

**Good Practice Guidance on:**

**The Procurement of Pharmaceutical “Specials”**

This guidance is aimed at: Community Pharmacy Practice

**Website Blurb:**

*Background:*

Over the last few years community 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.

Across the NHS, the spend on unlicensed medicines, commonly known as ‘Specials’ is rising. Within NHS Primary Care in England, the cost is currently estimated at approximately £100.2 million per annum and is rising much faster than the number of ‘Specials’ dispensed. With an increasingly open market, diverse pricing structures and a lack of price controls, there are signs that discounting schemes are beginning to disproportionately influence choice of supplier.

This guidance provides *good practice* advice on the key responsibilities for pharmacists when supplying ‘Specials’, and support in making appropriate choices for their patients. 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 unlicensed medicines. It does NOT apply to licensed products used outside the clinical indications of their licence i.e. “off-label” use.

**Content**

The document is divided into 8 sections:

1. Aim
2. General Information about ‘Specials’
3. Key Professional Responsibilities
4. Assessing Clinical Need
5. Choosing a Suitable Product
6. Choosing a Suitable Supplier
7. Good Record Keeping
8. Useful Resources

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

**Authors:**

This guidance has been prepared by:

Mark DasGupta                      Senior Prescribing Adviser, NHS Birmingham East & North  
[Mark.Dasgupta@benpct.nhs.uk](mailto:Mark.Dasgupta@benpct.nhs.uk)

Meghna Joshi                      Senior Professional Support Pharmacist (RPSGB)  
[Meghna.joshi@rpsgb.org](mailto:Meghna.joshi@rpsgb.org)

**Updated: 11/11/09**

|                 |   |
|-----------------|---|
| Carol Roberts   | Head of Medicines Management, NHS Waltham Forest<br><a href="mailto:Carol.Roberts@wf-pct.nhs.uk">Carol.Roberts@wf-pct.nhs.uk</a>  |
| Tim Root        | Specialist Pharmacist, Clinical Governance & Technical Services East & South East<br>England Specialist Pharmacy Services<br><a href="mailto:Tim.Root@chelwest.nhs.uk">Tim.Root@chelwest.nhs.uk</a> |
| Margaret Savage | Assistant Director, Medicines Management, Birmingham East and North<br><a href="mailto:Margaret.Savage@benpct.nhs.uk">Margaret.Savage@benpct.nhs.uk</a>   |
| Kevan Wind      | Medicines Procurement Specialist Pharmacist, London & East of England<br><a href="mailto:Kevan.Wind@southend.nhs.uk">Kevan.Wind@southend.nhs.uk</a>   |

And has been agreed by the National Pharmacy Boards

Date Published:  
Date for Review:

Signed off by:

DRAFT

**Updated: 11/11/09**

## 1. Aim

This document aims to:

- Provide 'good practice guidance' on the key professional responsibilities for pharmacists working in community pharmacy practice when dealing with the supply of unlicensed medicines, commonly known as '*Specials*'.
- Help support clinical governance in pharmacy.

## 2. General Information about '*Specials*'

- The term '*Specials*' has a number of meanings. In the context of this guidance it can be taken to include:
  - Batch manufactured products - made by a '*Specials*' manufacturers
  - Bespoke '*Specials*' - made by a *specials* manufacturer as a single pack for a named patient
  - Extemporaneously prepared medicines - made in a pharmacy under a pharmacist's direct supervision
- 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), guarantees that the quality, safety and efficacy of a medicine has been rigorously assessed, and must be displayed on the pack.
- For '*Specials*' however, an MHRA Manufacturer's '*Specials*' Licence' (MS) is required. This guarantees only that the manufacturing process itself was to regulatory standards. There has been no formal assessment of product safety or efficacy. A '*Special*' is therefore an unlicensed medicine. The manufacturer's MS number must be printed on the label.
- It is not uncommon for manufacturers holding an MS to make small quantities of medicine under the supervision of a pharmacist (i.e. under the exemptions allowed by section 10 of the Medicines Act 1968). This is extemporaneous dispensing. There is no guarantee that the extemporaneous dispensing process has been subject to any formal quality assurance and a MS number will not be printed on the label.

