wouldn’t automatically be recognised as an unlicensed special. Wholesalers typically categorise products as being either a “standard line” or “special obtain” item. Items classified as “special obtains” are those which the wholesaler may not have readily available in stock. When an order is placed at the wholesaler, the wholesaler will then specifically obtain the product on a bespoke ad-hoc basis. However; many items which are obtained in this way would not be considered a ‘special unlicensed

Where the unlicensed special is listed in Part VIIIB, the contractor will be paid this price regardless of how the product was sourced.
However, for those unlicensed specials and imports not listed in Part VIIIB, the contractor will be paid according to how the product was manufactured. Where the product is manufactured under an MHRA specials licence, pharmacy contractors need to endorse:

- the wholesaler’s invoice price less discount;
- the manufacturer’s licence number;
- the batch number of the product.

Where the product is manufactured under the section 10 exemption of the Medicines Act 1968 (when a product can be made on a pharmacy premises without the need for a licence), pharmacy contractors need to endorse the names, quantities and cost of the ingredients used in preparing the product.

Along with payment for the product, the contractor will also be paid the appropriate additional payment depending on whether the product was manufactured by a MHRA licensed specials manufacturer under their licence (they must endorse SP) or manufactured under the section 10 exemption by the contractor or by a 3rd party (they must endorse ED).

e) What should I do if I receive a prescription for sodium chloride 5% eye drops preservative free? Isn’t that in Part IX of the Drug Tariff?

It should be noted that whilst sodium chloride 5% eye drops preservative free is a product which appears with other unlicensed specials in Part VIIIB of the Drug Tariff, the standard version appears in Part IXA. Therefore, payment will depend on how the product was prescribed.

f) Can I claim broken bulk on unlicensed specials and imports?

Broken bulk cannot be claimed on unlicensed specials and imports manufactured or supplied by a company operating under an MHRA specials licence or importer’s licence.

However, if a product has been extemporaneously dispensed by the pharmacy contractor, broken bulk will be allowed on the ingredients used to make it. This is to cover times when the contractor may not have the opportunity to use the remainder of the ingredients opened when preparing the special.

g) Can I still claim out of pocket expenses on unlicensed specials and imports?

Yes, but the way in which they are claimed has changed.

Pharmacy contractors will now be paid a fixed fee (currently set at £20) for each unlicensed special or import that is manufactured or supplied by a company operating under an MHRA specials licence or importer’s licence. This fixed fee is to cover all costs incurred when sourcing the product. ‘SP’ must be endorsed on the prescription to claim this payment.

If a product is extemporaneously dispensed by the contractor or by a 3rd party, costs incurred are covered by another fixed fee (also currently set at £20). ‘ED’ must be endorsed on the prescription to claim this payment.

Pharmacy contractors must not include these expenses in the total they put on their monthly FP34c submission document.

For more information on endorsing unlicensed specials and imports, check out our unlicensed specials endorsing guide.
h) Do these new rules for unlicensed specials and imports apply to Welsh prescriptions?

Yes, these new rules will also apply to Welsh prescriptions.

i) What should I do with COCs/ COAs for prescriptions from other parts of the UK?

For prescriptions for unlicensed specials and imports not in Part VIIIIB originating from Wales, Scotland or Northern Ireland, the COCs and COAs should be retained for audit purposes, but there is no requirement for them to be sent to their health bodies.

j) Where can I find out the PCT (and its mailing address) of a prescriber?

If you need to find out who a prescriber’s PCT is, use the NHS Choices website (www.nhs.uk), which holds the most up-to-date information about health organisations.

k) How do I ensure patient confidentiality when sending the required information to PCTs?

Due to patient confidentiality reasons, it is important that patient details should not be sent to the PCT. Any patient details on the Certificate of Conformity (COC) or Certificate of Analysis (COA) should be removed before they are submitted. It is also advised that you photocopy the COC or COA when it arrives so that you can keep a copy for your own audit purposes.

l) I am finding it very difficult to get hold of a Certificate of Analysis (COA)/ Certificate of Conformity (COC) for an imported product, what should I do?

The Drug Tariff states that for imported unlicensed products not listed in Part VIIIIB, the contractor shall make every reasonable effort to obtain a Certificate of Analysis (COA)/ Certificate of Conformity (COC) for each imported product sourced.

However, it also says that where a COA/COC is not available, the contractor must stamp, date, initial and endorse the invoice with the invoice price less discount (where not clearly detailed by the supplier) and the prescriber’s details.

At the end of each month, the contractor shall send a copy of the appropriately endorsed COA/COC/invoice to the PCT of the prescriber, allowing the PCT to match expenditure to the special supplied.
APPENDIX 6: HOW TO ENDORSE UNLICENSED MEDICINES

From 1st November, the way in which unlicensed medicines will be reimbursed is changing. Some unlicensed medicines and their new reimbursement prices are to be included in the Drug Tariff, in a new section called Part VIIIB.

The requirements for endorsing unlicensed specials and imports vary depending on whether the product is listed in Part VIIIB or not and how the product was sourced. Below are examples of different situations and how the products should be endorsed.

Endorsement details required

**Product listed in Part VIIIB**

- ‘SP’ should be endorsed to claim the agreed fixed fee for sourcing the product from the supplier
- Alternatively, endorse ‘ED’ to claim the agreed fixed fee for extemporaneous dispensing, if the product has been extemporaneously dispensed by the contractor or a 3rd party.
- No price endorsement needed.

**Product not in Part VIIIB (not imports)**

- Invoice price of product minus any discount/ rebates
- Manufacturer’s MHRA specials licence number
- Batch number of unlicensed medicine
- ‘SP’ should be endorsed to claim the agreed fixed fee for sourcing the product from the supplier
- Alternatively, endorse ‘ED’ to claim the agreed fixed fee for extemporaneous dispensing, if the product has been extemporaneously dispensed by the contractor or a 3rd party.
Product not in Part VIIIB – this example is of an imported product

- Invoice price of product minus any discount/rebates
- Importer’s MHRA license number
- Batch number of imported medicine (if available)
- SP’ should be endorsed to claim the agreed fixed fee for sourcing the product from the supplier.

