Special Formulation And Unlicensed Products In Primary Care

A Guide For Pharmacists Working Within NHS Grampian

Co-ordinators:
Principal Pharmacist, Pharmaceutical Services, Pharmacy and Medicines Directorate

Consultation Group:
See relevant page in guidance

Approver:
Director of Pharmacy and Medicines Management

Signature:

Signature:

Identifier:
NHSG/Guid/Specials_001

Review Date:
February 2015

Date Approved:
February 2013

Uncontrolled when printed
Version 1
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Title: Special Formulation And Unlicensed Products In Primary Care - A Guide For Pharmacists Working Within NHS Grampian

Unique Identifier: NHSG/ Guid/ Specials_001

Replaces: New document

Lead Author/Co-ordinator: Principal Pharmacist, Pharmaceutical Services, Pharmacy and Medicines Directorate

Subject (as per document registration categories): Guidance

Key word(s): Special, formulation, unlicensed, community, pharmacy, medicine, imported, off-label

Process Document: Policy, Protocol, Procedure or Guideline

Guidance

Document application: NHS Grampian

Purpose/description: This guidance covers the ordering and supply of special formulations and unlicensed products (Specials) in Primary Care in NHS Grampian.

Group/Individual responsible for this document: Principal Pharmacist, Pharmaceutical Services, Pharmacy and Medicines Directorate

Policy statement: It is the responsibility of all staff to ensure that they are working to the most up to date and relevant policies, protocols procedures.
Responsibilities for ensuring registration of this document on the NHS Grampian Information/Document Silo:

Lead Author/Co-ordinator: Principal Pharmacist, Pharmaceutical Services, Pharmacy and Medicines Directorate

Physical location of the original of this document: Pharmacy and Medicines Directorate

Job title of creator of this document: Principal Pharmacist, Pharmaceutical Services, Pharmacy and Medicines Directorate

Job/group title of those who have control over this document: Principal Pharmacist, Pharmaceutical Services, Pharmacy and Medicines Directorate

Responsibilities for disseminating document as per distribution list:

Lead Author/Co-ordinator: Principal Pharmacist, Pharmaceutical Services, Pharmacy and Medicines Directorate

Responsibilities for implementation:
Organisational: Pharmacy and Medicines Directorate
Sector: CHP Lead Pharmacists
Area: Primary Care, Community Pharmacy

Review frequency and date of next review: This guidance will be reviewed at least every two years or sooner if current treatment recommendations change.

Responsibilities for review of this document:
Lead Author/Co-ordinator: Principal Pharmacist, Pharmaceutical Services, Pharmacy and Medicines Directorate

Revision History:

<table>
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<th>Summary of Changes (Descriptive summary of the changes made)</th>
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* Changes marked should detail the section(s) of the document that have been amended i.e. page number and section heading.
Special Formulation And Unlicensed Products In Primary Care - A Guide For Pharmacists Working Within NHS Grampian

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Acknowledgment

This document was based on an original document commissioned by the Scottish CAPO Group in October 1997. It was updated by Don Page, Technical Services Pharmacist, Information and Statistics Division and issued by the Association of Scottish Trust Chief Pharmacists and has been adapted to meet NHS Grampian needs.
Special Formulation And Unlicensed Products In Primary Care - A Guide For Pharmacists Working Within NHS Grampian

1. Introduction

This guidance covers the ordering and supply of special formulations and unlicensed products (Specials) in Primary Care in NHS Grampian.

It is recognised that it is sometimes necessary that specials are prescribed in Primary Care but the patient, prescriber and supplying pharmacist should all be aware when a special is being used and the implications of that.

This guidance aims to:

- Support the new Part 7S of the Scottish Drug Tariff.
- Support local implementation of Medicines and Healthcare products Regulatory Authority (MHRA), Royal Pharmaceutical Society (RPS) and General Medical Council (GMC) advice.
- Ensure that unlicensed, expensive ‘specials’ are not prescribed when appropriate licensed or more cost effective alternatives are available.
- Remind pharmacists of their responsibilities and liabilities with regard to the supply of specials.
- Outline the correct process to ensure pharmacists:
  - fulfil their legal and professional responsibilities.
  - know under what circumstances authorisation is a requirement for a special.
  - know how to obtain authorisation for a special.
  - know how to ensure full remuneration for the specials they supply.

