NHS Forth Valley Guidance for Community Pharmacists

Special Formulations and Unlicensed Products
Contents

NHS Forth Valley Guidance for Community Pharmacists - Special Formulations and Unlicensed Products ................................................................. 3
  Definition of a Special .................................................................................. 3
  Legal and Professional Considerations of Licensed Versus Unlicensed Products . 4
  Process for Checking, Authorising and Ordering a Special Ordered on a Prescription ..................................................................................... 5
  Suppliers of Specials ...................................................................................... 5
  Reimbursement ............................................................................................... 5
  Appendix 1 - Algorithm for Determining Supply .......................................... 7
  Appendix 2 ...................................................................................................... 8
  Useful Contact Details ................................................................................... 8
  Further Reading .............................................................................................. 8
NHS Forth Valley Guidance for Community Pharmacists - Special Formulations and Unlicensed Products

This guidance covers the supply of Special Formulations and unlicensed products in Primary Care in NHS Forth Valley. It is intended to inform pharmacists of what constitutes a special, why specials carry additional responsibilities, and consequently, why pharmacists ordering and dispensing them must be aware of their limitations. In this way pharmacists can provide better service to their patients, and ultimately NHS Forth Valley.

The aims of the guidance are:

- To inform pharmacists of their responsibilities and liabilities as regards the supply of special formulations and unlicensed products in primary care.
- To ensure the correct process is used to enable remuneration for these products.
- To ensure that unlicensed, expensive ‘specials’ are not prescribed when licensed, cost effective alternatives are available.

It is the Medicines and Healthcare products Regulatory Authority’s (MHRA) responsibility to ensure that licensed medicines and devices work, are safe, and are of appropriate quality. They do this by a process of licensing manufacturers, products, and distributors. It is strongly recommended that pharmacists involved in the supply of specials and unlicensed products should read the MHRA Guidance Note 14 on ‘The supply of unlicensed relevant medicinal products for individual patients’.

This NHS Forth Valley guidance aims to support that document by giving additional local information.

Definition of a Special

The term ‘special’ can be applied to any Medicinal Product, as defined by the Medicines Act 1968 that does not hold a full Marketing Authorisation (MA) or Product Licence (PL) or European Medicines Evaluation Authority Licence (EMEA). The MHRA refers to specials as ‘unlicensed relevant medicinal products placed on the market in order to meet the special needs of an individual patient’.

For the purposes of this guidance, Specials may include:

- Unusual and therefore unlicensed strengths of existing Licensed Medicines.
- Unusual presentations of existing Active Ingredients.
- Imported products (not otherwise available in the United Kingdom and not European Medicines Evaluation Agency (EMEA) approved).
- Other products not otherwise commercially available.

The MHRA guidance on specials, does not apply to products made as an extemporaneous product in the pharmacy under the supervision of a pharmacist in possession of a prescription for a specific patient issued by a doctor or dentist.

1 http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007547.pdf
Legal and Professional Considerations of Licensed Versus Unlicensed Products

The Licensing of Medicinal Products is covered by Parts One and Two of the Medicines Act 1968, as amended. The relevant Licensing Body is the MHRA, and for some products the European Medicines Evaluation Agency (EMEA). Additional requirements are enshrined in European Law. The following is a brief summary of the situation.

For a **LICENSED** Product:

- The granting of a PL/MA provides assurance of product quality and comprehensive data with respect to licensed indications and an approved Patient Information Leaflet.
- In the rare event of misadventure with a **licensed product** where the cause can be solely attributed to the product and it can be proved that the product was prescribed and used in accordance with the terms of the PL/MA, the **license holder is liable** for any claim that may be entertained.