Extemporaneously Dispensing

Where a special, not listed in Part VIIIB, has been prepared under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, either by the contractor or by a third party, the contractor must endorse:

- The names, quantities and cost of the ingredients used in preparing the special
- ‘ED’ to claim the agreed fixed fee for extemporaneously dispensing the product.

Please note:

- Out of pocket expenses for unlicensed specials and imports should not be claimed by using the endorsement ‘XP’ and should not be added to the out of pocket expenses total on the FP34c submission document.
- The endorsement ‘DNG’ (for ‘discount not given’) is no longer required as it is not valid for Part VIIIB products and it has become automatic for products not in Part VIIIB.
- Broken bulk cannot be claimed for an unlicensed special or import. It can only be claimed on the ingredients used when a product is extemporaneously dispensed.
- For non-Part VIIIB unlicensed medicines the Certificate of Authority (COA) or Certificate of Conformity (COC) should be stamped, dated, initialed (by the dispenser), and endorsed with the NET price and prescriber’s details before being sent to the prescriber’s PCT. Don’t forget to remove all patient details before sending to the PCT.
- For information on what to do with COCs/COAs for prescriptions from other parts of the UK, check out our unlicensed medicines and imports FAQs.

For further information, including the Specials list for November and some related FAQs, visit the NHS Prescription Services website (http://www.nhsbsa.nhs.uk/3473.aspx).
APPENDIX 7: HOW AND WHEN TO ENDORSE UNLICENSED SPECIALS AND IMPORTS

1. Is the unlicensed special or import listed in Part VIIIB of the Drug Tariff?
   - YES
   - NO

   2. Is the unlicensed product an import?
      - YES
      - NO

   3. Was the product extemporaneously dispensed?
      - YES
      - NO

Endorse:
- Pack size used
- Invoice price (minus discount/rebates)
- Manufacturer’s MHRA importers licence number
- Batch number of unlicensed item
- SP (for costs incurred in obtaining the item)

* Please note:

For specials not in Part VIIIB, stamp, date, initial and endorse the Certificate of Analysis (COA)/Certificate of Conformity (COC) with the invoice price less discount and prescriber’s details. At the end of each month, a copy of the endorsed COA/COC must be sent to the prescriber’s PCT.

For imports not in Part VIIIB, make every reasonable effort to obtain a COA/COC. Where one is available, endorse as above. Where one is not available, stamp, date, initial and endorse the invoice with the invoice price less discount (if not clear) and the prescriber's details. At the end of each month, a copy of the endorsed COA/COC/invoice must be sent to the prescriber’s PCT.
APPENDIX 8: ACTIONS FOR PCTS IN THE EAST OF ENGLAND FOLLOWING THE NEW ‘SPECIALS’ TARIFF

PCTs should send out PSNC advice documents to pharmacy contractors; ‘Unlicensed specials and imports FAQs’ and ‘Specials endorsing guide’. PCTs can also direct contractors to the PPD’s Q&A document on their website:

http://www.nhsbsa.nhs.uk/Documents/PrescriptionServices/20111011_Specials_Tariff_Q_and_A.pdf

Summary of contractor changes and actions

► Contractors will be paid the tariff price for specials listed in Part VIIIB, regardless of what they paid for it.

► Endorsements for specials listed in Part VIIIB will with be ‘SP’ or ‘ED’ depending on their source i.e. manufactured under an MHRA specials licence (‘SP’), extemporaneously dispensed under section 10 exemption (‘ED’), or imported (‘SP’).

  • Specials not listed in Part VIIIB will also be endorsed ‘SP’ or ‘ED’ depending on their source but they will also require additional endorsement information (see guidance)

  • Form FP34C should no longer be used to claim for out of pocket expenses, endorsement of ‘SP’ will suffice. The ‘ED’ endorsement will ensure that the extemporaneous dispensing fee is applied. Both payments are currently set at £20 but may differ in future.

  • No broken bulk can be claimed on products listed in Part VIIIB. However, if a special has been extemporaneously prepared by the contractor, broken bulk can be claimed on the ingredients.

  • In addition to the information contractors currently record and keep for 5 years when supplying specials, they should also record the prescriber details for inspection by their PCT.

  • For specials not listed in Part VIIIB contractors should stamp, date, initial and endorse the Certificate of Analysis (COA) / Certificate of Conformity (COC) with the price paid and the prescriber’s details. The contractor should also remove all patient identifiable information. The contractor should keep a photocopy of the COC / COA for audit purposes. At the end of every month the COC / COA along with the details of the prescriber should be sent to the prescriber’s PCT.

► PCTs should furnish the contractors with a contact name and address to which to send the COCs / COAs. The person designated by the PCT will receive the COCs / COAs for all specials not listed in Part VIIIB supplied in the month from pharmacy contractors.

  • The designated person in the PCT needs to transcribe the information in the COCs / COAs to an electronic document, i.e. an Excel sheet, to facilitate comparison to ePACT data (when it becomes available) and then file the COCs / COAs. The East of England SHA is working to determine whether the Eclipse programme can be used to assist in this process.

The Department would recommend that any PCT undertaking arrangements separate to the new arrangements should consult their legal teams to ensure they are operating within the law. The only remuneration arrangements for pharmaceutical services that PCTs have the power to determine locally are remuneration for enhanced services and some remuneration for local pharmaceutical services.
APPENDIX 9: MANAGING SPECIALS WITH NEW ARRANGEMENTS AND TARIFF: A GUIDE FOR COMMISSIONERS

March 2012

Collated by the East of England Specials Sourcing Group

1. BACKGROUND

• From 1st November 2011 contractors dispensing prescriptions for unlicensed specials and imports will be reimbursed under the new arrangements and products listed in Part VIIIB will be reimbursed at the fixed Drug Tariff price.

• The aim of the new arrangements is to create a more transparent system for reimbursing specials, linking the cost of reimbursement to the cost of the product, while providing value for money for the NHS. Having a Drug Tariff price will create an incentive for pharmacy contractors to procure in a manner that is cost-effective for the NHS. Further, the new arrangements will simplify the arrangements for claiming and payment for sourcing specials.