2. Guidance And Further Reading

Further guidance on specials can be found at:


MHRA at: http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedlicensure/Medicinesthatdonotneedlicensure/index.htm

3. 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).

For the purposes of this paper, the products may include:

- Non-standard and therefore unlicensed strengths of existing licensed medicines.
- Non-standard presentations of existing active ingredients.
- Non European Medicines Evaluation Agency (EMEA) approved imported products (not otherwise available in the United Kingdom).
- Other products not otherwise commercially available.

Please note that the MHRA guidance on specials does not apply to a product made up directly by the pharmacist, on the direct order of a doctor or a dentist, for a specific patient, if the prescription form is within the building where the compounding is occurring (i.e. extemporaneous dispensing of a prescription by the pharmacist in their pharmacy).

4. Prescribed Specials – The Prescriber’s Responsibilities

The prescriber should fully understand that prescribers of unlicensed medicines, or medicines prescribed outwith their marketing authorisation (off-label), have a personal liability for their prescription that cannot be transferred to the manufacturer or importer of the medicine.

5. Prescribed Specials – The Pharmacist’s Responsibilities

The pharmacist directly supplying a special bears shared clinical responsibility with the prescriber as to the suitability and safety of the product for use by the individual patient. The pharmacist is also considered 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.
It should be noted that a specials manufacturer license is specific to both the premises and the product. Some manufacturers may make products that are not covered by their license and it is up to the person ordering a product to ensure that the item ordered is covered by the specials license.

Supply of a special should not be entered into without due consideration of the needs of the patient and suitability of the special and must only be considered if there is no suitable licensed product available.

When presented with a prescription for a special or unlicensed product for a patient, the pharmacist as purchaser of the item has clear professional duties to discuss the appropriateness of the medication with the prescriber in terms of:

- availability of any licensed product that is therapeutically equivalent.
- Informing/reminding the prescriber of their responsibilities in prescribing a special including:
  - that they (the prescriber) will bear clinical responsibility for prescribing an unlicensed product.
  - that full prescribing information about the product is not always available.
  - the cost involved in obtaining the product.
  - the timescale for obtaining the product.

The pharmacist must inform/remind the patient that the product being dispensed is an unlicensed or special product and the implications of this, e.g. unlicensed, time delay etc.

6. Process For Checking, Authorising And Ordering A Special For A Prescription

When a prescription for a special is received in the pharmacy the following steps and checks should be undertaken in every case.

(1) Check if the patient has had the item dispensed before.
(2) Check if the special is clinically suitable for the patient.
(3) Check the BNF to see if a licensed alternative is available either in a different form or as an alternative proprietary product in the same class.
(4) Check if any licensed products could be used in an unlicensed way, e.g. tablets crushed or dispersed, or capsules opened. Is using a product in this way bioequivalent to the original? The Medicines Information Department at ARI may have information available to confirm this. In addition, the UKMI document ‘Therapeutic options for patients unable to take solid oral dosage forms’ may be a useful reference: http://www.nelm.nhs.uk/en/Original-search/?query=therapeutic+options+for+patients+unable.
(5) Determine the specific formulation that you need for the special.
(6) Determine if the product can be extemporaneously prepared.
(7) Use the formulation and additional information on packaging, labelling, storage, and expiry to form a specification for the product.
(8) Request costing information from specials companies based on this specification (including postage and packing, delivery or handling charges).
Medicines Information Department or Quality Assurance Department at ARI may already have information on suppliers to approach.

Note: At this point it may also be useful to check with these suppliers if alternative forms or strengths of the preparation requested are available more readily (e.g. a higher strength liquid which would enable the prescribed dose to easily given via an oral syringe). Also check the most cost effective quantity to purchase, e.g. 100 tablets may cost less than the 56 required.

(9) Contact the prescriber to provide information on alternative products, costs, time scales and to discuss the product options for the patient (strength, formulation, form, presentation).

(10) Agree the most appropriate option for the patient.

(11) If the prescriber confirms that the special is the most appropriate product for the patient then **NHS Grampian authorisation must be obtained prior to ordering the special unless the product:**

- is listed in Part 7S of the Drug Tariff.
- can be prepared extemporaneously in the pharmacy
- is available from Tayside Pharmaceuticals or Glasgow Western Infirmary Pharmaceutical Production Unit.
- is on the NHS Grampian Specials List (Appendix 2). NB the cost indicated in this list is the maximum that NHS Grampian will authorise Practitioner Services Division (PSD) to reimburse, should a pharmacist choose to use a source of supply other than that named on the list.
- is a repeat prescription for a specific patient where an authorisation number has previously been given for the same product, provided the cost has not increased since the last dispensing.

