Gateshead & South Tyneside
Local Pharmaceutical Committee
Passionate about pharmacy

Chairman: **Mr. David Carter** Secretary: **Mrs. Louise Lydon**

Sunderland
Local Pharmaceutical Committee
Delivering local pharmacy solutions in Sunderland

NHS South of Tyne and Wear
serving Gateshead Primary Care Trust, South Tyneside Primary Care Trust and Sunderland Teaching Primary Care Trust

Joint LPC / PCT Statement on the Supply of Specials

Background

Across the UK, expenditure on unlicensed medicines, commonly known as '*Specials,*' is rising. Across South of Tyne and Wear, the spend on '*Specials'* is approximately £2 million per annum. Prices of *'Specials'* are extremely variable and the final cost to the NHS can be high. Some '*Specials'* can cost more than one hundred times more than the licensed solid dosage form.

NHS healthcare professionals have a duty to make the best use of public resources; cost as well as clinical suitability and product quality must be considered when choosing appropriate preparations.

The Royal Pharmaceutical Society has produced good practice guidance for community pharmacists on the procurement and supply of pharmaceutical specials[1]

This statement has been produced jointly by South of Tyne and Wear PCTs and Gateshead and South Tyneside Local Pharmaceutical Committee and Sunderland Local Pharmaceutical Committee to encourage local community pharmacists to follow the good practice guidance and engage with local prescribers to ensure the effective procurement of specials.

Community pharmacists within South of Tyne and Wear are recommended to follow the good practice guidance outlined below.

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Chairman **Gateshead & South Tyneside Local Pharmaceutical Committee**	Chairman **Sunderland Local Pharmaceutical Committee**	Head of Medicines **Management NHS South of Tyne & Wear**

[1] RSPGB Good Practice Guidance on Dealing With Specials Pharmacy Professional 1 Jun 2010

GOOD PRACTICE GUIDANCE

1. **The main concern of the pharmacist is to ensure patients have timely access to safe and clinically appropriate medicines at all times**

2. **Ensure good practice guidance and professional standards are followed**

3. **Ensure standard operating procedures incorporate the procurement and supply of pharmaceutical specials and unlicensed products detailing the steps involved in the ordering or specials including risk assessments of the different options available**

4. **All prescriptions for unlicensed medicines and pharmaceutical specials should be clinically assessed by a pharmacist.**

5. **A products with a marketing authorisation must be supplied where such a product exists in a suitable formulation and is available in preference to an unlicensed product or food supplement.**

6. **Supply of a special should only be made when there is no available licensed product which fully meets the patient's clinical needs.**

7. **South of Tyne and Wear Specials Guidance should be followed wherever possible.[2]**

8. **Specials should be sourced from reputable suppliers. It is the responsibility of the pharmacist to ensure the integrity and quality of all products supplied to patients. Quality should not be assumed, pharmacists must take all reasonable steps to ensure the quality of the product including where appropriate:**

    a. **Obtaining a written formulation for the product**
    b. **Obtaining a certificate of analysis or conformity**
    c. **Verifying the strength, formulation and excipient details**
    d. **Have evidence to support the shelf-life of the product**

9. **The pharmacist has a professional responsibility to ensure appropriate use of NHS resources and value for money. Pharmacists should regularly check that their chosen supplier offers the best all round service including quality, promptness of supply and value for money.**

10. **The pharmacist should inform the prescriber of the unlicensed status of the product, the likely cost and any delays to supply. If requested the pharmacist should make recommendations for a suitable alternative UK licensed product. The pharmacist may wish to use the form attached for this purpose.**

11. **Where patients are receiving specials on a continuing basis the pharmacist should periodically confirm with the prescriber that the ongoing use of the special is appropriate. Similarly the prescriber should be informed if a licensed product becomes available.**

12. **The pharmacist should document all discussions with the prescriber in relation to unlicensed products.**

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[2] Therapeutic options for patients unable to take solid oral dosage forms. Guidance for prescribers and pharmacists NHS South of Tyne & Wear

Appendix One: Communication between Pharmacy and Prescriber
IN CONFIDENCE

PHARMACY NAME: *OR PHARMACY STAMP*
ADDRESS:

Telephone Number:
Fax Number:

UNLICENSED MEDICINAL PRODUCTS (named-patient items / specials)

Unlicensed Medicinal Product Name……..

