

Community Pharmacy

“Specials” Audit

2010/2011

AUDIT PACK

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INTRODUCTION

As a requirement of the Contractual Framework, Community Pharmacies are required to participate in a clinical audit programme which includes at least one pharmacy based audit and one multidisciplinary audit agreed by the Primary Care Trust in each financial year. As there are a number of concerns over the prescribing and supply of unlicensed specials, this has been chosen as the topic for this year.

In 2009/10 primary care prescribing of unlicensed specials in England cost the NHS over £111m and Primary Care Organisations are actively monitoring prescribing in this area.

Risk

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for ensuring that medicines and medical devices work, are safe and of appropriate quality. Most medicinal products have the necessary marketing authorisations or product licences before being placed on the market. However, unlike licensed products, unlicensed medicines may not have been assessed by the Licensing Authority against the criteria of safety, quality and efficacy.

For many patients the use of unlicensed products is unavoidable. However, their use may not be appropriate in all cases. In guidance produced by the Royal Pharmaceutical Society (RPSGB Fact Sheet 5: ***The Use of Unlicensed Medicines in Pharmacy***) pharmacists are reminded that it is a professional requirement that where a product is ordered on a prescription, a pharmacist must supply a product with a marketing authorisation, where such a product exists and is available, in preference to an unlicensed medicine or food supplement. Furthermore, both the supplying pharmacist and the prescriber should be aware that they each assume an increased level of liability for unlicensed products.

Every pharmacist, when making a supply of any medicinal product, assumes a duty of care to the patient. If a product without a marketing authorisation is supplied or a product is supplied outside its marketing authorisation indications and an adverse reaction is suffered, the supplying pharmacist may assume some liability with the doctor who prescribed it.¹

Pharmacists should also be aware that there may be no guarantee of the consistency of the product sourced from different manufacturers. Thus where a patient is supplied with an unlicensed item on a regular basis this should be made to the same formula from the same supplier, wherever possible.

Cost

In 2009/10 primary care prescribing of unlicensed specials in England cost the NHS over £111m. In Sheffield, the average cost of a special order product prescription over the last 12 months was £134.13 which compares to an average cost for total BNF prescribing of £9.47.

¹ RPSGB Fact Sheet 5: The Use of Unlicensed Medicines in Pharmacy

In September 2009 a total of 481 unlicensed specials were prescribed in Sheffield with an ingredient cost of £55,500 and annually, NHS Sheffield spends around £750k on such products. In many cases the GP is unaware of the cost of these prescriptions. Therefore it is vital that NHS resources are used appropriately.

Feedback of specials prescribing costs to practices is essential, as in many cases they are unaware of the cost of the special formulations. Whilst there is a valid clinical need for specials prescribing for certain patients there is also concern about wide scale prescribing of some formulations when cheaper equivalent licensed products are available. For example, prescribing Omeprazole liquid special 20mg/5ml (cost £6.95 per dose) instead of Losec 20mg MUPS (cost 41 pence per dose) which can be dispersed in water.

In summary, therefore, there is much that may have to be considered when prescribing or dispensing a special product:-

- The increased professional liability of both the prescriber and the pharmacist
- The higher cost of the product
- The limited shelf life of many 'specials'
- The time taken to obtain supplies compared to licensed medicines
- Whether the patient is aware that they have been prescribed an unlicensed product

AIM OF THE AUDIT

This audit has three key aims. Firstly it is intended to measure current practice against the guidance² issued by the Royal Pharmaceutical Society. A second aim is to highlight, across the health community, the risks and costs associated with the supply of unlicensed medicines. Thirdly, the audit is intended to highlight the financial benefit to the NHS through community pharmacy intervention.

² Legal and Ethical Advisory Service, Fact Sheet Five:- The Use of Unlicensed Medicines in Pharmacy (RPSGB)

CRITERIA AND STANDARDS

Criteria ³	Standard ⁴
There is a Standard Operating Procedure covering the supply of 'Specials' which includes the requirement to keep appropriate records for 5 years*.	100%
The GP is informed that the product is unlicensed	80%
The GP is informed of the cost of the product	80%
Where the supply of the prescribed item as ordered is deemed necessary, the pharmacist investigates whether a licensed alternative is available	80%
Patients are informed that their medicine is unlicensed, provided with written guidance and advised on the likely delay involved in ordering their medicine	80%
<p>*Appropriate record include, as a minimum:-</p> <ul style="list-style-type: none"> • the source of the product; • the person to whom and the date on which the product was supplied; • the quantity of each sale or supply; • the batch number of the product; • details of any adverse reactions to the product sold or supplied of which they are aware 	

³ Criteria are those aspects of care that you wish to examine or systematically developed statements that can be used to assess specific healthcare decisions, services and outcomes.