• On the 14th November the EoE Chief Pharmacist outlined actions that PCTs in EoE should undertake following the changes.

• This included references to support materials for Community Pharmacists from the NHSBSA and the PSNC.

• A draft letter was also included to inform community pharmacists of the requirements to provide “Specials” information to PCTs, where to send it and the PCT contact for any queries.

2. PURPOSE

• The purpose of this paper is to:
  • Suggest practical ways to implement the guidance so as to maximise the value for money for the NHS
  • Consider what actions can be undertaken by PCTs to ensure that community pharmacies are engaged with the new requirements to provide Specials information to PCTs
  • Investigate how PCTs can work with both GP and Community Pharmacy colleagues to ensure that the prescribing of specials is as safe and appropriate as possible.

3. VALUE FOR MONEY

• PCTs should review systems to ensure that the processes outlined by the Chief Pharmacist are in place.

• Once established the PCT in house procedures should be reviewed to ensure that community Pharmacies are:
  • Sending returns back to the PCT on a monthly basis
  • That the returns are complete and contain all of the non tariff specials dispensed by that pharmacy for that month.. This can be determined by reviewing the pharmacy returns against the details obtained by Epact. Eclipse should be able to support this moving forward.

• This data provides the PCT with valuable early information of what specials are being prescribed and the charges incurred by the dispensers.
• MMT are able to work with prescribers to explore the appropriateness on specials and to identify possible safer alternatives - different licensed formulations, different drugs, alternative delivery routes, etc,

• Earlier notification of the costs involved in dispensing of specials may give prescribers the opportunity of reviewing the cost effectiveness of such prescribing and enable earlier interventions that will help to deliver savings in this area. or to see if costs can be reduced by working with the dispensing contractors – varying the amount ordered, challenging invoice prices, seeking alternative suppliers etc.

4. ENCOURAGING COMMUNITY PHARMACY ENGAGEMENT

• Pharmacies not submitting specials returns or incomplete returns can be contacted and reminded of their obligations under their NHS Terms of Service with respect to specials that is outlined in part VIIIb of the tariff.

• Engagement with the Local Pharmaceutical Committee may be useful to generate local peer pressure to increase pharmacy participation with sending returns to the PCT.

• It would be hoped that by good communication with local contractors that good levels of engagement can be obtained

• However where this fails it is possible to use the pharmacy regulations to enforce pharmacy compliance with this requirement.

• Under the current regulations failure to comply with the terms of service would require referral to a disciplinary committee of another PCT in order to be proven. The outcome of this referral would be that the pharmacy is advised to comply with its terms of service in the future, where it is found that they are not so complying, and payments could be withheld. Such referrals are rare as the process is bureaucratic and time-consuming and few if any PCTs have such a discipline committee.

• New regulations are expected in the near future following a public consultation completed in January 2012. In these draft regulations there is stronger, clearer more direct action that a PCT can undertake to manage performance issues including concerns related to Tariff requirements for contractors to submit their specials documentation to the PCT.

• Regulation 11 of the 2012 Regulations provides that Drug Tariff terms are terms of service for the purposes of the Regulations. The new sanctions and dispute resolution arrangements apply to all of a contractor’s terms of service.

• Regulations 68 and 69 require pharmacy contractors and PCTs generally to make every reasonable effort to communicate and co-operate with each other to resolve any dispute relating to a contractor’s compliance with their terms of service. For contractors, this requirement is a condition of their inclusion in the PCT’s pharmaceutical list.

• A Pharmacy may request for the Local Pharmaceutical Committee to be part of the dispute resolution process. In which case the PCT must make every reasonable effort to communicate and co-operate with the LPC in its attempts to assist in resolving the dispute.

• If the dispute resolution process fails then there is provision under regulation 70 for the PCT to issue, once it has gone through local dispute resolution, a remedial notice to a pharmacy where it has breached a term of service and the breach is capable of remedy.

• The remedial notice must include the nature of the breach, the steps the contractor must take to remedy the breach, the period of time within which the required action is to be taken and an explanation of the contractor’s right of appeal to the NHS Litigation Authority. In addition, if the breach is a failure on the part of the pharmacy to provide a service that it is required to provide then the PCT would be able to withhold all or part of the remuneration due to that pharmacy provided that:
• The Primary Care Trust is satisfied that the breach to which the withholding relates is, or was, without good cause;
• The amount withheld is justifiable and proportionate, having regard to the nature and seriousness of the breach and the reasons for it; and
• The Primary Care Trust includes in the notice its duly justified reasons for both the decision to withhold remuneration and the amounts that are, and (where applicable) are to be, withheld.

• What constitutes a proportionate withholding of payments with regards to the submission of Specials data would need to be determined within the details of the individual remedial notice. However it is expected that in most cases it will not be the breach notice that will ensure that the vast majority of pharmacies will comply with their terms of service but the knowledge that there will be provision within the regulations so that PCTs can take such action and that some will do so.

• Until such time as these draft regulations come into force the action set out in 4.7 - 4.12 above is not available to PCTs. However as these regulations are still expected to come into force some time in the near future it could be a useful exercise to for PCTs to discuss with their LPC areas of concern, possible means of addressing poor performance and procedures for local dispute resolution in preparation for the introduction of the new regulation.

• When the regulations do come into force there will be supporting guidance to assist PCTs in managing regulatory issues. The section on “Performance sanctions including market exit for contractors providing pharmaceutical services” should be read and understood before embarking on any performance sanctions. This draft guidance is currently available at http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_130510

• Advice would also be available through Primary Care Commissioning for those registered PCTs.