For an **UNLICENSED** Product:

- the **pharmacist** directly supplying an unlicensed medicine bears **shared clinical responsibility** with the prescriber as to **suitability and safety of the product for use by the individual patient.** The **pharmacist** is also considered as the producer of the product under the Medicines Act and bears **direct responsibility for the formulation, quality, presentation and labelling of the product and that it meets dispensing standards.**
- Prior to making a supply to the patient, the **pharmacist** as ‘purchaser’ of the item, **has a clear duty to remind the prescriber of their responsibilities in prescribing a special** i.e. that they (the prescriber) will bear clinical responsibility for prescribing an unlicensed product and that full prescribing information about the product is probably unavailable.
- If a licensed product is available that is therapeutically equivalent to the unlicensed product requested on prescription, the pharmacist should contact the prescriber with a view to discussing the possibility of supplying the licensed product in place of the unlicensed one.

**When supplying an unlicensed product:**

- The pharmacist should **periodically** remind the prescriber of this if prescribing is to be continued long term, to **confirm that the special is still the only suitable preparation for the patient.**
- The patient should also be informed that the product dispensed to them is an unlicensed or special product and have this status explained to them.

A special or unlicensed product must only be considered if there is no suitable licensed product available (the references in Appendix 2 provide advice on alternatives). The prescriber and the dispensing pharmacist bear personal responsibility for the prescription and supply respectively of unlicensed specials, and any adverse events due to the use of a special.
Process for Checking, Authorising and Ordering a Special Ordered on a Prescription

1. Why is this product required?
2. Is it clinically suitable for the patient?
3. Check the item in the BNF to see if a licensed alternative strength or form is available. Do any equivalent alternative proprietary products exist (eg using a drug in the same therapeutic class)?
4. Determine the formulation that you need for the special and use this and additional information on packaging, labelling, storage, and expiry to form your specification to order the special or extemporaneously prepare the product. At this point it may also be useful to check if other more readily available forms or strengths would be able to be used (e.g. a higher strength liquid supplied with an oral syringe to measure the dose) as these tend to be more cost-effective. This may be either a licensed product, or where no licensed version exists, a product listed by the Specials manufacturer rather than a ‘bespoke’ Special.
5. Can the product be safely extemporaneously prepared?
6. Check if the special is available from Tayside Pharmaceuticals or Glasgow Western Infirmary Pharmaceutical Production Units.
7. Only if the product is not available from Tayside Pharmaceuticals or Glasgow Western Infirmary Pharmaceutical Production Units, get quotes from other specials manufacturers using the specification above, or contact the Pharmacy Prescribing Support Team at Euro House for further advice.
8. Contact the prescriber with the information you have gathered and discuss the most appropriate product for the patient (strength, formulation, form, presentation). Decide on the best option for the patient. Ensure the prescriber is aware of the unlicensed status of any Specials and the price of the product.
9. Contact the Pharmacy Prescribing Support Team with all the relevant information to seek NHS Forth Valley authorisation.
10. Make sure the patient and the prescriber are aware of any time delays in obtaining supply of the medicine.

Suppliers of Specials

A number of commercial companies provide special dispensed products. In addition a number of NHS units based in Scotland hold MHRA specials manufacturer licenses to cater for the requirements of their own site and other sites, including Community Pharmacies.

NHS Forth Valley recommends Tayside Pharmaceuticals and Glasgow Western Infirmary Pharmaceutical Production Unit as the first-line source of Specials in the first instance as these are the most cost-effective options for the NHS (contact details in Appendix 2)

Reimbursement

Information on payment for specials is given in the Scottish Drug Tariff Section 1 – General Information\(^2\). The Tariff requires the pharmacist to provide reasons to Practitioner Services Division (PSD) for the commissioning of a Special from a specials manufacturer.

Whenever a special has been supplied, the pharmacy must provide invoice evidence. Out of pocket expenses for postage and packing may also be claimed.

PSD may refer any item presented for pricing to NHS Forth Valley, who will make a decision as to whether full payment will be sanctioned. The Pharmacist should be able to justify why they elected to have a special prepared, and may have to fund the difference in cost if the Health Board feels that the product could have been supplied by another, more suitable means.
Appendix 1 - Algorithm for Determining Supply

Is a special product required? Is there a licensed product of a different strength or an acceptable alternative? Contact the prescriber to discuss the need for special / unlicensed formulation

Does the prescriber wish to continue with the special?

