Special Formulation And Unlicensed Products In Primary Care
A Guide For Pharmacists Working Within NHS Grampian

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Consultation Group:
See relevant page in guidance

Approver:
Director of Pharmacy and Medicines Management

Identifier:
NHSG/Guid/Specials/MGPG924

Review Date:
January 2021

Date Approved:
January 2018

Uncontrolled when printed
Version 3
Special Formulation And Unlicensed Products In Primary Care - A Guide For Pharmacists Working Within NHS Grampian

NHSG/Guid/Specials/MGPG924

NHSG/Guid/Specials/MGPG764, Version 2.1

Lead Pharmacists Aberdeen and Aberdeenshire H&SCP

Guidance

Special, formulation, unlicensed, community, pharmacy, medicine, imported, off-label

Guidance

NHS Grampian

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

Lead Pharmacists Aberdeen and Aberdeenshire H&SCP

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: Lead Pharmacists Aberdeen and Aberdeenshire H&SCP

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

Job title of creator of this document: Lead Pharmacists Aberdeen and Aberdeenshire H&SCP

Job/group title of those who have control over this document: Pharmacy and Medicines Directorate

Responsibilities for disseminating document as per distribution list:

Lead Author/Co-ordinator: Lead Pharmacists Aberdeen and Aberdeenshire H&SCP

Responsibilities for implementation:

Organisational: Pharmacy and Medicines Directorate
Sector: Lead Pharmacists Aberdeen and Aberdeenshire H&SCP
Area: Primary Care, Community Pharmacy

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

Responsibilities for review of this document:

Lead Author/Co-ordinator: Lead Pharmacists Aberdeen and Aberdeenshire H&SCP

Revision History:

<table>
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<th>Revision Date</th>
<th>Previous Revision Date</th>
<th>Summary of Changes (Descriptive summary of the changes made)</th>
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<td>Nov 2017</td>
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Special Formulation And Unlicensed Products In Primary Care - A Guide For Pharmacists Working Within NHS Grampian

1. Introduction

This guidance covers the local NHS Grampian process for the ordering and supply of special formulations and unlicensed products (Specials) in Primary Care in line with PCA(P)(2015) 17 – “Pharmaceutical Services: Amendments to Drug Tariff in respect of special preparations and imported unlicensed medicines” http://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf.

While it is recognised that sometimes it is necessary for a special preparation to be prescribed in Primary Care the patient, prescriber and pharmacist should all be aware of all the implications around the supply.

This guidance aims to:

- Recognise Part 7S and Part 7U 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, ‘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 that 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. 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. This means that the prescription form is within the building where the compounding is occurring (i.e. ex tempore dispensing of a prescription by the pharmacist in their pharmacy) and not made by another provider on behalf of the pharmacy contractor.

3. 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.

4. 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 licence is specific to both the premises and the product. Some manufacturers may also make products that are not covered by their licence and it is up to the person ordering a product to ensure that the item ordered is covered by the specials licence.

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 new 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.

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

5. Process For Checking, Authorising And Ordering A Special For A Prescription (Appendix 2)

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. If using a product in this way is it bioequivalent to the original? The Grampian Medicines Information Centre 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.
(5) Determine the specific formulation that you need for the special.
(6) Determine if the product can be extemporaneously prepared in the pharmacy.
(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 one Specials Company or wholesaler based on this specification (including postage and packing, delivery or handling charges).

Note: Information on the most cost effective supplier may already be available from the NHS Grampian Specials List appended to this guideline or available on request from your H&SCP Pharmacist using the specials e-mail (Appendix 1). Alternatively the Grampian Medicines Information Centre at ARI or your local H&SCP pharmacist may have information on the most appropriate 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 or Part 7U (see Section 7 below) of the Drug Tariff
- can be prepared extemporaneously in the pharmacy
- is available from Tayside Pharmaceuticals or Glasgow Western Infirmary Pharmaceutical Production Unit (or any other NHS manufacturing units in Scotland, England and Wales)
- is included in the NHS Grampian approved list
- is a repeat prescription for a named patient where an authorisation number has previously been given within the last 12 months for the same product and the current cost is no more than 20% greater than the original authorisation cost.