5. EXPECTATIONS

• It is expected that PCTs:
  • Will review the specials submissions from contractors to see that contractors are submitting their returns accurately, completely and timeously.
  • will discuss dispensing costs with contractors where appropriate to make them aware of the local and national price discrepancies and low cost providers
  • will review with prescribers the prescribing of specials to ensure that it is appropriate, safe, and cost effective.
The NHS spends £8 billion on medicines a year and in 2010 issued over 900 million prescription items. It is estimated that medicines worth over £300 million are wasted each year, of which at least half is avoidable. The Department of Health estimates that as many as 1 in 9 households have at least one prescribed medicine no longer being used. The cost to the NHS of people not taking their medicines properly and not getting the full benefits to their health is estimated at over £500 million a year. ¹, ²

Recent American and UK articles have encouraged prescribers to consider strategies for appropriate, safe and judicious prescribing. Prescribing principles should be considered to ensure medicines are used optimally. These include use of non drug therapies; being cautious about unproven drug uses; remaining vigilant to adverse effects of medicines and educating patients about these effects and monitoring which is required, so therapy is not stopped unnecessarily; exercising caution regarding new drugs; obtaining unbiased information before making a decision on whether to prescribe or not and sharing decisions with patients around adherence and whether to start or stop medicines. ³, ⁴

When speaking to patients about their medicines, health care professionals should review whether therapy is appropriate and still being adhered to. Pharmacy based services such as medicines use reviews are adherence-centred reviews with patients on multiple medicines, particularly those receiving medicines for long term conditions. Clinical medication reviews are a critical examination of a patient’s medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste. ⁵

Medicines optimisation may include stopping a treatment. Medicines should be stopped on an individual basis if:

• there is no valid or relevant indication for prescribing as assessed by changes in symptoms, signs, laboratory and diagnostic test results. ⁶
• the known possible adverse drug reactions outweigh the possible benefits. ⁶
• there is a risk of cumulative toxicity if particular medicines are taken together. ⁷
• the patient is choosing to not take/use the medication as prescribed or intended. ⁸
• unlicensed medicines (‘specials’) are being prescribed when an alternative medicine or formulation will provide the same therapeutic benefit. ⁹
• non-drug measures can provide benefit, without adverse effects. ¹⁰

If a medicine is no longer considered appropriate and is to be stopped, this should be discussed and a decision agreed between prescriber and patient. Good communication is essential for successful withdrawal of therapy that is no longer considered appropriate. ¹¹
The information in this table should be used as a pragmatic decision aid, in conjunction with other relevant, patient specific data. If therapy is considered appropriate, it should be continued. The information in the clinical and cost risk columns is the risk of continuing therapy based on maintenance doses and aimed to highlight areas which may be considered as a priority to focus on.

**BNF Chapter 1 - Gastrointestinal system**

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>H2 blockers / PPIs</td>
<td>Check if there is a valid indication for prescribing e.g. is an NSAID still being taken? There has been no proven peptic ulcer, GI bleeding or dyspepsia for 1 year. Continued use may contribute to C difficile infection.</td>
<td></td>
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</tr>
<tr>
<td>Laxatives</td>
<td>Previous use of opioid analgesics has reduced or stopped. Regular bowel movements occur without difficulty. Patient is eating &amp; drinking and has an adequate fluid intake. If &gt;1 laxatives are used, reduce and stop one at a time. Reduce stimulant laxative first, increase the dose of the osmotic laxative if necessary. Restart laxatives if relapse occurs.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**BNF Chapter 2 - Cardiovascular system**

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antihypertensives - ACE inhibitors, beta blockers, angiotensin II receptor blockers, diuretics, calcium channel blockers</td>
<td>Check if there is a valid indication for prescribing, is the BP at a normal level or too low? Do the known possible adverse drug reactions outweigh the possible benefits e.g. risk of falls; loop diuretic for ankle oedema – would compression hosiery be more appropriate? If &gt;1 antihypertensives are used, stop 1 at a time, maintaining the dose of the others without change. Restart antihypertensives if BP increases above 90 mm Hg diastolic and/or 150 mm Hg systolic (160 mm Hg if no organ damage).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitrates</td>
<td>The patient has not had chest pain for 6 months. The patient has reduced mobility.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statins / lipid lowering drugs</td>
<td>Re-evaluate the patients risk profile for primary &amp; secondary prevention of cardiovascular disease – is there a valid indication for prescribing? Stop in metastatic disease.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BNF class / Drugs</strong></td>
<td><strong>Considerations to optimise medicines use</strong></td>
<td>Clinical Risk</td>
<td>Cost Risk</td>
</tr>
<tr>
<td>----------------------</td>
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<tr>
<td>Aspirin</td>
<td>Check if there is a valid indication for prescribing e.g. re-evaluate the patients risk profile for primary prevention. Do the known possible adverse drug reactions outweigh the possible benefits?</td>
<td>Amber</td>
<td></td>
</tr>
<tr>
<td>Dipyridamole</td>
<td>Clopidogrel is now preferred over dipyridamole as more clinically and cost effective.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticoagulants – oral and injected</td>
<td>Are LMWHs/oral anticoagulants prescribed following hip/knee replacement surgery still required? Stop warfarin if the risk of falls outweighs the benefits. Long term warfarin use (&gt;6 months) is not recommended when the VTE was provoked by surgery, non surgical trigger factors or the VTE occurred in the calf only.</td>
<td>Amber</td>
<td></td>
</tr>
<tr>
<td>Peripheral vasodilators</td>
<td>Check if there is a valid indication for prescribing. Clinical effectiveness often not established. Do the known possible adverse drug reactions outweigh the possible benefits?</td>
<td>Amber</td>
<td></td>
</tr>
<tr>
<td>Digoxin</td>
<td>Check if there is a valid indication for prescribing. Do the known possible adverse drug reactions outweigh the possible benefits?</td>
<td>Amber</td>
<td></td>
</tr>
<tr>
<td>Theophylline</td>
<td>Monotherapy in COPD is not appropriate - safer, more effective alternatives are available.</td>
<td>Amber</td>
<td></td>
</tr>
<tr>
<td>Oral corticosteroids</td>
<td>Prednisolone maintenance in COPD is not usually recommended. The magnitude and speed of dose reduction and withdrawal should be determined on a case by case basis. Gradual withdrawal should be considered for those who have received more than 3 weeks treatment, those who have received more than 40mg prednisolone daily (or equivalent) or have other possible causes of adrenal suppression.</td>
<td>Amber</td>
<td>Amber</td>
</tr>
<tr>
<td>Inhaled corticosteroids</td>
<td>In asthma – review every 3 months, has control been achieved, if yes: reduce dose slowly (by 50% every 3 months) In COPD – if an inhaled corticosteroid is not appropriate, a long acting antimuscarinic bronchodilator can be used with a long acting beta2 agonist.</td>
<td>Amber</td>
<td>Red</td>
</tr>
</tbody>
</table>
### BNF Chapter 4 - Central Nervous system

