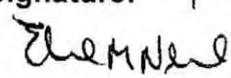
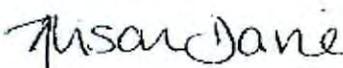


**Special Formulation and Unlicensed Products in
Primary Care**

**A Guide for Pharmacists Working Within NHS
Grampian**

Co-ordinators: Lead Pharmacists Aberdeen and Aberdeenshire H&SCP	Consultation Group: See relevant page in guidance	Approver: Director of Pharmacy and Medicines Management
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Signature:  		Signature: 
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Identifier: NHSG/Guid/Specials/ PCPG1378	Review Date: May 2026	Date Approved: May 2023
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March 2023	Nov 2017	Review with minor updates throughout including reference to imported unlicensed medicines.	Throughout document
March 2023	Nov 2017	2. Definition Of a Special updated to remove EMEA and replace with MHRA as no longer in EU	2. Definition Of a Special page 2
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March 2023	Nov 2017	9. NHS Grampian Specials List updated – no longer available on SHOW	9. NHS Grampian Specials List Page 6
March 2023	Nov 2017	10. Vitamins and Minerals updated to include indication and emphasis authorisation must be obtained when supplied by a Specials Manufacturer	10. Vitamins and Minerals Page 7
March 2023	Nov 2017	11. Products initiated In Hospital reworded and simplified.	11. Products initiated In Hospital Page 7
March 2023	Nov 2017	12. Endorsing – information updated as per ISD Endorsing Guideline	12. Endorsing Page 7-8
March 2023	Nov 2017	Appendix 1 - contact numbers and email addresses updated.	Page 11
March 2023	Nov 2017	Appendix 2 - NHS Grampian Specials Process – A Step by Step Guide updated	Page 12
March 2023	Nov 2017	Appendix 3 - NHS Grampian Request Form for Authorisation to Order Specials updated	Page 13

* 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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Special Formulation and Imported 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 unlicensed Special formulations and imported unlicensed medicines (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](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’ or unlicensed imported medicines 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) granted by MHRA.

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.
- Imported products not approved by MHRA (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. extemporaneous 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 out with 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 an unlicensed Specials UK 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 an unlicensed Special or imported unlicensed medicine 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 unlicensed the implications of this, e.g. time delay.

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 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.
- 3) 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 NHS SPS website has useful information available at [Swallowing difficulties – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)
- 4) Check if the Special is clinically suitable for the patient.
- 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 at least one Specials Company or importer 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 Specials Team using the Specials e-mail ([Appendix 1](#)).
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 be 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 advise they have prescribed an unlicensed medicine and provide information on alternative products (where applicable), costs, timescales and to agree the prescription with the patient. Discuss the product options for the patient (strength, formulation form, presentation).
- 10) If the prescriber confirms that the Special (unlicensed medicine) 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 Pharmaceutical Specials Services Tayside (or any other NHS manufacturing unit in Scotland, England and Wales)
 - is included in the NHS Grampian approved pre-authorized Specials List
 - is a repeat prescription for a named patient where there is current authorisation in place (max duration of authorisation is 12 months) for the same product and the current cost is no more than 20% greater than the original authorisation cost.
- 11) To request NHS Grampian authorisation, the contractor must fully complete the 'Request Form for Authorisation to Order Specials' ([Appendix 3](#)) and email to the Specials Team (gram.specialsaberdeenshire@nhs.scot) for approval by the appropriate Health and Social Care Partnership (H&SCP) lead pharmacist (see [Appendix 1](#)). The contractor must provide at least one quote, detailing the lowest price for which the Special in question can be obtained and any handling/delivery charge. Any additional information to support the request should be documented in comments box. 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. Request forms not fully completed will be returned, which will delay the authorisation process.
- 12) When authorisation is given, pharmacists will be provided with the authorisation number on an updated copy of the request form. This form should be saved and then used for reauthorisation in 12 months where this is required.
- 13) Order the product from the agreed source.
- 14) When ordering an unlicensed Special manufactured in the UK or in another country, 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. For imported products licensed in the country of origin but do not hold a UK license, the manufacturer may not provide a COA/COC.
- 15) Appropriate records of the supply must be kept for 5 years.

6. Re-Authorisation

A flow chart in respect of the supply options is included in 'PCP(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](http://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf).