(12) **NHS Grampian authorisation can be requested, following e-mail submission of the fully completed ‘Request Form for Authorisation to Order Specials’** (Appendix 3) from the appropriate Health and Social Care Partnership (H&SCP) lead pharmacist (see Appendix 1) or if they are not available, from the Pharmacy and Medicines Directorate. The contractor must provide one quote, detailing the lowest price for which the special in question can be obtained. Authorisation will either be given at this point, or failing that, further investigation or alternative supply arrangements suggested. Note: NHS Grampian reserve the right **not** to authorise the supply of a special if the product price quoted by the contractor is not considered to be the lowest purchase price available. Contractors may be required to seek alternative suppliers.

(13) **When authorisation is given, pharmacists will be provided with the authorisation number on an updated 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 which should be retained by the community pharmacist with the authorisation form as part of the record of supply.

(16) **Appropriate records of the supply must be kept for 5 years.**

6. **Re-Authorisation**


Re-authorisation of specials is required after 12 months along with a clinical revalidation with the prescriber. Contractors should use the updated specials authorisation form (Appendix 3) to request authorisation for the initial supply and also subsequent annual authorisation (for the same product and patient). It is the responsibility of the contractor to maintain appropriate records to enable annual clinical re-validation and the reauthorisation of supply.
For those patients started on a special prior to November 2015, NHS Grampian reserves the right to contact the contractor where it has been identified that an alternative supplier may provide the product at a lower cost and it is considered that reauthorisation is necessary.

7. **Part 7U - Limited List Of Reimbursable Unlicensed Products**

- Part 7U is a list of marketed products without formal marketing authorisation that are not included in the ACBS list, but are supplied from time to time on prescription.
- The ISD price is obtained from a manufacturer's price list against a known branded product. Each line is expected to be held in stock by a large pharmaceutical wholesaler. Payment of "out of pocket expenses" is not allowed for these products as it is already factored into the drug tariff price.
- Part 7U is provided solely to facilitate correct reimbursement for these products. Inclusion of particular products on the list does not represent an endorsement by NHS Grampian that these products should be prescribed.
- NHS Grampian will follow up these lines under the "pay and report" process.

8. **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.

9. **NHS Grampian Specials List**

An NHS Grampian Specials List of products has been compiled and is available on request from your H&SCP Pharmacist using the specials e-mail ([Appendix 1](#)).

This lists products, and their suppliers, where the price indicated is the benchmark price which will be used to provide authorisation for supply. Pharmacists are under no obligation to purchase the products from the manufacturers/suppliers specified. However, where a product appears on this list, NHS Grampian will guarantee only to authorise reimbursement to a contractor for that product at the price listed.

If a contractor can obtain a special medicine at the same, or lower cost, than that specified in the NHS Grampian Specials List then authorisation is not required. Always check the latest list for details.

This list will be regularly reviewed and community pharmacy contractors should check the SHOW website for the latest update.
10. **Vitamins And Minerals**

Discussion with the prescriber must cover the availability of alternative products and the costs. If an over the counter product is available that is not a licensed medicine the prescriber must decide if this can be supplied or if an unlicensed medicine must be provided. Note: Products licensed as food supplements would not be considered acceptable for the treatment of an established deficiency, as there could be a much larger deviation from the stated dose than in a licensed medicinal product.

If an unlicensed medicine is required authorisation must be obtained.

11. **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.

12. **Endorsing**

- Items listed in the drug tariff do not require to be endorsed with payment information as these will be paid according to the prices listed in Part 7S or 7U. These prices are calculated to include handling charges and out of pocket expenses. No additional expenses will be paid unless in exceptional circumstances and these must be pre-authorised by the Health Board through the H&SCP Pharmacists (Appendix 1).

- The products included in the NHS Grampian approved Specials List must be treated in the same way as non-7S/U items. Although they have been 'pre-authorised' they **must** still be endorsed as below.

- The endorsements required for non-7S/U items are:
  - price paid excluding VAT (SP)
  - fixed non 7S £30 handling charge (HC)
  - approved out of pocket expenses – including wholesaler handling charges (PP)
  - manufacturer license number (MIL)
  - batch number (BAN).

- Endorsements **must** be made electronically using the pharmacy PMR system as well as on the paper prescription. Care must be taken to select the correct price.

- All costs must be in the format pppp, i.e. £30=3000.
13. Payment, Reimbursement Or Recovery of Payment By Practitioner Services Division (PSD)

Information on payment for specials is given in the Scottish Drug Tariff, Part 7S. Full instructions for required paperwork and endorsements for specials prescriptions are available in PCA(P)(2015)17 on the Scottish Health on the Web (SHOW) website http://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf 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, Community Pharmacy Scotland 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.