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzodiazepines</td>
<td>Is use required if physical and psychological health and personal circumstances are stable? If the patient is willing, committed and compliant, and has adequate social support, refer to a withdrawal clinic. 23 Withdrawal should be gradual to avoid confusion, toxic psychosis and convulsions. 19 With long term use, risk of adverse effects including falls, exceeds therapeutic benefit of continued use. 15, 19, 24</td>
<td>Amber</td>
<td></td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>Check if there is a valid indication for prescribing. Do the known possible adverse drug reactions outweigh the possible benefits? 6 In dementia patients with behavioural and psychological symptoms, review and discontinue unless there is extreme risk or distress for the patient. 26 Standardized symptom evaluations and drug cessation attempts should be undertaken at regular intervals. 27, 28 Are chlorpromazine or trifluoperazine being taken with other medicines that have anticholinergic activity and can increase risk of cognitive impairment e.g. TCADs, oxybutynin, chlorphenamine? 7 Withdrawal after long term therapy (1-2 years) should be gradual and closely monitored to avoid relapse. 19</td>
<td>Amber</td>
<td>Red</td>
</tr>
<tr>
<td>Antidepressants - Selective serotonin reuptake inhibitors (SSRIs), Tricyclic antidepressants (TCADs), others e.g. MAOIs, agomelatine, duloxetine, reboxetine, venlafaxine, mirtazapine</td>
<td>Check if there is a valid indication for prescribing. For a single episode of depression treat for 6-9 months; for multiple episodes, treat for at least 2 years, no upper duration of treatment has been identified. Dosulepin should not be prescribed. 25 Do the known possible adverse drug reactions outweigh the possible benefits? e.g. TCADs can worsen dementia, glaucoma, constipation, urinary retention; SSRIs may induce clinically significant hyponatraemia. 6, 15 Are TCADs being taken with other medicines that have anticholinergic activity and can increase risk of cognitive impairment e.g. chlorpromazine, oxybutynin, chlorphenamine? 7 Reduce dose of antidepressants gradually to avoid withdrawal effects. 19</td>
<td>Amber</td>
<td>SSRI: Red</td>
</tr>
<tr>
<td>Opioid analgesics</td>
<td>Is pain still severe enough to warrant a regular opioid? The risk of falls/constipation can outweigh the benefits. Consider non-drug options, switch to regular paracetamol. 6 Review laxatives.</td>
<td>Red</td>
<td>Red</td>
</tr>
<tr>
<td>Levodopa – carbidopa</td>
<td>Check if there is a valid indication for prescribing. Do the known possible adverse drug reactions outweigh the possible benefits? 6</td>
<td>Amber</td>
<td></td>
</tr>
<tr>
<td>Drugs for dementia</td>
<td>If MMSE &lt;10, medicines may be continued if they help with behaviour. 16 NICE recommends memantine if MMSE&lt;10. Review benefit, use should only continue if the MMSE score is ≥10 and treatment has a worthwhile effect on the global, functional or behavioural symptoms. 29</td>
<td>Amber</td>
<td></td>
</tr>
</tbody>
</table>
### BNF Chapter 5 – Infections

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibacterials</td>
<td>Check if there is a valid indication for prescribing. Inappropriate uses – a bacterial infection has resolved; a viral infection has been diagnosed; prophylactic treatment prescribed but no pathogen isolated. Treatment of asymptomatic bacteriuria (ASB) in older patients and diabetes patients has no beneficial effects. There is a lack of evidence to evaluate the effect of preventing catheter associated-ASB with antibiotics. Is fluid intake adequate?</td>
<td>Amber</td>
<td>Red</td>
</tr>
<tr>
<td>Antifungals</td>
<td>Skin scrapings should be taken if systemic therapy is being considered or if there is doubt about the diagnosis. When a course of treatment of appropriate length has been finished, do not continue indefinitely e.g. oral and topical nystatin. For finger and toe nail infections, cure is achieved in only a minority of patients, the relapse rate is high.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### BNF Chapter 6 - Endocrine system

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisphosphonates</td>
<td>Check if there is a valid indication for prescribing. Has treatment been taken for 5 years or more? Do the known possible adverse drug reactions outweigh the possible benefits? If the patient is at low risk of falls, are these still needed? Prolonged immobility is a risk factor for low BMD.</td>
<td>Amber</td>
<td></td>
</tr>
</tbody>
</table>

### BNF Chapter 7 - Obstetrics, gynaecology & urinary tract disorders

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha blockers</td>
<td>Check if there is a valid indication for prescribing. Use is generally not indicated if a patient has a long term (&gt;2 months) catheter in situ.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### BNF Chapter 8 - Malignant disease & immunosuppression

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxics, immunosuppressants</td>
<td>What outcome is expected, do the known possible adverse drug reactions outweigh the possible benefits? 6, 10 Refer to doctor who initiated treatment.</td>
<td>Amber</td>
<td>Red</td>
</tr>
</tbody>
</table>

### BNF Chapter 9 - Nutrition & blood

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium, potassium &amp; iron supplements</td>
<td>Check if there is a valid indication for prescribing, do the known possible adverse drug reactions outweigh the possible benefits. 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins</td>
<td>Check if there is a valid indication for prescribing, e.g. does the patient have a disorder which requires vitamin &amp; mineral supplements. 6,19</td>
<td>Amber</td>
<td></td>
</tr>
<tr>
<td>Calcium + vitamin D</td>
<td>Does the patient have adequate levels through diet/sunlight exposure? If the patient is not mobile, is this still needed? 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sip feeds</td>
<td>Check if there is a valid indication for prescribing. Has a dietician recently reviewed the patient; is the patient able to prepare, or have someone else prepare fortified food and therefore does not need sip feeds. 8</td>
<td>Red</td>
<td></td>
</tr>
</tbody>
</table>