Reauthorisation of Specials (unlicensed medicine) authorised for more than one issue is required after 12 months along with a clinical revalidation with the

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. Requests for these products must still be discussed with the prescriber to advise that it is an unlicensed medicine and to confirm there is no alternate licensed product available.

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.

10. Vitamins and Minerals

Discussion with the prescriber must cover the availability of alternative products and the costs, together with the indication. 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. We do not expect supplies to come from a Specials manufacturer unless specifically requested by the Prescriber - in this situation, authorisation must be obtained.

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.

11. Products Initiated In Hospital

If a patient has been discharged from hospital, or advised by a hospital specialist to be prescribed a Special (unlicensed medicine), the hospital pharmacist can be contacted for advice on the specification, formulation and the source of supply. Where difficulty of supply is an issue, the Specials Team should be contacted for advice.

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-Part 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:
 - SP – Invoice price (excluding VAT) less any discount or rebate obtained
 - XP hc3000 – £30 payment for sourcing the most cost-effective product
 - XP pp – Any other Out of Pocket expenses
 - MIL - manufacturer licence number

- BAN - batch number
- 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. A copy of the invoice should be submitted to PSD along with the paper prescription.
- All costs must be in the format pppp, i.e. £30=3000.
- The invoice, or a legible copy, should be submitted to PSD with the paper prescription form as evidence of the claim, but the price claimed must be declared on the prescription form or PSD cannot make an accurate payment

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 <https://www.publications.scot.nhs.uk/> and [http://www.sehd.scot.nhs.uk/pca/PCA2015\(P\)17.pdf](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, could be considered.
- Where Pharmaceutical Specials Services, Tayside (PSS) is used to obtain Specials (or other NHS Production Unit), 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 a NHS Production Unit e.g. Pharmaceutical Specials Services, Tayside or is on the NHS Grampian (pre) approved list.
- Authorisation must be requested by submitting the request form ([Appendix 3](#)) to the Specials Team ([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:

[http://www.sehd.scot.nhs.uk/pca/PCA2015\(P\)17.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf)

[http://www.sehd.scot.nhs.uk/pca/PCA2013\(P\)04.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2013(P)04.pdf)

MHRA at:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicenc e/Medicinesthatdonotneedalicence/index.htm> .

Royal Pharmaceutical Society at:

[specials-professional-guidance.pdf \(rpharms.com\)](https://www.rpharms.com/specials-professional-guidance.pdf)

General Medical Council at (please copy and paste into web browser):

<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices>

16. Consultation Group

Sarah Buchan	Pharmaceutical Care Services Improvement and Development Manager
Alison Davie	Aberdeen City HSCP Lead Pharmacist
Anne Marshall	Pharmacist, Pharmacy Champion
Stuart McIntosh	Moray HSCP Lead Pharmacy Technician
Elaine Neil	Aberdeenshire HSCP Lead Pharmacist
Sarah O'Beirne	Lead Pharmacist, Grampian Medicines Information Centre, ARI
Karen Proctor	Aberdeenshire HSCP Primary Care Pharmacy Technician
Susan Reid	Aberdeenshire HSCP Lead Pharmacy Technician
Christine Thomson	Moray HSCP Lead Pharmacist

Appendix 1 - Contact Information

Practitioner Services Division	(Ask for a Group Leader)	
	Aberdeen	Tel: 01224 358400
	Edinburgh	Tel: 0345 300 1024
	Glasgow	Tel: 0141 300 1300
Community Pharmacy Scotland	www.cps.scot	Tel: 0131 467 7766
ISD Customer Services Desk		Tel: 0131 275 7050
Scottish Drug Tariff web link	http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff	
MRHA Website	www.mhra.gov.uk	
ISD	http://www.isdscotland.org/	
Pharmaceutical Specials Services, Tayside	01382 496702 tay.pssoffice@nhs.scot	
Grampian Medicines Information Centre, ARI	gram.medinfo@nhs.scot	Tel: 01224 552316
Pharmacy and Medicines Directorate	gram.pharmaceuticalcareservices@nhs.scot	Tel: 01224 556527
For authorisation of Specials requests		
H&SCP Specials Teams	Email address	
Moray HSCP	gram.specialsmoray@nhs.scot	
Aberdeen City HSCP	gram.specialsaberdeen@nhs.scot	
Aberdeenshire HSCP	gram.specialsaberdeenshire@nhs.scot	