⁴ Standards are the percentage of events that should comply with the criteria

METHOD

Take time to read the audit forms, appendices and references thoroughly, then plan what needs to happen and who needs to be involved, including what you want them to do, e.g. will the pharmacist need to complete the audit forms or can they be delegated to support staff with the pharmacist supporting them and checking the content? Communicate the process to those who need to know e.g. healthcare assistants, dispensers, technicians, locum pharmacists, etc. and decide who will be responsible for posting the forms once completed.

There are two data collection sheets which must be completed, the first sheet is used to record each prescription requesting an unlicensed product and the second sheet collects information on pharmacy procedures and record keeping. Both have been designed to be simple and should take little time to complete. You will not be required to return any patient identifiable information.

It is important that all dispensary staff are aware of the audit and understand that when a prescription for an unlicensed product is presented they must alert the pharmacy team member leading the audit. The month of September has been selected for data collection. Each time a prescription for an unlicensed medicine is presented the pharmacist should, in all cases, investigate whether a suitable, licensed product is available. The UKMi document "Choosing Medicines for Patients with Swallowing Difficulties" has been included (Appendix E) to help pharmacists and GPs identify a suitable alternative. Pharmacists are also encouraged to access a second document, "Therapeutic options for patients unable to take solid oral dosage forms" a link to which has been included in the references section.

An entry should be started on the Data Collection Sheet (Appendix A). The GP should then be contacted and advised on the cost of the product and the availability of a suitable alternative. A suitable template fax form has been included in this pack (Appendix B). To minimise any delay to the patient the GP should be asked to respond as soon as possible.

Where the patient is being supplied with an unlicensed medicine they must be informed of the status of the product and should be provided with written information where possible. To help you, an example of a suitable leaflet has been included in Appendix D which can be simply photocopied or used as a basis for your own leaflet. Appendix A entry should be completed with the action taken.

Following the audit you should reflect on current performance against the advice/guidance. In most cases this should lead to the development of an action plan outlining how you will implement changes to improve your practice. (Appendix F)

The forms must be completed and returned by the 15th October 2010. Please return completed audit form to Virginia Fieldsend, Clinical Effectiveness Officer, Sheffield PCT, 722 Prince of Wales Road, Sheffield S9 4EU, retaining a copy for your records.

TIMESCALES

1st September – 30th September 2010	Data collection within community pharmacies
15th October 2010	Deadline for submitting data collection forms to PCT
1st January 2011	Data analysis and production of report
1st February 2011	Dissemination of report to all community pharmacies

REFERENCES

Therapeutic options for patients unable to take solid oral dosage forms

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

Commitment to Pharmacy (RPSGB)

<http://www.rpharms.com/practice--science-and-research/specials.asp>

Legal and Ethical Advisory Service, Fact Sheet Five:–

The Use of Unlicensed Medicines in Pharmacy

<http://www.rpsgb.org/pdfs/factsheet5.pdf>

Record of Supplies of Unlicensed Medicines

<http://www.rpsgb.org/pdfs/restoolsupplyunlic.pdf>

The Supply of Unlicensed Relevant Medicinal Products for Individual Patients (MHRA Guidance Note 14)

<http://www.mhra.gov.uk/home/groups/islic/documents/publication/con007547.pdf>

Pharmacy
Label/Stamp

APPENDIX A – DATA COLLECTION SHEET (PRESCRIPTION TALLY)

Important note: Each unlicensed item that is changed by the GP to a licensed product and recorded on this form will attract a payment of £15 and be paid automatically. Claims during September for not dispensing an unlicensed product under the “Sheffield Not Dispensed Scheme” will NOT be accepted.

Date	Product	GP is informed product is unlicensed (E.g. via fax) (Y/N)	GP is informed of cost of product (Y/N)	The pharmacist investigated the availability of an alternative (Y/N)	GP Elects to Change Prescription (Y/N)	Cost of initial, unlicensed product, if known (£)*	Cost of alternative product (£)	Patient Informed (Y/N)
Total (£)						£	£	

* Please include handling fee and postage as appropriate

Please return completed audit forms to Virginia Fieldsend, Clinical Effectiveness Officer, Sheffield PCT, 722 Prince of Wales Road, Sheffield S9 4EU by 15 October 2010. (Please retain a copy for your records.)