### BNF Chapter 10 - Musculoskeletal & joint diseases

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAIDs</td>
<td>Check if there is a valid indication for prescribing. Is an NSAID still needed/appropriate e.g. long term treatment of gout but no prophylaxis is prescribed. 15 Do the known possible adverse drug reactions outweigh the possible benefits e.g. &gt;3 months use for symptom relief in mild osteoarthritis, use in patients with severe hypertension/heart failure/chronic renal failure. 6,15 If topical NSAIDs are continued indefinitely, review the need for use; short courses are generally advised. 19</td>
<td>Amber</td>
<td>Amber</td>
</tr>
<tr>
<td>DMARDs</td>
<td>Discontinue penicillamine if there is no improvement within 1 year. 19 Consider withdrawal of azathioprine and ciclosporin if there is no improvement within 3 months of use. 19 Refer to doctor who initiated treatment.</td>
<td>Amber</td>
<td></td>
</tr>
</tbody>
</table>
TNF inhibitors
Psoriatic arthritis/Ankylosing spondylitis - discontinue adalimumab, etanercept and infliximab if there is inadequate response after 12 weeks.19
Rheumatoid arthritis/Juvenile idiopathic arthritis – withdraw adalimumab, etanercept and infliximab if response is not adequate within 6 months.19

BNF Chapter 11 - Eye

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye drops/ointments</td>
<td>Review need for preservative free eye drops - is there a valid indication for prescribing (e.g. previous preservative toxicity), are eye drops instilled more than 4 times per day?19 Have antibiotic preparations been continued without a review or stop date?19</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BNF Chapter 12 - Ear, nose & oropharynx

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drops, sprays, solutions etc</td>
<td>Is the medicine still required? Have antibiotic / steroid / sympathomimetic preparations been continued without review or a stop date?19</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BNF Chapter 13 – Skin

<table>
<thead>
<tr>
<th>BNF class / Drugs</th>
<th>Considerations to optimise medicines use</th>
<th>Clinical Risk</th>
<th>Cost Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creams, ointments</td>
<td>Has the condition resolved and continued use may cause adverse effects or exacerbate the condition e.g. preparations containing antibacterials or corticosteroids.19 Is the patient using sufficient emollient to avoid use of steroids or development of ulcers?8</td>
<td>Amber</td>
<td></td>
</tr>
</tbody>
</table>
Written by Katie Smith, Director, East Anglia Medicines Information Service for the NHS East of England PrescQIPP workstream.
Tel: 01473 704431, katie.smith@ipswichhospital.nhs.uk,
Comments received from Denise Farmer, Associate Director of NHS Clinical Pharmacy Service, East of England and Val Shaw, Deputy Chief Pharmacist, Cambridge University Hospitals NHS Foundation Trust.
Published and reviewed September 2011, due for review September 2012.

References
8. Medication review in care homes. NHS Cambridgeshire, March 2010
16. Dr Viveca Kirthisingha, Consultant Community Geriatrician, Cambridgeshire Community Services, January 2011
17. Petersen LK, Christensen K et al. Lipid-lowering treatment to the end? A review of observational studies and RCTs on cholesterol and mortality in 80+year old. Age and Ageing 2010; 39: 674-80
Optimising safe and appropriate medicines use

This leaflet is to help you understand why your doctor is reviewing the medicines you take to check they are still appropriate to treat your conditions.

Medicines are prescribed to treat symptoms or diseases. When a medicine is prescribed for you, you should be given information on possible side effects, how long to take it for and when to stop taking it.

For each of the medicines you are taking, you should know which of the following applies:

• The medicine should only be taken for a specific number of days to treat a particular condition, for example, antibiotics to treat a bacterial infection.

• The medicine may need to be continued for a number of weeks or months and then stopped when symptoms are reduced or the disease is under control, for example, iron tablets for anaemia.

• For conditions, like asthma, diabetes and high blood pressure you may have to keep taking your medicines every day to keep the signs and symptoms of the disease under control.

It is good practice for your doctor(s) to review the medicines you are taking and check that you are taking the medicine, it is treating the condition and not causing any side effects.

Your doctor may suggest stopping a medicine because:

• Your health or a particular condition has improved or changed and it is no longer needed.

• The side effects outweigh the benefits and they are making you feel unwell.

• You have chosen not to take the medicine.

• You are not able to take the medicine.

• Other treatments which do not involve medicines can be used instead.

Your doctor should involve you in any decision about your medicines. The decision to start or stop a medicine should be shared between you and your doctor and be based on your individual clinical needs, priorities and values.
APPENDIX 13: ADULT SPECIALS PATIENT INFORMATION LEAFLET

PHARMACEUTICAL SPECIALS

Information for patients and carers

This leaflet is about the use of ‘specials’ or unlicensed medicines in children. Please read the leaflet carefully. Keep it somewhere safe so that you can read it again.

The medicine and the strength your child has been described is:

HOW IS MY MEDICINE DIFFERENT?
The medication that you require is not commercially available and is tailor made to your child’s requirements. This is a pharmaceutical special. Many companies make pharmaceutical specials routinely and have to meet standards and provide certificates of quality and safety.

HOW SHOULD YOU TAKE THIS MEDICATION?
Your pharmacist, doctor or nurse will take you through how much of and how often you should give this medicine. The instructions will also be printed on the medication label. An oral syringe will be provided if needed. Your pharmacist will answer any further questions you may have.

DOES THIS MEDICINE REQUIRE ANY SPECIAL STORAGE?
Your medicine may require storage in a fridge or out of the sunlight. This information can usually be found on the label. Make sure that your medication is stored correctly.

HOW LONG WILL YOUR MEDICATION KEEP?
Unlicensed medicines often have short shelf lives. Please check and make note of when your medicine expires. Do not use expired medication. It is important that you do not let your supply run out before going to your doctor for a prescription. Remember a prescription can take 2-3 days to get ready.

HOW DO YOU OBTAIN FURTHER SUPPLIES?
Take the prescription from your doctor and the container of your current supply as well as this leaflet to your local pharmacy (chemist).

Give your pharmacist one or two weeks to obtain the supply for you.

If your medicine has a short shelf life, only order enough to last till the expiry date. If the medicine’s shelf life is two weeks or less, check if your doctor would be able to write separate prescriptions to cover a month’s supply.

Ask your pharmacist to record below where they sourced the medication. They may also find it useful to note on the back of this leaflet the exact ingredients of your medication. This will ensure that you can obtain future supplies easily and consistently.

The pharmacist can order your medication from:
WHERE CAN YOU GET FURTHER INFORMATION?

The doctor or pharmacist will be able to tell you more about your medicine. The MHRA website contains general information about specials:

www.mhra.gov.uk

You can also find useful leaflets about specific medicines on the NHS Direct website:

http://www.nhsdirect.nhs.uk/

Use this box to make a note of any useful information about your medicine, such as reminders about when you need to order a new supply.
Information for parents and carers

This leaflet is about the use of ‘specials’ or unlicensed medicines in children. Please read the leaflet carefully. Keep it somewhere safe so that you can read it again.

The medicine and the strength your child has been described is:

HOW IS MY CHILD’S MEDICINE DIFFERENT?

The medication that your child requires is not commercially available and is tailor made to your child’s requirements. This is a pharmaceutical special. Many companies make pharmaceutical specials routinely and have to meet standards and provide certificates of quality and safety.

HOW SHOULD YOU GIVE THIS MEDICATION?

Your pharmacist, doctor or nurse will take you through how much of and how often you should give this medicine. The instructions will also be printed on the medication label. An oral syringe will be provided if needed. Your pharmacist will answer any further questions you may have.

DOES THIS MEDICINE REQUIRE ANY SPECIAL STORAGE?

Your child’s medicine may require storage in a fridge or out of the sunlight. This information can usually be found on the label. Make sure that your child’s medication is stored correctly.

HOW LONG WILL YOUR CHILD’S MEDICATION KEEP?

Unlicensed medicines often have short shelf lives. Please check and make note of when your child’s medicine expires. Do not use expired medication. It is important that you do not let your supply run out before going to your child’s doctor for a prescription. Remember a prescription can take 2-3 days to get ready.

HOW DO YOU OBTAIN FURTHER SUPPLIES?

Take the prescription from your child’s doctor and the container of your current supply as well as this leaflet to your local pharmacy (chemist). It can take your pharmacist one or two weeks to obtain some so make sure you allow for this.

If your child’s medicine has a short shelf life, only order enough to last till the expiry date. If the medicine’s shelf life is two weeks or less, check if your child’s doctor would be able to write separate prescriptions to cover a month’s supply.

Ask your pharmacist to record below where they sourced the medication. They may also find it useful to note on the back of this leaflet the exact ingredients of your child’s medication. This will ensure that you can obtain future supplies easily and consistently.

The pharmacist can order your child’s medication from:
WHERE CAN YOU GET FURTHER INFORMATION?

The doctor or pharmacist will be able to tell you more about your child’s medicine. You can also find useful leaflets about specific medicines as well as a more detailed leaflet on unlicensed medicines on the Medicines for Children website:

www.medicinesforchildren.org.uk

Use this box to make a note of any useful information about your medicine, such as reminders about when you need to order a new supply.
APPENDIX 15: PATIENT INFORMATION LEAFLET - INTESTINAL FAILURE

This leaflet has been written to help you develop a greater understanding of intestinal failure. It has been written by members of the Intestinal Failure Team at St Mark’s Hospital, which is one of 3 centres in the country who specialise in caring for patients with this condition.

What is intestinal failure?
Intestinal failure is a rare condition in which:
1. The small intestine is unable to digest and absorb the correct amounts of nutrients.
2. The body does not reabsorb fluids produced normally by the intestines, such as digestive juices.

This can lead to problems such as weight loss and diarrhea, which can result in malnutrition and dehydration.

To understand why this happens, it is important to consider what happens in a person without intestinal failure. (See picture below.)

Movement of fluid and nutrients through the intestine

Common causes of intestinal failure
- Removal of a large amount of small intestine
- Severe disease of, or damage to, the small intestine
- Complications following abdominal surgery
- Problems with a movement within the intestine

Some people with intestinal failure may have a stoma (an opening of the bowel onto the surface of the abdomen) - it depends on the reason why intestinal failure developed. The treatment may differ slightly for people who have a stoma and those who do not.

Eating
Eating helps keep the inside lining of your intestine healthy and is an important social activity.

When you have had a large part of your intestine removed, your body finds it difficult to absorb all the nutrients you need to keep healthy. You may need to eat a lot more food than you used to. Your doctor will advise you.

It is important that you avoid drinking alcohol, as this will help your intestine absorb as much as possible and will reduce your output.

Some people with intestinal failure will need to have extra nutrition in the form of a liquid feed through a tube into the stomach (enteral nutrition), or liquid feed directly into the vein (parenteral nutrition).

Drinking
In a person with intestinal failure most of the fluid that is taken by mouth will not be absorbed and will be passed straight out of the body. As this happens you will feel increasingly thirsty because sodium (salt) has been flushed out and you will become dehydrated.

To stop this happening you have to drink less and more. The more you drink the more dehydrated you will become.

It is important to remember that this only happens to people with intestinal failure. In a person without intestinal failure if they feel thirsty and drink more, they will not become dehydrated.

The following diagrams help explain this.

WATER/TEA (low salt drink)

ELECTROLYTE MIX (high salt drink)

Fluid from your body moves into your intestine and is passed out
APPENDIX 16: ST. MARK’S ELECTROLYTE MIX SOLUTION

What is St Mark’s Electrolyte Mix (solution)?

Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals

Expiry: 28th February 2011

Background

St Mark’s Electrolyte Mix is a glucose-electrolyte solution, also known as an oral rehydration solution (ORS) which is used in the management of Short Bowel Syndrome (1). Short Bowel Syndrome occurs as a result of extensive intestinal resection or functional abnormality and reduces the small bowel’s capacity to absorb fluid and nutrients (2,3). This can lead to dehydration, weight loss, malabsorption of fluids, and electrolyte imbalance (3). One of the main aims of management is to increase fluid uptake and improve absorption (2,4,5). Most patients will require fluid, electrolyte and nutrient supplementation, and some patients may require intravenous nutrition (IVN) or intravenous fluids (IVF) to maintain health and growth (4-6). ORS are important in the maintenance of adequate fluid balance as they help decrease the need for IVN or IVF (4-7).

Answer

Patients with short bowel have a disrupted fluid and nutrient absorption process leading to excessive fluid losses (8). Drinking hypotonic fluid (e.g. tea, coffee, water, carbonated drinks) will lead to sodium and fluid moving from the body into the intestine and being passed out (3,6). This will result in a high output and sodium depletion. Isotonic fluids are glucose-electrolyte solutions which optimise the ratio of sodium to glucose and allow greater fluid and sodium absorption across the jejunum (5,7,9,10). The glucose present in the intestinal mucosa promotes the passive absorption of both salt and water via a solvent drag mechanism (4,5,10). At least 90mmol/L of sodium are necessary to maximise the water and sodium absorption (7,9,11).

The original standard World Health Organisation (WHO) oral rehydration solution contains a sodium concentration of 90mmol/L, but it also contains potassium which can cause hyperkalaemia in some patients (1). Standard “sport drinks” are not suitable as they contain a high sugar content and low sodium content (10). There are many proprietary solutions available, however these are costly and have low sodium content (5). Due to the lack of suitable preparations available, St Mark’s Hospital has produced a unique solution called “St Mark’s Electrolyte Mix”. This is a glucose-electrolyte mix which contains 90mmol/L of sodium and no potassium.

The patient should make the solution up fresh every day using the following measurements:

- 20g (six level 5ml spoonfuls) of glucose
- 2.5g (one heaped 2.5ml spoonful) of sodium bicarbonate
- 3.5g (one level 5ml spoonful) of sodium chloride (salt)

This is then dissolved in 1 Litre of tap water, and the patient should drink up to the prescribed volume throughout the day (1). Two to three litres per day may be necessary to maintain hydration (7).

The powders can be purchased from community pharmacies and supermarkets, and will often be cheaper than a single prescription charge.
Patients should be strongly encouraged to avoid plain water or hypotonic fluid consumption when they are thirsty and to substitute it with ORS (3,5,11). Patients may benefit from separating their ingestion of fluid from the intake of food (7).

The patient may find the solution bitter in taste due to the sodium bicarbonate. This can be minimised by storing the solution in the refrigerator and/or by the addition of a small amount of fruit juice or lemon or lime squash and sipping through a straw. If this continues to be a problem, the sodium bicarbonate can be replaced by the same quantity of sodium citrate (1).

Summary

St Mark’s Electrolyte Mix is a type of oral rehydration solution used in the management of short bowel syndrome. It has to be made daily using the stated formula and if the patient finds the solution unpalatable then advise as above.

Limitations Disclaimer

• Medicines Q&As are intended for healthcare professionals and reflect UK practice.
• Each Q&A relates only to the clinical scenario described.
• Q&As are believed to accurately reflect the medical literature at the time of writing.
• See NeLM for full disclaimer.

References

Quality Assurance


Date Prepared: 4th February 2009

Checked by: Alexandra Denby, Regional Manager. London Medicines Information Service (Northwick Park Hospital).

Date of check: 9th March 2009

Search strategy:

• Embase: Oral rehydration solution AND (short bowel syndrome OR intestinal failure)
• Medline: Rehydration solution AND short bowel syndrome
• Micromedex: oral rehydration solution or rehydration
APPENDIX 26: TREND OF SPEND ON SPECIALS SINCE PUBLICATION OF SPECIALS TOOLKIT ACROSS THE EAST OF ENGLAND

The following graph shows the overall trend in spend on Specials across the East of England since the publication of the Specials toolkit.

The following graph shows the change in average monthly cost per 1000 patients on Specials according to PCT across the East of England region since the Specials toolkit was published.
APPENDIX 27: SPEND ON SPECIALS IN THE EAST OF ENGLAND SHA COMPARED NATIONALLY

The Prescription Service have collated further information about the volume and cost of Special order products including specific PCT data. This can be accessed at the following link:

http://www.nhsbsa.nhs.uk/PrescriptionServices/3201.aspx
REFERENCES


Prescriber Volume 19, issue 19, 5th Oct http://www.prescriber.co.uk/

BNF for Children 2008 http://bnfc.org/bnfc/

The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 [SI 1994/3144], (the MA Regs.)

http://www.opsi.gov.uk/si/si1994/Uksi_19943144_en_1.htm


http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedallicence/Medicinesthatdonotneedallicence/index.htm

Peterborough and Stamford Hospitals NHS Foundation Trust Policy for Unlicensed Medicines.

Calderdale and Huddersfield NHS Trust guidelines


Medicines for children website http://www.medicinesforchildren.org.uk/

Carers UK http://www.carersuk.org/Home

Processes involved in the route of a medicine - Adapted from the medicines act (lecture) by Dr David Wright


ACKNOWLEDGMENTS

Sincere thanks to the various East of England PCTs and NHS Trusts who have shared their practice and contributed to this document.

• Members of the East of England Specials Stakeholder Group

• Jonathan Andrews, Michael Dennis, Denise Farmer, Carol Roberts, Liam Cahill, Val Shaw, Stephanie Sprakes, Paula Wilkinson, Kevan Wind, Kelvin Rowland-Jones, Jessica Good, Sandhu Balbir-Singh, James Kent, Karen Homan and Melitta Mudaly