Where the special has been prepared under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, the contractor will be paid the cost of the ingredients used to manufacture the special.

NHS Grampian will seek to recover any unauthorised expenditure; where authorisation has not been sought or where the contractor has purchased at a higher price than was pre-authorised. The difference between the expected price (where authorisation has not been sought) or the authorised price and the actual price paid will be reclaimed.

14. 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 processes for obtaining a special which will ensure reimbursement of the cost of that special. Failure to follow the processes in this guidance and obtain authorisation when required 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 (Part 7S & Part 7U).
- 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.
• Authorisation for Specials must be obtained prior to ordering except where the products are in Part 7S/7U of the Drug tariff, or prepared extemporaneously, or available from Tayside Pharmaceuticals or Glasgow Western Infirmary Pharmaceutical Production Unit, or is on the NHS Grampian (pre) approved list.
• Authorisation must be requested by submitting the request form (Appendix 3) to the appropriate H&SCP 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.

15. Guidance And Further Reading

Further guidance on specials can be found at:

SHOW at:

MHRA at:
http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Medicinesthatdonotneedalicence/index.htm

Royal Pharmaceutical Society at:

General Medical Council at:
http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp

UK Medicines Information at:

QA294Therapeutic options for patients unable to take solid dosage forms -
https://www.sps.nhs.uk/articles/what-are-the-therapeutic-options-for-patients-unable-to-take-solid-oral-dosage-forms/

16. Consultation Group

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Lesley Thomson
Aberdeenshire H&SCP Lead Pharmacist

Sandy Thomson
Moray H&SCP Lead Pharmacist
## Appendix 1 - Contact Information

<table>
<thead>
<tr>
<th>Practitioner Services Division</th>
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<tr>
<td></td>
<td>Aberdeen</td>
</tr>
<tr>
<td></td>
<td>Tel: 01224 358300</td>
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<tr>
<td></td>
<td>Edinburgh</td>
</tr>
<tr>
<td></td>
<td>Tel: 0131 275 7433</td>
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<td></td>
<td>Glasgow</td>
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<td></td>
<td>Tel: 0141 207 1615</td>
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<tr>
<td>Community Pharmacy Scotland</td>
<td></td>
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<tr>
<td></td>
<td>Tel: 0131 467 7766</td>
</tr>
<tr>
<td>ISD Customer Services Desk</td>
<td></td>
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<tr>
<td></td>
<td>Tel: 0131 275 7050</td>
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<tr>
<td>Scottish Drug Tariff web link</td>
<td><a href="http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff">http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff</a></td>
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<td>MRHA Website</td>
<td><a href="http://www.mhra.gov.uk">www.mhra.gov.uk</a></td>
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<tr>
<td>ISD</td>
<td><a href="http://www.isdscotland.org/">http://www.isdscotland.org/</a></td>
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| Tayside Pharmaceuticals                  | Tel: 01382 632 052        |
| Glasgow Western General Pharmaceutical Production Unit | Tel: 0141 451 5820 |

| Grampian Medicines Information Centre, ARI | grampian.medinfo@nhs.net | Tel: 01224 552316 |
| Pharmacy and Medicines Directorate       | nhsq.pmu@nhs.net          | Fax: 01224 553371 |

| For authorisation of specials requests   | Email address             |
| H&SCP Pharmacists                        | nhsq.specialsmoray@nhs.net|
| Moray                                   |                           |
| Aberdeen City CHP                       | nhsq.specialsaberdeen@nhs.net |
| Aberdeenshire CHP                       | nhsq.specialsaberdeenshire@nhs.net |
## Appendix 2 - NHS Grampian Specials Process - A Step by Step Guide

### NHS Grampian Specials Process
#### A Step by Step Guide

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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</table>
| 1.   | **Prescription received for new “special” for an individual patient**  
Is there an alternative licensed product that may be suitable (including off-label use)?  
Is the “special” clinically suitable for the patient? |
| 2.   | Identify product specification  
- Can it be extemporaneously prepared in the pharmacy?  
- If not identify - suitable supplier and obtain costs including postage and packing, handling charges, shelf life, etc. |
| 3.   | Contact prescriber  
- Advise that the medicine is unlicensed and provide estimate of cost.  
- Advise on alternative licensed options or use of licensed medicines "off-label"  
- Does the prescriber still wish to continue to prescribe the special? |
| 4.   | If the prescriber does not wish to continue with a prescription for a special - make alternative arrangements.  
If they still wish to continue - follow the process below. |
| 5.   | Is the product listed in Part 7S or 7U of the Drug Tariff?  
Is the product on the NHS Grampian Specials List and can be obtained for the same price or less?  
Is the preparation available from an NHS manufacturing unit within Scotland/ England/ Wales?  
If Yes to above points – proceed with dispensing product.  
If No - continue to follow the process below. |
| 6.   | Request NHS Grampian authorisation  
- Complete the form ‘Request Form for Authorisation to Order Specials’.  
- Provide quote from the cheapest supplier of the product.  
- E-mail fully completed form to appropriate H&SCP Specials email address. |
| 7.   | Form will be returned with an authorisation number or pharmacist will be contacted by H&SCP lead pharmacist for further discussion. |
| 8.   | Once authorisation has been obtained a supply can be made.  
- Endorse prescription electronically and on paper with invoice price ex VAT, less any rebate plus any additional costs **which have been authorised**.  
- Endorse the fixed non Part 7S fixed handling fee of £30.  
- Obtain a Certificate of Analysis (COA) or Certificate of Conformity (COC) from the supplier and retain within pharmacy as part of the record of supply.  
- Ensure that appropriate records of the supply are kept for 5 years. |
| 9.   | Keep secure records of this supply and subsequent supplies of the authorised special for the named patient. |
| 10.  | Repeat reauthorisation must be requested:  
- After 12 months if supply is to continue for the patient.  
- If the price of the product increases by 20% or more from the agreed authorised price. |
# Appendix 3 - 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/NHS_Grampian/index.html](http://www.communitypharmacy.scot.nhs.uk/nhs_boards/NHS_Grampian/index.html).

<table>
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<tr>
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<th>Medical Practice:</th>
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<tr>
<td>Contractor Code:</td>
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<thead>
<tr>
<th>Pharmacy telephone number:</th>
<th>Name of Prescriber that the request has been discussed with:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact pharmacist name:</td>
<td></td>
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<table>
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<tr>
<th>Date request submitted:</th>
<th>Patient CHI number:</th>
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## PRESCRIPTION DETAILS

<table>
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<th>Name of product:</th>
<th>Form:</th>
<th>Dose:</th>
<th>Quantity:</th>
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</table>

## SUPPLIER DETAILS

<table>
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<tr>
<th>Company name:</th>
<th>Pack size:</th>
<th>Quoted cost* for full quantity (excl VAT):</th>
</tr>
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<tbody>
<tr>
<td>Cost of Postage/Carriage:</td>
<td>Any other additional cost:</td>
<td></td>
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</table>

Have you discussed this request with the prescriber? **YES**
Have you made the prescriber aware that the product is a special? **YES**
Is the prescriber aware of the implications of this? **YES**
Have you suggested any licensed alternatives? **YES** **NO**

Comments:

Save the completed form and e-mail to the relevant H&SCP email address for authorisation:
- nhsg.specialsaberdeen@nhs.net
- nhsg.specialsaberdeenshire@nhs.net
- nhsg.specialsmoray@nhs.net

The product **must** only be ordered after authorisation has been granted.

### Initial Authorisation - to be completed by Authorising Officer:

- □ Product is authorised (for this patient):
  - For this prescription only □ or for 12 months from date below □
  - Authorisation number: ___________
  - Authorising Officer: ___________
  - Date: ___________

- □ Product has NOT been authorised. Alternative instructions:

### Reauthorisation at 12 months - to be completed by community pharmacy.

- Ongoing clinical appropriateness confirmed with prescriber? **YES** □ **NO** □
- Cost for full quantity of item: ___________
- Supplier: ___________

- **To be completed by Authorising Officer:**
  - Authorisation number: ___________
  - Authorising Officer: ___________
  - Date: ___________

### Reauthorisation at 24 months - to be completed by community pharmacy.

- Ongoing clinical appropriateness confirmed with prescriber? **YES** □ **NO** □
- Cost for full quantity of item: ___________
- Supplier: ___________

- **To be completed by Authorising Officer:**
  - Authorisation number: ___________
  - Authorising Officer: ___________
  - Date: ___________


- Records of ALL special products supplied must be kept as detailed in the circular.
- Prescription should be endorsed electronically and on paper as per the circular.