CRITERIA	Please Indicate
There is a Standard Operating Procedure in place to cover the supply of unlicensed medicines	YES/NO
Appropriate records are kept of each supply of an unlicensed medicine which include:-	
<ul style="list-style-type: none"> • The source or supplier of the product 	YES/NO
<ul style="list-style-type: none"> • The person to whom the supply was made 	YES/NO
<ul style="list-style-type: none"> • The date of the supply 	YES/NO
<ul style="list-style-type: none"> • The batch number of the product 	YES/NO
<ul style="list-style-type: none"> • Details of any adverse reactions to the product supplied 	YES/NO

Declaration

I confirm that I have not received any prescriptions for an unlicensed product during the month of September.

Signed _____ Print _____ Date ____/____/2010

APPENDIX C – Informing GP Template FAX

Supply of unlicensed medicinal products ("specials") for individual patients

The Medicines Control Agency (pre-decessor organisation to MHRA) has issued guidance on the use of “specials” — products made up by a licensed manufacturer for treatment of individual patients, on the order of a doctor or dentist.

The guidance suggests that specials should be used only where there is no suitable licensed product available and prescribers should be aware of the following factors associated with the supply of “Specials”: -

- The increased professional liability
- The higher cost of the product
- The limited shelf life
- The time taken to obtain supplies

Good practice directs that pharmacists **should alert the prescriber to the unlicensed status of the product**, preferably before it is ordered, and in any event before the product is administered.

With this in mind we would like to point out that the item below falls into this category. Unless we hear from you, **by the end of today**, to the contrary we will supply the prescription, as written, to the patient. I have included a suggested alternative, where one is available.

Patient

Address

Prescription for

Dated

Approx cost £

Alternative, suitable product for consideration

Signed(Pharmacist)

Date

Please insert Pharmacy Label or Stamp

APPENDIX D – “Informing Patients” (Template Leaflet)

Use of Unlicensed Medicines

PATIENT INFORMATION

What is this leaflet about?

You have been given this leaflet because a medicine that you have been prescribed does not have a licence, known as a marketing authorisation, issued by the Medicine and Healthcare Products Regulatory Agency (MHRA). This leaflet is intended to help answer any questions that you may have. Please talk to your doctor or pharmacist if there is anything further that you would like to know.

Pharmaceutical companies must hold a marketing authorisation for each medicine that they sell in the United Kingdom. The MHRA issue these licences only after they have assessed information on the quality, safety and efficacy of the medicine.

Why don't all medicines have licences?

There are a number of reasons why a medicine may not have a licence, or marketing authorisation:

- It is currently undergoing clinical trials, but does not yet have a licence;
- The medicine used to be licensed in the UK, but is no longer available;
- It is only available from abroad and needs to be imported; or
- The medicine needs to be made specially

Why have I been given an unlicensed medicine?

You have been prescribed an unlicensed medicine, because no suitable licensed alternative is available to treat your condition. However, the person treating you will have thought very carefully about prescribing the most appropriate medicine.

Should I be worried about taking unlicensed medicines?

The prescriber will have explained to you why they think that this medicine is the right one for you. If you are worried about taking this medicine, talk to your doctor or pharmacist about your concerns. They may be able to give you further information or help to put you in touch with a support group for your illness or condition.

If you do experience any unpleasant or unexpected effects whilst taking the medicine, you should report this to your doctor or pharmacist.

What else do I need to know?

Sometimes, it will take longer for the pharmacist to order in an unlicensed medicine. In which case, you will need to allow one or two weeks for the pharmacist to obtain further supplies of your medicine. You should bear this in mind, if you need to get a repeat prescription from your doctor.

Insert your pharmacy
details here

Choosing medicines for patients unable to take solid oral dosage forms

Selecting suitable formulations for adult patients with swallowing difficulties or feeding tubes.

A stepwise approach is suggested

STEP 1

Use a licensed medicine in a suitable formulation.

For example:

- Licensed liquid preparation
- Soluble tablets
- Powders or granules for suspension

In order to use a licensed medicine, consider switching to a different agent in the same class, or to a different route of administration.

For example, consider:

- Fluoxetine liquid (licensed preparation) as an alternative to sertraline tablets.
- Aspirin dispersible tablets instead of clopidogrel tablets.
- HRT patches instead of tablets.

Consider the patient's method of feeding:

Patients on liquid feeds may take oral liquid medicines, dispersible tablets or solid preparations dispersed in water prior to administration. For patients on thickened fluids, liquid medicines can be mixed with products like *Thick and Easy*.

Patients on soft-food diets may be able to swallow crushed tablets or the contents of capsules given with food.

Patients with enteral feeding tubes may have oral medicines given by this route.

Why licensed status matters

To be granted a licence a medicine must meet quality standards and be shown to be safe and effective. Licensed medicines usually come with a patient information leaflet and are considered the safest choice.