Appendix 2 - NHS Grampian Specials Process - A Step by Step Guide

NHS Grampian Specials Process A Step by Step Guide

1.	<p>Prescription received for new “Special” for an individual patient</p> <p>Is there an alternative licensed product that may be suitable (including off-label use)? Is the “Special” clinically suitable for the patient?</p>
2.	<p>Identify product specification</p> <ul style="list-style-type: none"> • 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.	<p>Contact prescriber</p> <ul style="list-style-type: none"> • 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.	<p>If the prescriber does not wish to continue with a prescription for a Special - make alternative arrangements.</p> <p>If they still wish to continue - follow the process below.</p>
5.	<p>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?</p> <p>If Yes to above points – proceed with dispensing product.</p> <p>If No - continue to follow the process below.</p>
6.	<p>Request NHS Grampian authorisation</p> <ul style="list-style-type: none"> • Complete a new form ‘Request Form for Authorisation to Order Specials’. • Provide a quote from the cheapest supplier of the product. • E-mail fully completed form (attach as a word document) to the Specials Team email address.
7.	<p>Form will be returned with an authorisation number or pharmacist will be contacted by Specials Team for further discussion.</p>
8.	<p>Once authorisation has been obtained a supply can be made.</p> <ul style="list-style-type: none"> • 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.	<p>Keep secure records of this supply and subsequent supplies of the authorised Special for the named patient.</p>
10.	<p>Repeat reauthorisation must be requested:</p> <ul style="list-style-type: none"> • If the price of the product increases by 20% or more from the agreed authorised price – complete a new Request Form. • After 12 months if supply is to continue for the patient - Complete the relevant Reauthorisation at 12 months or 24 months on the initial authorised Request form for the patient.

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

Pharmacy name: Contractor Code:	Medical Practice:
Pharmacy telephone number: Contact pharmacist name:	Name of Prescriber and Designation that the request has been discussed with:
Date request submitted:	Patient CHI number:
PRESCRIPTION DETAILS Name of product: Form: Dose: Quantity:	SUPPLIER DETAILS Please state the most cost effective quote. (NB. You may have to contact more than one supplier). Company name : Pack size: Cost per Pack: Quoted cost* for full quantity (excl VAT): Cost of Postage/Carriage: Any other additional cost: *Cost should be for the full quantity that will be dispensed
Have you discussed this request with the prescriber? YES <input type="checkbox"/> Have you made the prescriber aware that the product is a Special? YES <input type="checkbox"/> Is the prescriber aware of the implications of this? YES <input type="checkbox"/> Have you suggested any licensed alternatives? YES <input type="checkbox"/> NO <input type="checkbox"/>	
Comments:	
Save the completed form and e-mail to for authorisation to:- gram.specialsaberdeenshire@nhs.scot The product must only be ordered after authorisation has been granted.	
Initial Authorisation - to be completed by Authorising Officer: <input type="checkbox"/> Product is authorised (for this patient): For this prescription only <input type="checkbox"/> or for 12 months from date below <input type="checkbox"/> Authorisation number: Authorising Officer: H&SCP <input type="checkbox"/> P&MD <input type="checkbox"/> Date: <input type="checkbox"/> Product has NOT been authorised. Alternative instructions:	
Reauthorisation at 12 months - to be completed by community pharmacy. Ongoing clinical appropriateness confirmed with prescriber? YES <input type="checkbox"/> NO <input type="checkbox"/> Cost for full quantity of item: Supplier: Dose: Cost per Pack: Pharmacist Name:	Reauthorisation at 24 months - to be completed by community pharmacy. Ongoing clinical appropriateness confirmed with prescriber? YES <input type="checkbox"/> NO <input type="checkbox"/> Cost for full quantity of item: Supplier: Dose: Cost per Pack: Pharmacist Name:
To be completed by Authorising Officer: Authorisation number: Authorising Officer: Date:	To be completed by Authorising Officer: Authorisation number: Authorising Officer: Date:
Specials Circular available at: http://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf <ul style="list-style-type: none"> 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. 	