

NHS TAYSIDE

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

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

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Consultation Group

See Page 8

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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 was been adapted to meet NHS Grampian needs. NHS Tayside has further adapted the document to meet NHS Tayside requirements.

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

1. Introduction

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

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 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, expensive 'specials' are not prescribed when appropriate licensed or more cost effective alternatives are available.
- Remind pharmacists and prescribers of their responsibilities and liabilities with regard to the supply of specials.
- Outline the correct process to ensure pharmacists/prescribers:
 - 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:

SHOW at:

[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/Doesmyproductneedallicence/Me dicinesthatdonotneedallicence/index.htm> .

Royal Pharmaceutical Society at:

<http://www.rpharms.com/pharmacy-practice-resource/specials.asp>

General Medical Council at:

[http://www.gmc-uk.org/static/documents/content/Prescribing_Guidance_\(2013\).pdf](http://www.gmc-uk.org/static/documents/content/Prescribing_Guidance_(2013).pdf)

NELM at:

QA294 Therapeutic options for patients unable to take solid dosage forms - <http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Therapeutic-options-for-patients-unable-to-take-solid-oral-dosage-forms/>

Royal College of Paediatrics and Child Health at:

The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice -

<http://www.rcpch.ac.uk/system/files/protected/page/RCPCH%20Revised%20Statement%20on%20Unlicensed%20Medicines%20October%202010%20FINAL.pdf>

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 (EMA).

For the purposes of this guideline, 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 (EMA) 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

A product holding a Marketing Authorisation (MA) will do so following evaluation by the MHRA or EMA of all data regarding the product from 'Indications' and 'Doses' through to the source of raw materials, precise method and location of manufacture and 'Quality Checks' provided through the whole manufacturing process. The MA Holder is obliged to ensure that full Product Information is supplied to both the prescriber and dispenser of the product. The marketing Authorisation confers liability upon the Holder for the product in use when the terms of the license are complied with. This means that in the extremely rare event of misadventure 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 Marketing Authorisation the Holder is liable for any claim that may be entertained. For an unlicensed product, no such liability exists. The prescriber bears clinical responsibility for prescribing the product.

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. (The prescriber should ask themselves whether an

acceptable licensed product might be suitable instead.)

5. Prescribed Specials – 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 pharmacist ordering the 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 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 is required 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) Where the product is not exempt from authorisation as detailed in para 11 below the pharmacist should request costing information from at least two specials companies or wholesalers based on this specification (including postage and packing, delivery or handling charges).

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 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 Tayside authorisation must be obtained prior to ordering the special unless the product:**
 - is listed in Part 7S or Part 7U of the Drug Tariff.
 - can be prepared extemporaneously in the pharmacy
 - is available from Tayside Pharmaceuticals or Glasgow Western Infirmary Pharmaceutical Production Unit.
 - is a repeat prescription for a specific patient and product where an authorisation number has previously been granted for either 6 or 12 months, provided the cost has not increased since the last dispensing and the authorisation is still valid.
- (12) NHS Tayside authorisation can be requested following e-mail submission of the fully completed 'Request Form for Authorisation to Order Specials'. Requests must be emailed to pharmacyspecials.tayside@nhs.net.
- (13) A 6 or 12 month authorisation may in some cases be granted for individual patients on a long term unlicensed medicine. If this is required this should be specified on the individual request. This is at the discretion of the authorising officer.
- (14) An authorisation code will be e-mailed back to the senders e-mail address or failing that, further investigation or alternative supply arrangements suggested.
- (15) An email reply will be sent within 24 hours Monday to Friday. If an email reply has not been received with 24 hours or the request is urgent the pharmacist should call 01382 596992.
- (16) When authorisation is given, pharmacists will be provided with an authorisation code, which they should then add into the box provided in their copy of the request form if the form has not been sent back with this incorporated.
- (17) Order the product from the agreed source.
- (18) When ordering a special, the pharmacist must also obtain a Certificate of Analysis (COA) or Certificate of Conformity (COC) from the supplier.

- (19) Each month the pharmacist will submit to Diane Robertson, (Community Pharmacy Development, Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee DD3 8EA), a copy of **all COA/ COCs** for specials received in that month, each **appropriately endorsed** (see PCA(P)(20013)4 point 6 and Appendix 1 (contact information)).
- (20) Appropriate records of the supply must be kept for 5 years.
- (21) For queries regarding specials (not authorisation) pharmacists should either email as per the authorisation email address (if not urgent) or call 01382 596992 and ask to speak to Diane Robertson, David Gill or David Coulson with a specials query.