Yes

No

Agree an alternative treatment with the prescriber and arrange for a new prescription. Supply as normal. Inform the patient

Can the product be safely prepared extemporaneously?

Yes: prepare by extemporaneous method and make appropriate endorsement and claim

No

Has the patient had the product before?

No

Identify product specification

Is the product available from Tayside Pharmaceuticals (01382 632052) or Glasgow Western General Pharmaceutical Production Unit? 0141 211 2882)

If no NHS supply available contact the Pharmacy Prescribing Support Team for advice on cost effective suppliers or provide the Team with a cost effective supplier that you have identified

Has the patient had the product before?

No

Do you have the product specification? Does the supplier still provide the product?

Yes

Order and supply

No

Has the patient had the product before?

No

Identify product specification

Is the product available from Tayside Pharmaceuticals (01382 632052) or Glasgow Western General Pharmaceutical Production Unit? 0141 211 2882)

If no NHS supply available contact the Pharmacy Prescribing Support Team for advice on cost effective suppliers or provide the Team with a cost effective supplier that you have identified

No

Remember - Prescribers may not have intentionally selected an unlicensed Special
Information on alternatives to Specials available at: http://tinyurl.com/FVSpecials
Check periodically to ensure that a special is still appropriate (new licensed product may have become available)
An unlicensed Special should only be used when no licensed alternative is appropriate
Tayside Pharmaceuticals (01382-632052)/Glasgow Western Infirmary (0141-211 2882) are the recommended first-line sources for Specials where possible
Prices for ‘stock’ listed Specials are more cost-effective than ‘bespoke’ specially requested strengths etc

NHS Forth Valley October 2012
Appendix 2
Useful Contact Details

<table>
<thead>
<tr>
<th>Practitioner Services Division</th>
<th>(Ask for a Group Leader)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edinburgh</td>
<td>0131 275 6600</td>
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<tr>
<td>Glasgow</td>
<td>0141 207 1615</td>
</tr>
<tr>
<td>Community Pharmacy Scotland</td>
<td>0131 467 7766</td>
</tr>
<tr>
<td>Scottish Drug Tariff web link</td>
<td><a href="http://tinyurl.com/ScotDT">http://tinyurl.com/ScotDT</a></td>
</tr>
<tr>
<td>MHRA Website</td>
<td><a href="http://www.mhra.gov.uk">www.mhra.gov.uk</a></td>
</tr>
<tr>
<td>Tayside Pharmaceuticals</td>
<td>01382 632052</td>
</tr>
<tr>
<td>Glasgow Western Infirmary</td>
<td>0141 211 2882</td>
</tr>
<tr>
<td>Pharmaceutical Production Unit</td>
<td></td>
</tr>
<tr>
<td>Medicines Information</td>
<td>01324 566725</td>
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<tr>
<td>Department, FVRH</td>
<td></td>
</tr>
<tr>
<td>Forth Valley Community</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Show Pages (Specials</td>
<td><a href="http://tinyurl.com/FVS">http://tinyurl.com/FVS</a></td>
</tr>
<tr>
<td>Information)</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Prescribing Support</td>
<td><a href="mailto:FV-UHB.prescribingsupport@nhs.net">FV-UHB.prescribingsupport@nhs.net</a></td>
</tr>
<tr>
<td>Team</td>
<td></td>
</tr>
</tbody>
</table>

Further Reading

NELM QA294 Therapeutic options for patients unable to take solid dosage forms
http://www.communitypharmacy.scot.nhs.uk/nhs_boards/NHS_Forth_Valley/documents/QA294_2_Therapeutic_options_patients_unable_take_solid_oral_dosage_forms_Jan111.pdf

Royal College of Paediatrics and Child Health The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice