

**Community Pharmacy
Multidisciplinary Audit Report
Unlicensed Specials**

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1.0 Introduction

Specials are special-order unlicensed medicines made to meet the needs of an individual patient. Unlicensed medicines may be prescribed in clinical situations where it is judged that, on the basis of available evidence, unlicensed use is in the best interest of the patient. Prescription of unlicensed medicine is the responsibility of the prescriber. If in doubt clinicians should discuss with pharmacist colleagues before prescribing.

These unlicensed products are very expensive when compared with licensed alternatives. In some situations prescribing an unlicensed special may be the only alternative. Pharmacists throughout the supply chain have a responsibility for procuring and supplying specials in a professional manner. Over the past few years pharmacists have increasingly bought in specials rather than prepare products extemporaneously in the pharmacy. Pharmacists have key professional responsibilities when providing advice about, supplying and supporting patients in their choices. There are patients who do benefit from specials and the RPSGB have produced good practice guidance on the procurement and supply of pharmaceutical specials.

Background

The RPSGB made the following recommendations so that patients receive medication that is safe, appropriate for their condition and their circumstances, with minimal clinical risk;

- A special is prescribed and supplied only when there is no available licensed medicine which fully meets the patients' clinical needs.
- That it is appropriate and that continued supply is justified
- Any special supplied is fit for purpose
- Procurement is from an appropriate source
- Risk to patients is minimised
- That relevant records are kept

The RPSGB guidance includes a useful decision aid flow chart that recommends that specials are only used when there is no available clinically appropriate licensed medicine.

2.0 Aim of the audit

- To record the number of patients receiving unlicensed specials on prescription over a one month period
- To ascertain the amount of interventions and recommendations made by Pharmacies
- To check the awareness of GPs and patients of specials prescriptions
- To check that specials are procured in a cost effective safe manner.

3.0 Project Team

Ruth Kent, Pharmacy Project Manager (Lead)
Harriet Murch, Clinical Pharmacy Lead (Clinical adviser)
Debbie Morris, Prescribing Information Lead (Data)

With special thanks to Croydon PCT for providing the basis of this audit

4.0 Standards

Std No.	Audit Standards	Target	Results
1	Percentage of Patients aware that the medicine was Unlicensed	90%	73%
2	Percentage of Prescribers who were aware that the medicine was unlicensed	100%	81%
3	Percentage of specials prescriptions where a possible alternative was discussed with the prescriber	80%	8%
4	Percentage of items dispensed at a value for money price	100%	50%

5.0 Methodology

1. The audit took place over a period of **1month** using the Unlicensed Special audit form (appendix 2)
2. Patient identifiable information was not recorded on the form, although a record may have been kept in the pharmacy for future reference.
3. Information recorded on the form;
 - The name of the prescriber and the practice
 - Full details of the 'special' preparation
 - Pharmacists asked the patient/their representative whether the prescriber informed them that the prescription was for an unlicensed preparation
 - Pharmacists checked if the prescriber was aware that the product was unlicensed
 - Pharmacists evaluated the script for any suitable licensed alternatives for the patient, and summarise any communication with the prescriber.
 - When the prescription was changed as a result, details of the item dispensed was recorded
 - The estimated cost of the preparation was recorded

6.0 Results

Pharmacies who took part in the audit

Of the 41 pharmacies approached, 38 (95%) completed questionnaires resulting in data collection a total of 175 items.

Data was recorded on between 1 and 31 patients per pharmacy

Table 1: Returns from Pharmacies

Pharmacy Name and quantity of special	Took part in audit		Pharmacy Name and quantity of special	Took part in audit
Boots Pharmacy Eye (2)	yes		Halls Farcet (0)	yes
Alpha Chem Werrington (7)	yes		Halls the Chemist Thorney (6)	yes
Pharmacy First (1)	yes		Halls the Chemist Orton Wistow (0)	yes
Werrington Pharmacy (10)	yes		Halls the Chemist Castor (0)	yes
Park Rd Pharmacy (6)	Yes		Hampton Pharmacy (2)	yes
Asda (2)	yes		Jhoots (4)	yes
Boots Bretton HC (3)	yes		City Pharmacy Lincoln Rd (9)	yes
Boots Bretton Boots Rightwell East (7)	yes		Lloyds Nene Valley (3)	yes
Boots Queensgate (4)	yes		Lloyds Bushfield	yes(ate)
Boots Serpentine Green (3)	yes		Millfield Pharmacy (10)	yes
Walton Pharmacy (Rowlands) (3)	yes		National Co-op Chadburn Paston (5)	yes
Dogsthorpe Pharmacy (3)	yes		National Co-op Millfield (5)	yes
Eastchem (Alpha) (0)	yes		National Co-op Stanground (4)	yes
Ginton (1)	yes		National Co-op Westwood (0)	yes
Chemistree	no		Shrives	no
National Co-op Westgate house (0)	yes		Tesco Instore (0)	yes
Odedra (8)	Yes		Thomas Walker Pharmacy (12)	yes
Rowlands Pharmacy Westgate (1)	yes		West Town Chemist (10)	yes
Sainsbury Bretton (2)	yes		Newborough Pharmacy (1)	yes
Graham Young (31)	yes		Sainsbury Oxney Rd (4)	yes

Pharmacy Name and quantity of special	Took part in audit		Pharmacy Name and quantity of special	Took part in audit
Granville Pharmacy (5)	yes			
Total no. Pharmacies	41		Total no. Pharmacies taking part	38

Pharmacists were asked if the Patient was aware that the item is unlicensed

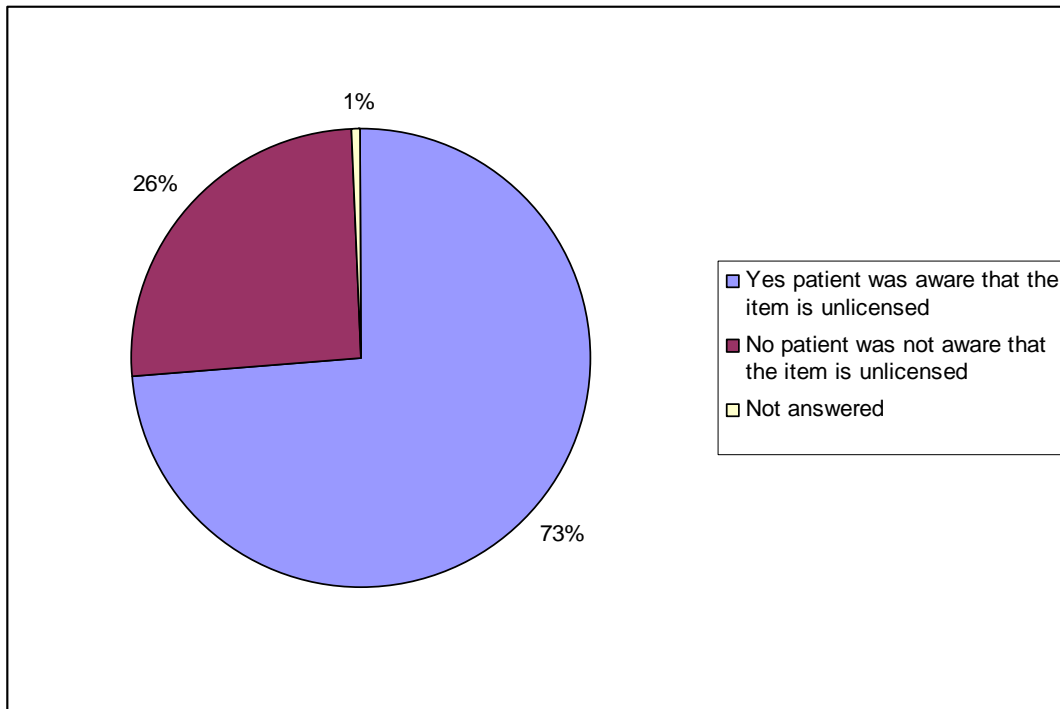
Out of the 175 prescriptions for unlicensed specials reported in the audit;

Yes patient was aware that the item is unlicensed = **128 (73%)**

No patient was not aware that the item is unlicensed = **45 (26%)**

Not answered = 1 (less than 1%)

The graph below shows the results of the question
'Is the Patient was aware that the item is unlicensed'



Pharmacists were asked if the Prescriber was aware that the item is unlicensed

Out of the 175 special reported in the audit;

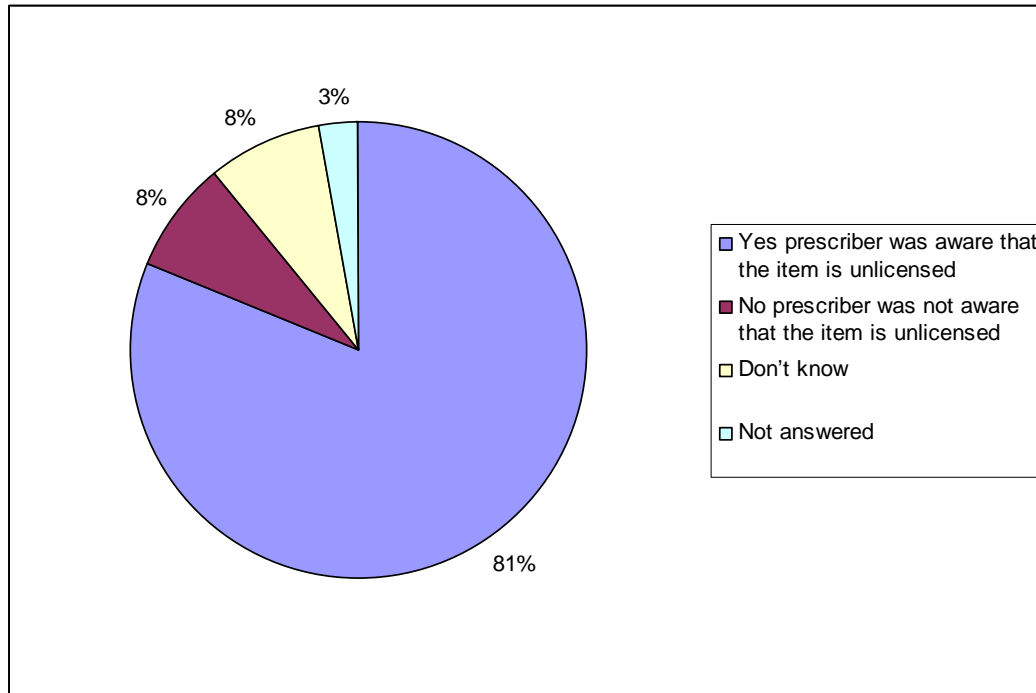
Yes prescriber was aware that the item is unlicensed = **142 (81%)**

No prescriber was not aware that the item is unlicensed = 14 (8%)

Don't know =14 (8%)

Not answered = 5 (3%)

The graph below shows the results of the question
'Is the Prescriber was aware that the item is unlicensed'



Possible alternatives discussed with the prescriber

Out of the 175 special reported in the audit;;

No = 79 (45%)

Left blank = 33 (19%)

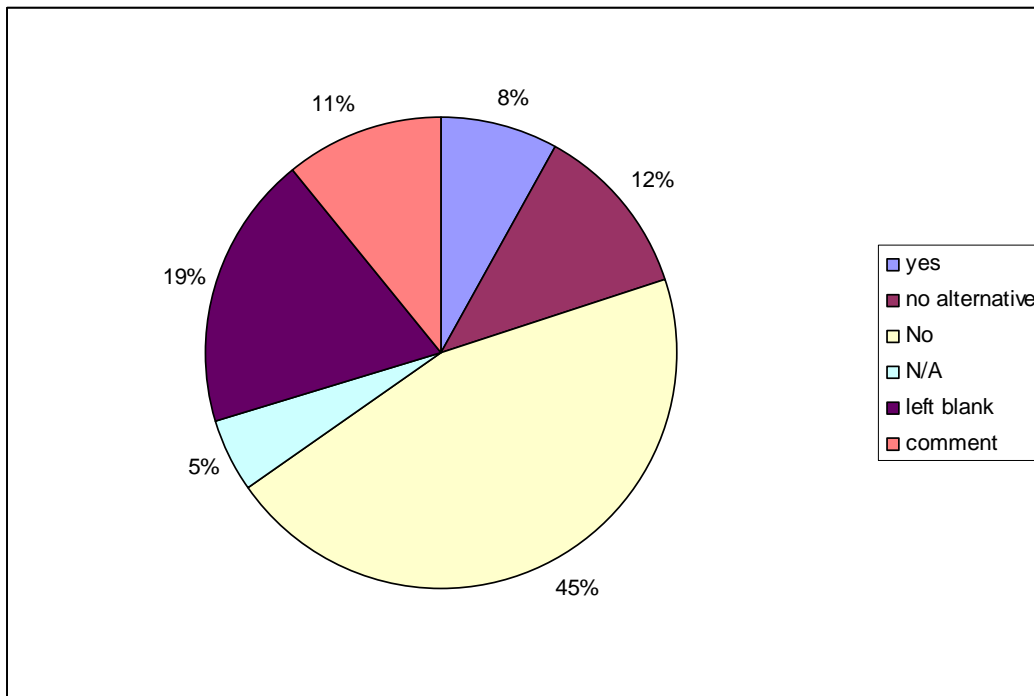
No alternative =21 (12%)

Comment made = 19 (10%)

Yes = 14 (8%)

N/A = 9 (5%)

The graph below shows the results of the question
'Was a possible alternative discussed with the prescriber'



Details of discussion between Pharmacist and Prescriber

- Left message with surgery as Dr in clinic
- Discussed with the nurse
- no alternative
- Patient wanted GP to prescribe
- not practical 20 week old baby
- advised Dr product over £3000, on PCT red list, not dispensed should be dispensed by child hospital
- pack size supplied was cheaper, Sodium Chloride 30% 2 x 300ml
- 1 yr old no alternative
- rang surgery explained cost £900, suggested alternative, Minims Prednisolone cost £10
- patient can only take liquid
- Losec MUPS discussed as an alternative, Patient changed to Losec MUPS £11.60
- discussed previously with Pts GP – no change
- Difficult to get through to prescriber
- Cant take tabs
- patient previously unsuccessfully treated with 30mg in 5ml, Phenytoin 90mg in 5ml Rosemont x 500ml supplies £277.16
- GP had said would discuss alternative with patient
- No alternative available due to PEG delivery
- GP did not wish to discuss - long term treatment
- patient can not swallow tabs
- from hospital

Item supplied

Out of the 175 specials reported in this audit;
Number of items given as prescribed = 168 (96%)
Number of items changed a result of pharmacists intervention = 7 (4%)
Cost avoidance as a result of pharmacist interventions approx = £1,200

Cost

The total cost of **special prescriptions** were reported for 166 items =
£33704.29
The total cost of the **items changed** as a result of pharmacist interventions was
= **£53.81**
Range of cost of specials from £1252.62 to £8.09

Cost avoidance as a result of **pharmacist interventions** approx = £1,200

NB some pharmacies also reported costs for postage, packing delivery charges and out of pocket expenses. This data set is not complete as it was not covered in this audit.

Percentage of items dispensed at a value for money price

Out of all of the 175 entries submitted by pharmacies as specials 155 items were true unlicensed special medicines. The other 20 items consisted of items that required special ordering by the pharmacies such as gluten free products and Risperdal Consta, but did not require a 'one off' manufacture process.

Of the 155 items that were true unlicensed special medicine 78 (51%) were obtained from preferred value for money suppliers.

A more cost effective supply of the specials dispensed would have been available for 64 (42%) of the items. A saving of >£10,000 for the month would have been made on these items if preferred suppliers had been used.

NHS Peterborough ePACT report for unlicensed special

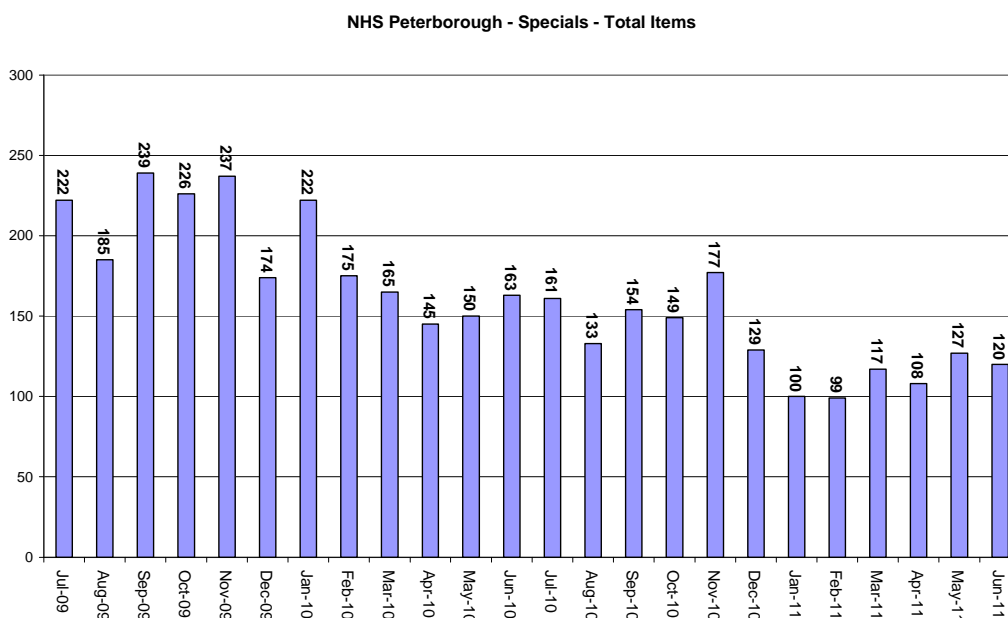
Of the 155 items that were true unlicensed special medicine 8 (5%) were from prescribers outside the NHS Peterborough catchment area so were not reflected in the NHS Peterborough ePACT report.

Of those 147 items shown on the NHS Peterborough ePACT report 4 (3%) were not shown on the ePACT tag for the June data (this may be because the prescription may not have been submitted for payment as the pharmacy was waiting for an invoice).

NHS Peterborough Specials Data

MMT prescribing data below shows that there is a downward trend on identifiable specials items over the last 2 years. The data below does not reflect

the full amount of specials reported in the audit due to a variation in prescription processing dates.



7.0 Conclusions

Specials are unlicensed products which are very expensive when compared with licensed alternatives. In some situations prescribing an unlicensed special may be the only alternative. NHS Peterborough the medicines management team recommend reviewing use of all these products both from a governance and a financial perspective and use monthly ePACT data to highlight these scripts to GP surgeries.

The number of pharmacies taking part in this years audit has slightly fallen from 40 pharmacies in 2010 to 38 pharmacies in 2011 who submitted audit returns.

Data was recorded on between 1 and 31 patients per pharmacy with 7 pharmacies having no patients submitting prescription for specials during the month of the audit at all. It would be expected that numbers of specials prescriptions fall as the PCT prescribing support team continue to raise awareness of reviewing the appropriateness of continuing with unlicensed medicines for all of these patients.

ePACT prescribing data shows that there is a downward trend on identifiable specials items over the last 2 years. Also that of the 155 items that were true unlicensed special medicine 8 (5%) were from prescribers outside the NHS Peterborough catchment area so were not reflected in the NHS Peterborough ePACT report.

Of those 147 items shown on the NHS Peterborough ePACT report 4 (3%) were not shown on the ePACT tag for the June data. This accurate prescribing

data enables the measurement of changes to the way unlicensed products are being prescribed and dispensed.

The majority of patients (73%) presenting prescription for specials were aware that the item was unlicensed, while 26% were not aware. It is important that patients understand what their medicine is, know the risks and the appropriate way to use any unlicensed products. Prescribers and pharmacists should work towards fully informing patients about their medicines.

The majority of prescribers (81%) issuing a prescription for specials were aware that the item was unlicensed, while only in 8% of cases possible alternatives were discussed with the prescriber. This would indicate that communication between prescribers and dispensers in order to discuss potential alternatives to unlicensed specials should be improved. However it may have been that some pharmacists were unable to ascertain the prescribers knowledge of this or that they have had previous discussions about it.

In 12% of the prescriptions received for specials no alternative medicine would have been available and 10% of pharmacies commented on the reasons and issues behind the script. 79% did not discuss the special prescription although it is unknown if previous discussions had taken place.

96% of the items given were as prescribed, while there were 7 prescriptions (4%) changed as a result of pharmacists intervening. This created an approximate cost avoidance of £1,200

The total cost of the special prescriptions was £33704.29 for 168 items, and the total cost of the items changed as a result of pharmacist interventions was £53.81. The range of the cost of specials was from £1252.62 to £8.09
NB some pharmacies also reported costs for postage, packing delivery charges and out of pocket expenses. This data set is not complete as it was not covered in this audit.

Out of all of the 175 entries submitted by pharmacies as specials 155 items were true unlicensed special medicines. The other 20 items consisted of items that required special ordering by the pharmacies such as gluten free products and Risperdal Consta, but did not require a 'one off' manufacture process.

Of the 155 items that were true unlicensed special medicine 78 (50%) were obtained from preferred value for money suppliers and 8 (5%) were from prescribers outside the NHS Peterborough catchment area so cannot be reflected in this ePACT report.

NHS Peterborough MMT prescribing data shows that there is a downward trend on identifiable specials items over the last 2 years. Although this data is not taken from this audit it shows that the results of actively working to increase patient safety and deliver value for money prescribing by reducing the amount of unnecessary specials prescriptions is having success.

8.0 Recommendations

- Pharmacists should ask the patient/their representative whether the prescriber informed them that the prescription was for an unlicensed preparation.
- Pharmacists should check if the prescriber is aware that the product is unlicensed.
- Pharmacists evaluate the script for a suitable licensed alternatives or use of a licensed product 'off license' for a patient, and summarise this in any communication with the prescriber.
- Clear communication channels between practices and pharmacies should be set up and maintained.
- When the prescription is changed as a result of a pharmacist intervention, details of the item dispensed are correctly recorded
- The cost of the preparation is monitored and checks are made for more cost appropriate alternatives.
- Pharmacist engage with the NHS Peterborough Medicines Management Team to support best practice were specials are concerned.
- Pharmacists access the NHS Peterborough 'specials mailbox' via this email address p-pct.specials@nhs.net to highlight concerns about prescription for unlicensed specials.

It is also best practice that the name of the prescriber, the practice and full details of the 'special' preparation appear on the prescription

Tips to help prescribers identify Specials from the NPC

Specials can be difficult to identify at the point of prescribing and prescribers may be unaware that they are considering prescribing one. Here are some tips. If in doubt clinicians should discuss with pharmacist colleagues before prescribing:

- If a medicine is not in the British National Formulary (BNF) it could be a Special.*
- Dermatology products, eye drops and liquid preparations are more commonly formulated as Specials.
- Electronic prescribing systems may not identify Specials. Some systems may use the letter 'U' to indicate an unlicensed medicine, or misleadingly highlight the cost of Specials as 'zero'.
- Clinical systems can be used to highlight that a Special is being selected and potentially suggest alternatives.
- Community pharmacists may wish to check with prescribers if they think a prescriber is unaware they are prescribing a Special. Pharmacists have a responsibility to help ensure that prescribers are aware they are prescribing an unlicensed medicine.
- In hospitals, clinical pharmacists may highlight to prescribers they are prescribing a Special.

** For some preparations the BNF and BNF for Children indicate whether the preparation needs to be obtained through a 'special-order' manufacturer, or a specialist importing company. Where an unlicensed drug is included in the BNF, this is indicated in square brackets after the entry. When the BNF suggests a use (or route) that is outside the licensed indication of a product ('off-label' use), this too is indicated. In the BNF for Children individual drug entries give an indication of the licensed status of the drug.'*

Literature Review

RPSGB guidance <http://www.rpharms.com/best-practice/specials.asp>

Patient information on specials;

<http://www.nhs.uk/chq/Pages/1004.aspx?CategoryID=73&SubCategoryID=101>

Prescribing Specials – five guidance principles for prescribers;

http://www.npc.nhs.uk/improving_safety/prescribing_specials/resources/5_guiding_principles.pdf

Appendix 1

Letter to pharmacies

NHS Peterborough Community Pharmacy Audit 2011

Dear Colleague

This year we are asking all Community Pharmacies to carry out an audit on prescriptions dispensed for 'specials'. This audit forms part of the work we are carrying out to ensure that specials are prescribed and dispensed following RPSGB guidance <http://www.rpharms.com/best-practice/specials.asp>

The audit will run for the entire month of June 2011. We have enclosed a copy of the audit sheet that we require you to fill in detailing every prescription for a special that you receive in June and the key steps in decision-making carried out to provide an appropriate product to the patient.

- For each script, please enter the name of the prescriber and the practice in the first column.
- Enter full details of the 'special' preparation in the second column.
- Please ask the patient/their representative whether the prescriber informed them that this prescription is for an unlicensed preparation for the answer to the third column. NB If the patient was not aware before you discussed it please answer no. Patient information on specials can be found at; <http://www.nhs.uk/chq/Pages/1004.aspx?CategoryID=73&SubCategoryID=101>
- Please state if the prescriber is aware that this product is unlicensed in the fourth column.
- If you have evaluated the script for any suitable licensed alternatives for the patient, please enter details of this and summarise any communication with the prescriber.
- If the prescription was changed as a result, please enter details of the item dispensed in the sixth column.
- Finally, in the last column please enter the estimated cost of the preparation.

All completed audit forms should be returned to me at the following address:

Pharmacy Team
2nd Floor, Town Hall, Bridge Street
Peterborough, PE1 1FA

By 31st July 2011

Appendix 2

Community Pharmacy Multidisciplinary Audit - Unlicensed Specials

Pharmacy name and address

Name and Address of GP Practice	Name of unlicensed special including strength, form, quantity	Patient is aware that item is unlicensed? Yes/No	The prescriber is aware that this product is unlicensed? Yes/No	Possible alternatives discussed with prescriber * Yes/No - Details	Item supplied including strength, form, quantity	Estimated cost of item supplied
Example Dr T Ardis, Tennant Practice	Paracetamol oral suspension 500mg in 5ml	No	No	Yes - Paracetamol 250mg in 5 ml or Paracetamol dispersible tablets 500mg	Paracetamol dispersible tablets 500mg	Drug Tariff price

Community Pharmacist Name Signature Date

**See enclosed guidance – ‘Dealing with special’ for decision aid and flow chart*

Please return to Ruth Kent, NHS Peterborough, 2nd Floor Town Hall, Peterborough, PE11FA. Tel: 01733 758619
by **8th July 2011** in the prepaid envelope provided or email to Ruth.kent@peterboroughpct.nhs.uk