(12) NHS Grampian authorisation can be requested following e-mail submission of the fully completed ‘Request Form for Authorisation to Order Specials’ from the appropriate Community Health Partnership (CHP) lead pharmacist (see Appendix 1) or if not available, from the Pharmacy and Medicines Directorate. Authorisation will either be given at this point, or failing that, further investigation or alternative supply arrangements suggested.

(13) When authorisation is given, pharmacists will be provided with an authorisation number which they should then add in the box provided to their copy of the request form

(14) Order the product from the agreed source.

(15) When ordering a special, the pharmacist must also obtain a Certificate of Analysis (COA) or Certificate of Conformity (COC) from the supplier.

(16) Each month the pharmacist will submit to the Pharmacy and Medicines Directorate, via fax or e-mail a copy of all COA/ COCs received in that month, each appropriately endorsed (see PCA(P)(20013)4 point 6 and Appendix 1 (contact information)).

(17) Appropriate records of the supply must be kept for 5 years

A flow chart ‘Algorithm of Supply Process for a Special’ of the steps required in order to make a supply is available in Appendix 3.
7. **Product Specification**

It is the responsibility of the pharmacist supplying a special to understand and define the specification and formulation of the product that they require from the specials manufacturer. As part of this, it is necessary for the pharmacist to fully understand the intended use of the medicine. The ‘specification’ will include information on formula, labelling and the storage requirements of the product and any other appropriate details, e.g. any patient information.

8. **Pre-Authorisation Of Specified Products**

NHS Grampian has pre-authorised all specials products available from either Tayside Pharmaceuticals or Glasgow Western General Pharmaceutical Production Unit i.e. no request for authorisation form is required.

In addition, an NHS Grampian Specials List of products has been compiled (Appendix 2) indicating specific products which can be ordered without authorisation provided they are obtained at a cost not exceeding that provided by the supplier quoted. Pharmacists are under no obligation to purchase the products on the NHS Grampian Specials List from the manufacturers/suppliers specified. However, where a product appears on a pre-authorised list, NHS Grampian will only guarantee to authorise full reimbursement to a contractor for that product at the price listed. If the invoice price being claimed is more than the price listed for the product on one of the pre-authorised lists, full reimbursement is not guaranteed and NHS Grampian reserves the right to claim back excessive costs.

This list will be regularly reviewed and distributed to community pharmacy contractors in Grampian. It is intended that this list will available on the NHS Grampian community pharmacy webpage of the SHOW web site.

9. **Choosing A Different Supplier Of Specials**

A number of commercial companies provide special products. In addition a number of other NHS production/manufacturing units hold MHRA specials manufacturer licenses to cater for the requirements of their own site and other hospitals.

NHS Grampian recognises that there will be occasions when supplies from manufacturers, other than those specified on the pre-authorised lists, may be needed. Where a product can be obtained at, or under, the prices listed on the pre-authorised lists for these products, no authorisation is required.

Where a product is:

- unavailable from the listed suppliers.
- unavailable at the listed price from the listed or another manufacturer.
- not listed in the NHS Grampian Specials List (Appendix 2)

then contractors must request authorisation to purchase the product.

Failure to follow the processes in this guidance, in particular, where pharmacies fail to use the information available with regard to listed products, invoice excessive
charges for products that appear on the NHS Grampian Specials List (Appendix 2) or fail to get authorisation prior to ordering, may result in NHS Grampian refusing to authorise payment or seeking to claw back excessive claims for reimbursement.

10. Products Initiated In Hospital

If a patient has been discharged from hospital on a special, the hospital pharmacist can be contacted for advice on the specification and formulation that was used and the source of supply. Where difficulty of supply is an issue, the hospital concerned may be willing to supply the product or provide a suitable formula for extemporaneous preparation in the pharmacy. This would be at the discretion of the hospital pharmacy, and would take account of clinical responsibility for the patient, where this has been retained by the hospital specialist. Where the product is supplied in this way, the pharmacy will be invoiced by the hospital for the product, and this invoice can be sent with the prescription (suitably endorsed) when it is submitted for payment to PSD.