## 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:

Updated: 11/11/09

- 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 is available, in preference to an unlicensed product or food supplement.
- 3.13 Reimbursement claims for NHS or other professional services are honest and accurate.

To maintain *good practice* and adhere to the code and standards of practice, 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 prescribed and supplied *only* when there is no available licensed medicine which fully meets the patient's clinical needs.
- Any '*Specials*' product supplied is *fit for purpose* - are of the appropriate quality and clinically appropriate
- They understand their legal responsibilities when supplying '*Specials*'
- They minimise legal risk to prescribers 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

The pharmacist, under the Medicines Act, is responsible and accountable for the quality of the products they supply. The outsourcing of the preparation does not in itself change the final accountability being with the pharmacist. Pharmacists need to be clear about the liability which they accept every time they order and dispense an unlicensed medicine, they are responsible for the quality of the product

**Comment [HW1]:** This needs to be checked with Legal and Ethical Advisory Service

To refute an allegation of negligence in the event of an incident or claim of any sort, the pharmacist would need to be able to prove that they had taken all reasonable steps to order an appropriately formulated product and to ensure that the product received was exactly what they'd ordered. The principle of "caveat emptor" applies. The bottom line is that an incident happened and the product had been made by a third party, the pharmacist who ordered and supplied the '*Special*' to the patient would need to be able to prove they had taken all the steps as recommend in this guidance to be able to offer a robust defence against an allegation of negligence.

## GOOD PRACTICE

The following *good practice* issues have been highlighted when dealing with '*Specials*':

### 4. Assessing Clinical Need

#### *Practice Tip*

Supply of a '*Special*' is justified only when there is no available licensed medicine which fully meets the patient's clinical needs. (*Reference: MHRA Guidance Note 14 – see below*)

When considering the clinical need for a '*Specials*' it is good practice to:

- Make every reasonable effort to identify a UK licensed product, or near equivalent, to the prescribed '*Special*' that meets the patient's clinical needs.
- Where no appropriate licensed medicine is available, and it is essential to supply a '*Special*', consider options such as:
  - Can the product be extemporaneously dispensed in the pharmacy?
  - Should it be bought in from an external manufacturer?
  - Would a soluble or dispersible formulation; or crushing of tablets by the patient, be suitable?
- Choose the option which presents the lowest risk to the patient.
- Always contact the prescriber to discuss appropriate alternatives

**Comment [HW2]:** Does this conflict with the message that pharmacists should outsource rather than prepare extemp?

Updated: 11/11/09

- Continually review requirements as circumstances may change e.g. a child prescribed a liquid formulation may now be old enough to swallow tablets
- Make a record of this assessment; it is recommended to keep a record of this for at least 5 years

Saying all that, there are patients who benefit from 'Specials' and these should be supplied in a timely manner.

In order to demonstrate you have robust procedures in place consider the following:

- An SOP for ordering 'Specials' demonstrates that the pharmacist has understood the need to define 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 specification supplied by the pharmacist.

If all these steps are taken it will demonstrate a robust defence, should an allegation of negligence be brought against the pharmacist

## 5. Choosing a Suitable Product

### *Practice Tip*

To ensure quality of the product, always ask for a certificate of analysis or a certificate of conformity with every product

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. A certificate of conformity is a signed statement by the manufacturer that they believe the product complies with the purchaser's specification.

Pharmacists have a professional responsibility to ensure that the prescriber and patient are aware of the unlicensed nature of any 'Specials' dispensed. This requirement is detailed in MHRA Guidance Note 14: The Supply of Unlicensed Relevant Medicinal Products for Individual Patients 2008. (<http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007547.pdf>)

### *Safety and Quality considerations*

Whether a 'Special' is made by an external supplier under section 10 or under an MS, the pharmacist who supplies the product to the patient remains legally responsible for its quality, regardless of who made it and how.