Prescriber Name……..……..

Dear Prescriber
You have prescribed a preparation for which no UK licensed product is available for the following patient:

MHRA guidance is that:
- An alternative licensed product should be supplied wherever possible.
- Prescribers, suppliers and patients are aware when an unlicensed product is being used.

Patient Name	
Date of Birth	
Address	

- The item prescribed is the first supply from this pharmacy for this patient.
- I will not place an order for this product until I receive confirmation that you would like me to proceed.
- If you wish to discuss alternatives please contact me on the telephone number provided above.

Additional Information for prescriber:	
Possible alternative licensed product(s) or suggestion	
For this unlicensed product	
Expected cost	Shelf life
Delivery time	Pack size
Other information	

Prescriber to inform community pharmacy by return of fax:	Tick whichever applies
Please proceed with order and dispense as prescribed (and any subsequent prescriptions for this product for this patient).	
Cancel the item, I will review and provide a new prescription for an alternative product	
GP Signature Print Name Date	

Appendix Two

Further information

- **Medicines legislation**

The Medicines for Human Use (Marketing Authorisations Etc. Regulations 1994/SI 3144) requires that medicinal products are licensed before they are marketed in the UK. Each product must have a Marketing Authorisation (MA) (sometimes called a product licence) granted. The MA sets out the terms and conditions of its manufacture, quality assurance and use. The indications and dosage are listed in the Summary of Product Characteristics (SmPC).

- **UK Exemptions to licensing**

The Medicines and Healthcare products Regulatory Agency (MHRA) allows for certain exemptions from licensing which includes the manufacture and supply of medicines for individual named-patients ('specials').[3] The MHRA conditions for specials are: that there is a bona fide unsolicited order, the product is formulated in accordance with the requirement of a doctor or dentist registered in the UK, and the product is for use by their individual patients on their direct personal responsibility.

The special may either be made extemporaneously in community or hospital pharmacy, or in premises with a manufacturer's (specials) licence issued by the MHRA It may also be imported from abroad.

A 'special' may not be advertised and may not be supplied if an equivalent licensed product is available which could meet the patient's needs.

Essential records must be kept and serious adverse drug reactions reported to the MHRA.

- **MHRA Risk Hierarchy for the use of unlicensed medicines** [4]

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

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

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

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[3] The MHRA Guidance Note 14, 'The supply of unlicensed relevant medicinal products for individual patients', provides guidance to manufacturers about the conditions under which they may manufacture and supply 'specials' and their legal obligations.
http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Medicinesthatdonotneedalicence/index.htm Date Accessed 17th December 2009.

[4] MHRA November 2009. Summary Report for Importation of Unlicensed Medicines 01 Apr 2009 – 30 Jun 2009. Risk Hierarchy for the use of unlicensed medicines
http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON068207
Date Accessed 27th January 2010.

The least acceptable products are those that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK).

Hence, for example, the use of melatonin products from the USA, where melatonin products are classed as supplements, not pharmaceuticals and may not be made to expected standards of pharmaceutical GMP should be avoided whenever possible.

- **Advice from Royal Pharmaceutical Society of Great Britain (RPSGB)**

The RPSGB offers members advice on the subject in two publications:

- Use of Unlicensed Medicines in Pharmacy (2007).[5]
- Procurement of Pharmaceutical "Specials" (2009).[6]

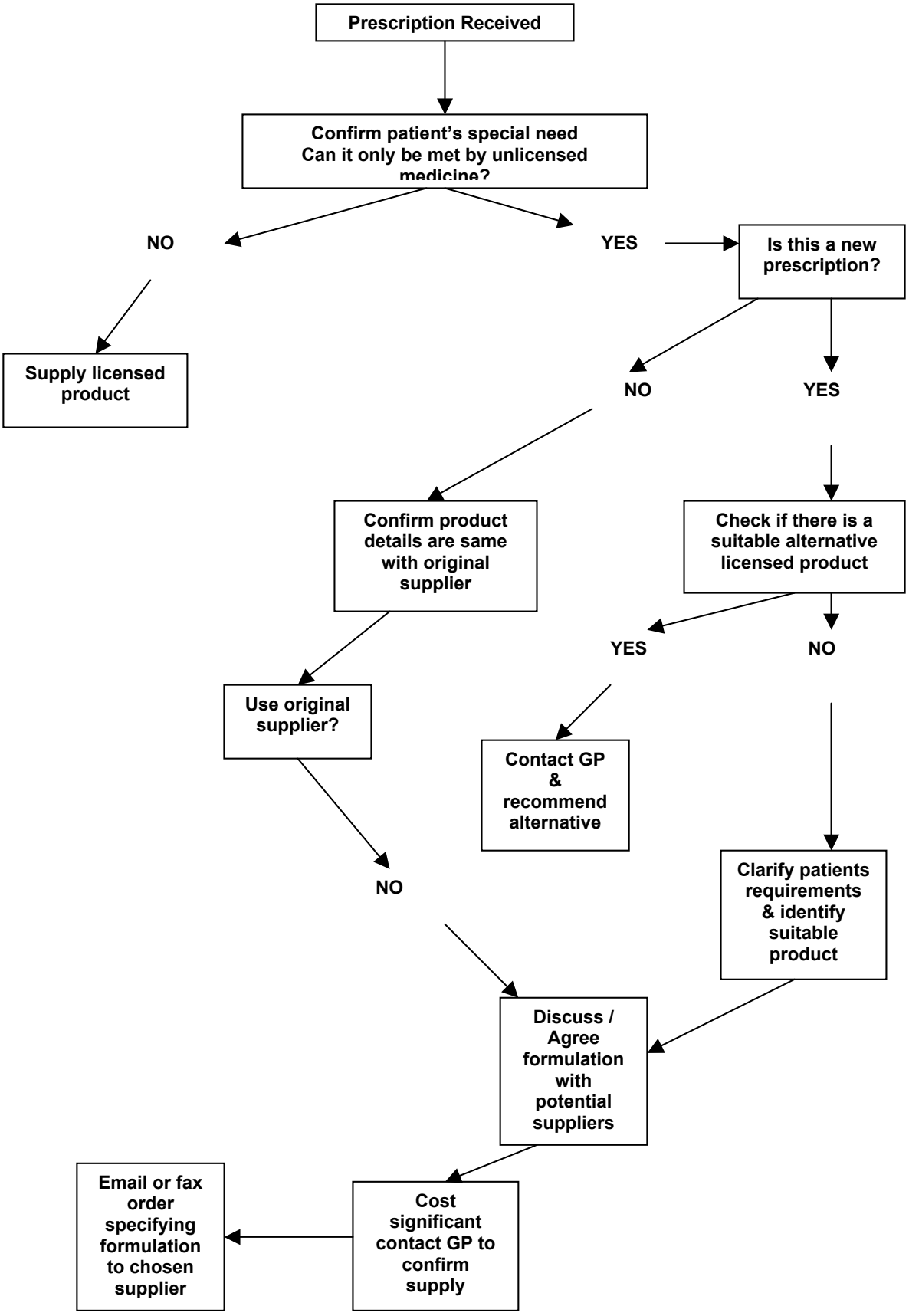
The RPSGB guidance to pharmacists includes advice that the pharmacist

- Should make every reasonable effort to identify a UK licensed product, or near equivalent, to the prescribed 'Special' that meets the patient's clinical needs.
- Always contact the prescriber to discuss alternatives.
- Regularly check that the chosen supplier is offering value for money on their products.

Appendix 3 Decision Aid / Flow Chart

[5] RPSGB 2007. Legal and Ethical Advisory Service Fact Sheet Five The Use of Unlicensed Medicines in Pharmacy 5http://www.rpsgb.org.uk/pdfs/factsheet5.pdf Date Accessed 17th December 2009.

[6] RPSGB 2009. Good Practice Guidance on The Procurement of Pharmaceutical Specials http://www.rpsgb.org.uk/pdfs/epb0911-04-app1.pdf Date Accessed 17th December 2009.


Prescription Received
Confirm patient's special need
Can it only be met by unlicensed medicine?
NO
YES
Is this a new prescription?
Supply licensed product
NO
YES
Confirm product details are same with original supplier
Check if there is a suitable alternative licensed product
YES
NO
Use original supplier?
Contact GP & recommend alternative
NO
Clarify patients requirements & identify suitable product
Discuss / Agree formulation with potential suppliers
Email or fax order specifying formulation to chosen supplier
Cost significant contact GP to confirm supply