11. Payment Or Reimbursement By Practitioner Services Division (PSD)


Full instructions for required paperwork and endorsements for specials prescriptions are available in PCA(P)(2013)4 on the Scottish Health on the Web (SHOW) website and in the Scottish Drug Tariff.

In line with MHRA Guidance, prescriptions for special formulations that are deemed to be pharmaceutically equivalent to an existing licensed product would not be paid at invoice price unless it is proved that the licensed versions were genuinely unavailable or unsuitable for the patient. PSD maintains a list of products that are formally unobtainable, and this may be checked by contacting one of the pricing offices or checking the Scottish Drug Tariff.

Pharmacists are reminded that under the RPS guidance they have an obligation to seek best value for the NHS. It is expected that in discharging their obligation pharmacies will obtain quotations for a particular product from different suppliers prior to requesting authorisation to order a special.

12. Summary

There are occasions when after discussion with the prescriber, the patient’s needs dictate that there is no other choice than to supply a special product.

This NHS Grampian document describes the acceptable processes for obtaining a special which will guarantee full reimbursement of the cost of that special. Where pharmacies are sourcing products from other suppliers or where the cost to be reimbursed will exceed the maximum cost for the listed products, pharmacies require authorisation from NHS Grampian prior to ordering. Failure to follow the processes in this guidance, and in particular failure to apply for authorisation where needed,
may result in pharmacies not being fully reimbursed for the specials medicines they have supplied.

The following directions apply:

- The Scottish Drug Tariff contains a list of specials that attract a set reimbursement payment and which may be ordered without prior authorisation (Section 7S).
- Extemporaneous preparation, within the pharmacy, should be considered.
- Where either Tayside Pharmaceuticals or Glasgow Western Infirmary production units are used to obtain specials, these specials may be ordered without prior authorisation.
- The NHS Grampian Specials List (Appendix 2) contains details of items and their suppliers for which pre-authorisation has been given but for which NHS Grampian will only pay the listed cost as a maximum.
- Authorisation for Specials must be obtained prior to ordering except where the products are in Part 7S of the Drug tariff, or prepared extemporaneously, or available from Tayside Pharmaceuticals or Glasgow Western Infirmary Pharmaceutical Production Unit, or on the NHS Grampian Specials List (Appendix 2).
- Authorisation must be requested by submitting the request form (Appendix 4) to the appropriate CHP Lead pharmacist (Appendix 1). Pharmacy contractors must not proceed with ordering or supply of the item unless authorisation has been granted. Where authorisation is not granted further direction will be given.
- Pharmacy contractors must keep full records of procurement and supply of specials. There is a further requirement to submit information on specials products supplied to NHS Grampian each month, in accordance with PCA(P)(2013)4 item 6.

13. Consultation Group

Louise Black Aberdeenshire CHP Lead Pharmacist
Alison Davie Aberdeen City CHP Lead Pharmacist
Caroline Hind Deputy Director of Pharmacy and Medicines Management
Linda Juroszek Aberdeen City CHP Lead Pharmacist
Joan MacLeod Aberdeen City CHP Lead Pharmacist
Elaine Neil Aberdeenshire CHP Lead Pharmacist
Wendy Robertson Principal Pharmacist, Pharmaceutical Services, Pharmacy and Medicines Directorate
Lesley Thomson Aberdeenshire CHP Lead Pharmacist
Sandy Thomson Moray CHP Lead Pharmacist
Craig Rore Medicines Information Department, ARI
Susan Healy Principal Pharmacist, Pharmacy Department, ARI
Contact Information

<table>
<thead>
<tr>
<th>Practitioner Services Division</th>
<th>(Ask for a Group Leader)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aberdeen</td>
<td>Tel 01224 358300</td>
</tr>
<tr>
<td>Edinburgh</td>
<td>Tel 0131 557 3733</td>
</tr>
<tr>
<td>Glasgow</td>
<td>Tel 0141 332 0787</td>
</tr>
<tr>
<td>SPGC</td>
<td>Tel 0131 467 7766</td>
</tr>
</tbody>
</table>

| ISD Customer Services Desk    | Tel 0131 551 8899        |

| MRHA Website                  | [www.mhra.gov.uk](http://www.mhra.gov.uk) |
| ISD                           | [www.show.scot.nhs.uk/isd](http://www.show.scot.nhs.uk/isd) |

| Tayside Pharmaceuticals       | Tel 01382 632 183        |
| Glasgow Western General Pharmaceutical Production Unit | Tel 0141 211 2882 |

| Medicines Information Department, ARI | grampian.medinfo@nhs.net | Tel 01224 552316 |
|                                      |                          | Fax 01224 553371 |
| Pharmacy and Medicines Directorate  | nhsg.pmu@nhs.net         | Tel 01224 556527 |
|                                      |                          | Fax:01224 556002 |

For authorisation of specials requests

<table>
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<tr>
<th>CHP Pharmacists</th>
<th>Email address</th>
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<tr>
<td>Moray</td>
<td><a href="mailto:nhsg.specialsmoray@nhs.net">nhsg.specialsmoray@nhs.net</a></td>
</tr>
<tr>
<td>Aberdeen City CHP</td>
<td><a href="mailto:nhsg.specialsaberdeen@nhs.net">nhsg.specialsaberdeen@nhs.net</a></td>
</tr>
<tr>
<td>Aberdeenshire CHP</td>
<td><a href="mailto:nhsg.specialsaberdeenshire@nhs.net">nhsg.specialsaberdeenshire@nhs.net</a></td>
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</table>
NHS Grampian Specials List

List correct as of 28th February 2013. Always refer to the latest NHS Grampian Specials List available on the NHS Scotland Community Pharmacy Web site:
http://www.communitypharmacy.scot.nhs.uk/nhs_boards/grampian.html

The attached list identifies some product for which pre-authorisation is granted provided the cost does not exceed that quoted from the named supplier. Pharmacy contractors are still required to discuss the appropriateness of supplying these products with the GP. The costs quoted will be the maximum paid to a pharmacy ordering these products from any source and are correct at the time of printing.

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<th>Product</th>
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<th>Expected cost</th>
<th>Notes</th>
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<tr>
<td>Acetylcysteine capsules 600mg</td>
<td>Martindale 0800 137 627</td>
<td>£13.31/60 capsules plus P&amp;P</td>
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<tr>
<td>Amisulpiride Suspension 100mg/mL</td>
<td>Glasgow Western Infirmary 0141 211 2882</td>
<td>£43.00/60mL</td>
<td>Smaller strength solutions available on the Drug Tariff.</td>
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<tr>
<td>Bio-Melatonin 3mg</td>
<td>Pharma Nord (UK) Ltd. Telford Court Morpeth Northumberland NE61 2DB, Tel 01670 519989</td>
<td>£15.44 / 60 tablets ex VAT plus carriage and handling £10.50</td>
<td>See GP agreement letter for Bio-melatonin. Bio-Melatonin 3mg Tablets are suitable for vegetarians. Bio-Melatonin 3mg is an Unlicensed Medicine within the UK but is licensed within the EC in Hungary. There is an agreement between Pharma Nord Ltd and the NHS Grampian Medical Director allowing prescribers in Grampian to write prescriptions without the requirement to complete individual patient specific authorisation. If the patient is unable to swallow tablets, Bio-Melatonin® tablets can be crushed and sprinkled on food or mixed with water, milk or yoghurt.</td>
</tr>
<tr>
<td>Diltiazem Cream 2% x 30g (Anoheal®)</td>
<td>Alliance Healthcare E-mail <a href="mailto:specials.orders@alliance-healthcare.co.uk">specials.orders@alliance-healthcare.co.uk</a> Tel 01773 515 599 Fax 0845 0518 779</td>
<td>£96.97 exc Vat £20 carriage</td>
<td></td>
</tr>
<tr>
<td>Product</td>
<td>Obtain from</td>
<td>Expected cost</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>--------------------------------------</td>
<td>---------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Dantrolene Suspension 25mg/5mL</td>
<td>Glasgow Western General 0141 211 2882</td>
<td>£61/500mL</td>
<td>Other strengths and volumes are available on request.</td>
</tr>
<tr>
<td>Levomepromazine 6mg tablets</td>
<td>IDIS 01932 824 000</td>
<td>£63.55/28 tablets</td>
<td></td>
</tr>
<tr>
<td>Menthol in Aqueous Cream 0.5%, 1% and 2% in various sizes (Dermacool®)</td>
<td>Available through your wholesaler</td>
<td>Prices up to approx £6</td>
<td></td>
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<tr>
<td>Midodrine tablets 2.5mg</td>
<td>IDIS Tel 01932 824 000</td>
<td>Gutron £42.50 /50</td>
<td></td>
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<tr>
<td>Magnesium Glycerophosphate Tablets 97.2mg(4mmol) (Magnaphate)</td>
<td>AAH</td>
<td>£20.96/50</td>
<td>Unlicensed, but branded consistent product.</td>
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<tr>
<td>Propylene Glycol 40% in Aqueous Cream</td>
<td>Tayside Pharmaceuticals 01382 632 183</td>
<td>£10.71/200g</td>
<td></td>
</tr>
<tr>
<td>Sildenafil suspension 10mg/5mL</td>
<td>Glasgow Western General 0141 211 2882</td>
<td>£157.50/1000mL</td>
<td>Other strengths and volumes are available on request.</td>
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<tr>
<td>Sodium Chloride Eye Drops 5%</td>
<td>Tayside Pharmaceuticals 01382 632 183</td>
<td>£5.34/5mL</td>
<td></td>
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<tr>
<td>Tacrolimus suspension</td>
<td>Glasgow Western General 0141 211 2882</td>
<td>1mg/5mL</td>
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<td></td>
<td>£120/2.5mg/5mL</td>
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<td></td>
<td></td>
<td>£180/5mg/5mL</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>£180/100mL</td>
<td></td>
</tr>
<tr>
<td>Venlafaxine Oral Suspension 37.5mg/5mL</td>
<td>Glasgow Western General 0141 211 2882</td>
<td>£44/100mL</td>
<td>Other strengths and volumes are available on request.</td>
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Endorsing guidance for electronic and paper prescriptions is available at [http://www.communitypharmacy.scot.nhs.uk/endorsing_guide/Section1/introduction.html](http://www.communitypharmacy.scot.nhs.uk/endorsing_guide/Section1/introduction.html) to ensure that the correct fee is paid to contractors.
The pharmacist should contact the prescriber to discuss the need for special and to consider if:
- a special is actually required
- a licensed product of a different strength or form is available as an acceptable alternative
- tablet formulation can be crushed and dissolved or dispersed or capsules opened
- the cost is acceptable.

Following this discussion, does the prescriber still wish to prescribe the special?

No

Yes

Identify product specification

Agree alternative arrangements as required

- Is the product listed in Part 7S of the Drug Tariff?
- Is the product on the NHS Grampian Specials List?
- Can you appropriately prepare the product extemporaneously?
- Is the product available from Tayside Pharmaceuticals or Glasgow Western Infirmary?

Complete and submit email authorisation request to CHP pharmacist including appropriate quotes

Has request been authorised?

Yes

Make a supply

If the answer to all of these is No

No

If the answer to any one of these is Yes

Make the appropriate endorsements and submissions and keep secure records as required
NHS Grampian Request Form for Authorisation to Order Specials

This form must be completed if the product requested does not fall into any of the categories listed on page 5 of the NHS Grampian guidance “Special Formulation and Unlicensed Products in Primary Care – A Guide for Pharmacists” available at http://www.communitypharmacy.scot.nhs.uk/nhs_boards/grampian.html

1. Pharmacy name: Pharmacy telephone number: Pharmacist name:

2. Medical Practice: Prescriber name:

3. Date request submitted:

4. CHI number:

5. Product details:
   Name:
   Form:
   Dose:
   Quantity:

6. Have you discussed this request with the prescriber? YES NO
   Have you made the prescriber aware that the product is a special? YES NO
   Is the prescriber aware of the implications of this? YES NO
   Have you suggested any licensed alternatives? YES NO
   Does the prescriber still wish to go ahead with this product? YES NO

Comments:

Details of quotes from 2 different suppliers
(where possible)

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<th>Supplier 1 name</th>
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<th>Cost of Postage/Carriage:</th>
<th>Any other additional cost:</th>
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<th>Any other additional cost:</th>
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</table>

Save the completed form and E-mail to the relevant CHP email address for authorisation. The product **must** only be ordered after authorisation has been granted.

To be completed by Authorising Officer:

Authorised?: YES NO Authorisation number: 

Authorising Officer Name: Date:

Authority: CHP P&MD

If authorisation not granted what are the alternative instructions:

To be completed by the Community Pharmacy after authorisation has been granted:

Supplier: Batch Number:

- Expire date of product:
  - A copy of this form and the COA/COC must be sent to the Pharmacy and Medicines Directorate at the end of each month.
  - A copy of the endorsed invoice for the product should be submitted with the prescription when it is sent for pricing.