Where a decision is taken to supply a 'Special', the following points around *quality* should be considered:

**Updated: 11/11/09**

- Pharmacists should specify to the supplier exactly what they require, which includes strength, formulation and excipients
- 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 check strength, formulation and excipients.
  - Comes with a certificate of analysis or a certificate of conformity
  - Is pharmaceutically appropriate and suitable for the patient
  - Has evidence to support the labelled shelf life of the product
  - Ideally comes with an information leaflet, although this is not yet a legal requirement
- If the shelf life / expiry date does not allow for the initial supply to cover the full intended duration of the treatment, this should be drawn to the patient's attention and appropriate arrangements for further supplies should be made
- 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>

**Comment [HW3]:** Do we need to explain which excipients are acceptable?

## 6. Choosing a Suitable Supplier

### PRACTICE TIP:

Pharmacists are recommended to have a written Standard Operating Procedure (SOP) in place detailing the steps involved in the *ordering* of '*Specials*' including risk assessments of the different options available.

An appropriately licensed '*Specials*' manufacturer should be used wherever possible in preference to actually preparing extemporaneous products. To ensure good practice when choosing a suitable '*Specials*' manufacturer, it is recommended to:

- Use one of the mainstream *specials* suppliers, or a local NHS hospital manufacturing departments listed in the BNF, <http://www.bnf.org/bnf/bnf/current/106216.htm>
- Choose a supplier who:
  - Gives the best balance of validated shelf-life, presentation, supply and cost
  - Holds an appropriate Manufacturer's '*Specials*' Licence and will make the product under that licence only
  - Can provide a certificate of analysis or certificate of conformity.
  - Is able to deliver the product within a suitable time period.
- Consider if the patient has already been started on treatment and where the original supply was sourced from **and aim to use the same supplier if possible**
- Give priority to suppliers with a proven supply record
- Regularly check that your chosen supplier is offering value for money on their products
- Avoid manufacturers offering excessive levels of discount (often linked to high list prices)
- Order '*Specials*' direct from manufacturers rather than using intermediaries, where possible, so as to avoid excessive handling costs and mark ups
- **Consider getting a quote from more than one supplier**

### *Urgent Deliveries*

Where an urgent delivery is required, this should not be subsidised by the use of high cost suppliers. Most '*Specials*' manufacturers are able to supply emergency orders within a reasonable timeframe, subject to an additional 'carriage supplement'.

It is recommended to only claim for reimbursement of the dispatch costs of urgent supplies. These should be claimed through the *carriage fees/ out of pocket expenses*

**Updated: 11/11/09**

## 7. 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 5 YEARS  |
|---|
| A record of the risk assessment and reasons for the decision to purchase and supply a 'Special' and the specification of the product agreed with the supplier (see <i>safety and quality considerations</i> ) should be documented and kept on file in the pharmacy for at least five years |
| Documentation to verify the specifications i.e. <u>certificate of analysis</u> or a <u>certificate of conformity</u> 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                |
| A dispensing label and patient address label can be attached to <u>certificate of analysis</u> or a <u>certificate of conformity</u> . This can be filed as an adequate audit trail.  |
| The source of the product i.e. manufacturer details   |
| The person to whom the product was sold or supplied   |
| The date the product was supplied   |
| The quantity of each sale or supply   |
| The batch number and expiry date of the product (listed on <u>certificate of analysis</u> or a <u>certificate of conformity</u> )   |
| 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.  |

## 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.

**MHRA: Guideline 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>)

The MHRA document is the definitive document which outlines all of the requirements

The interpretation of these documents is that contractors have a contractual and ethical obligation to source products which (1) represent value for money for the NHS when procuring medicines and (2) wherever possible, ensure that an appropriate licensed product is supplied (or recommended to the prescriber).

**Updated: 11/11/09**

**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.portal.nelm.nhs.uk/QA/default.aspx>. You need to be a member of the National electronic Library for Medicines (NeLM) to view this document.

DRAFT

Updated: 11/11/09