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

9. Products Initiated In Hospital

If a patient has been discharged from hospital on a special, the hospital pharmacist can be contacted for advice and the Ninewells Area Pharmacy Office for 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.

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

Information on payment for specials is given in the Scottish Drug Tariff, Part 7S at: http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/Docs/SDT_Part7S_Preface.pdf.

Part 7U at:

<http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/Drugs-and-Preparations-with-Tariff-Prices.asp>

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

11. 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 Tayside 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, pharmacies require authorisation from NHS Tayside prior to ordering. **Failure to follow the processes in this guidance, and in particular failure to apply for authorisation where needed, will 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 and 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 or Part 7U of the Drug tariff, or prepared extemporaneously, or available from Tayside Pharmaceuticals or Glasgow Western Infirmary Pharmaceutical Production Unit.
- Authorisation must be requested by submitting the request form (Appendix 3) to pharmacyspecials.tayside@nhs.net. 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 Tayside each month, in accordance with PCA(P)(2013)4 item 6.

- The prescription should be endorsed as previously with the addition of the authorisation code.

12. Consultation Group

Frances Rooney	Director of Pharmacy
David Coulson	Acting Head of Medicines Governance
David Gill	Head of Pharmacy Angus CHP
Diane Robertson	Community Pharmacy Development

Area Pharmaceutical Committee
Chair and Vice Chair Area Pharmacy Contractors Committee

Contact Information

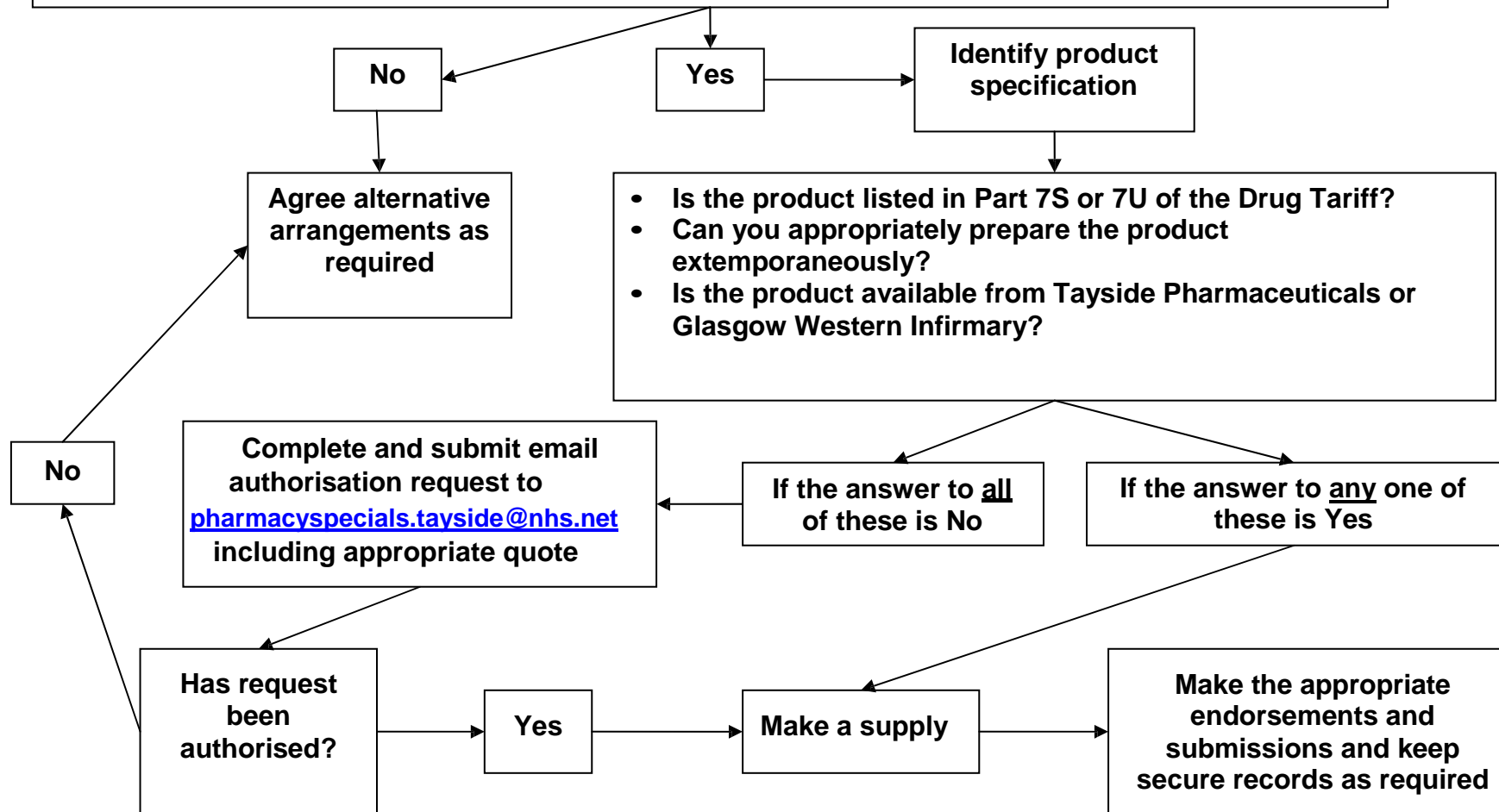
Practitioner Services Division	(Ask for a Group Leader)	
	Aberdeen	Tel 01224 358300
	Edinburgh	Tel 0131 557 3733
	Glasgow	Tel 0141 332 0787
	SPGC	Tel 0131 467 7766
ISD Customer Services Desk		Tel 0131 551 8899
Scottish Drug Tariff web link	http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff	
MRHA Website	www.mhra.gov.uk	
ISD	http://www.isdscotland.org/index.asp	
Tayside Pharmaceuticals	Tel 01382 632 052 Fax 01382 632060	
Ninewells Area Pharmacy Office	Tel 01382 632036 Fax 01382 632822 pharmacyoffice.tayside@nhs.net	
Glasgow Western General Pharmaceutical Production Unit	Tel 0141 211 2754 Fax 0141 2111967	
Medicines Information Department, Ninewells		Tel 01382 632351 Email Tay-UHB.medinfo@nhs.net
Pharmacy Medicines Governance	For enquiries regarding specials	Tel 01382 596992
For authorisation of specials requests		
All requests should be emailed	pharmacyspecials.tayside@nhs.net	
Authorisation Officers		
Lead Officer Diane Robertson	01382 596992 dianerobertson3@nhs.net	
David Gill	01382 596992 david.gill@nhs.net	
David Coulson	01382 596992 david.coulson@nhs.net	

Algorithm Of Supply Process For A Special

The pharmacist should contact the prescriber to discuss the need for special and to consider if:

- a special is necessary
- 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?



NHS Tayside Request Form for Authorisation to Order Specials

This form must be completed if the product requested does not fall into one of the following categories:

- Is listed in part 7S or part 7U of the Drug Tariff
- Can be prepared extemporaneously in the pharmacy
- Is available from Tayside Pharmaceuticals or Glasgow Western Infirmary Pharmacy Production Unit – pre-authorized.
- Is a repeat prescription for a specific patient and product where an authorisation number has previously been granted for either 6 or 12 months, provided the cost has not increased since the last dispensing and the authorisation is valid. Patient must be reviewed each time as per policy to ensure appropriate.

Please remember to look at other options and reasons for prescribing before automatically proceeding to order as a special in all cases.

To be emailed to pharmacyspecials.tayside@nhs.net

Contact Number for enquiries – 01382 596992

Pharmacy Contractor Code	
Name and address of Community Pharmacy Telephone Number	
Community Pharmacists Name	
Prescribers Name and General Practice (or other source)	
Practice Code	
CHI	
Product Details (Name, Form, Strength, Dose, Quantity)	
Quoted Cost (Excluding VAT) for FULL quantity Cheapest of at least 2 quotes	£
Additional Costs (Postage/Carriage)	£
Supplier Details	
Comments or Exceptional Circumstances Please specify or request is for this script only or if it is a long term patient request for 6 months or 12 months.	
Authorisation is	Authorisation Number
<input type="checkbox"/> for this prescription only	Authorising Officer
<input type="checkbox"/> 6 months (until) __/__/__ (insert date)	Date
<input type="checkbox"/> 12 months (until) __/__/__ (insert date)	
<input type="checkbox"/> This product has not been authorised (give alternate instructions)	

Records of all special products must be kept as detailed in part 6 of the circular

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

A copy of the endorsed COA/COC (or invoice) as per point 6 of the circular must be sent to the Pharmacy Department, East Day Home at the end of each month. Please remember to endorse the authorisation code on prescription and paperwork

A copy of the invoice for the product should be submitted with the prescription when it is sent for pricing.