Special-order medicines are unlicensed and are not required to meet the same standards as licensed medicines. Prescribers take greater responsibility when using them.

In most cases a licensed preparation will be available that meets the patient's needs.

Cost

Special-order medicines are often considerably more expensive than licensed medicines. They may have short shelf-lives compared with licensed alternatives and may need fridge storage.

For example, bendroflumethiazide liquid is 75 times more expensive than tablets:

- 28 doses of 2.5mg tablets costs 80p.
- 30 doses of 2.5mg/5ml liquid (150ml) costs £60.

NB: Bendroflumethiazide tablets can be dispersed in water for administration orally or via feeding tubes.

STEP 2

Use a licensed medicine in an unlicensed manner, for example by crushing / dispersing tablets in water or by opening capsules.

For example:

- Ramipril capsules can be opened and the contents mixed with water.
- Bendroflumethiazide tablets can be dispersed in water.

Both the above examples are suitable for administration orally or via a feeding tube.

Not all medicines are suitable for administration in this way and it is important to check beforehand. See over for where to get advice.

As before, consider switching to a different agent or route of administration in order to use a licensed product.

Is it needed?

If the patient is taking medicines that aren't needed or aren't working, stop or change them.

Care staff may only give licensed medicines in an unlicensed way if there is a written direction in the patient's care plan.

Practical directions are overleaf.

STEP 3

In the few situations where there is no licensed option, consider using a 'special'.

Special-order ('special') liquid medicines are unlicensed and expensive. They should only be used if there is no licensed medicine that meets the patient's needs.

**Licensed medicines should be used where possible.
Special-order medicines are unlicensed and expensive and should only be used if there is no licensed alternative.**

Practical directions

Always check beforehand if a tablet is suitable for dispersing / crushing, or a capsule suitable for opening.

• **Crushing / dispersing tablets**

Many immediate-release tablets can be dispersed in water without crushing; some medicines need crushing first. Some tablets (e.g. modified release) are not suitable for crushing.

For medicines that are suitable for crushing, crush using a pestle and mortar, a tablet crusher or between two metal spoons.

Only crush medicines one tablet at a time; do not crush all the patient's medicines together. Crushing or dispersal should only be performed immediately before administration.

• **Opening capsules**

Some hard gelatin capsules can be opened and their contents mixed with water or administered with food. Some capsules are too small to manipulate. Capsules should only be opened immediately before administration.

• **Giving medicines in soft food**

Some capsule contents or crushed tablets can be given with cold soft food such as a teaspoon of yoghurt or jam. Use a small amount of food to ensure the full dose is taken.

Crushed tablets or capsule contents may taste very bitter to patients taking them orally. Mask the taste by giving with strong flavours such as blackcurrant.

Medicines should only be administered in food with the patient's knowledge and consent. Hiding medication in food is considered 'covert administration' and is only allowed in certain circumstances.

• **Administering medicines via feeding tubes**

Feeding tubes should be flushed with water before and after each medicine is administered. If a liquid medicine is thick or syrupy, dilution may be required. Some patients are fluid restricted; this needs to be taken into account.

When administering crushed tablets or opened capsules via a feeding tube, add the powder to 15-30ml water and mix well. Draw into a 50ml oral syringe and administer. If you have used a mortar or tablet crusher, rinse this with water and administer the rinsings also.

Suggested protocol for administering medicines via feeding tubes:

1. Stop the feed (leaving a feeding break if necessary).
2. Flush the tube with 30ml water.
3. Prepare the first medicine for administration, and give it.
4. Flush with 10ml water.
5. Repeat stages 3 and 4 with subsequent medicines.
6. Flush with 30ml water.
7. Re-start the feeding (leaving a feeding break if necessary).

Care staff may only administer medicines in an unlicensed manner on the instruction of the prescriber.

A written direction to crush or disperse tablets or to open capsules must be documented in the patient's care plan.

Where can I get advice?

For advice on choosing appropriate dosage forms or to check if tablets or capsules can be dispersed, crushed or opened, contact your PCT medicines management team or UKMi medicines information centre.

Medicines Management team North – 0114 305 1667 South 0114 2716430

Contact details for UKMi medicines information centres are available at www.ukmi.nhs.uk. Click on the map then search for your local or regional centre.

• **Medicines Q&A**

This leaflet accompanies a *Medicines Q&A* document which provides further information and lists options available in several therapeutic areas for adult patients with swallowing difficulties or feeding tubes.

Access it online via the National electronic Library for Medicines, www.nelm.nhs.uk (see bottom of the page for the full link).

• **Reference texts**

Details of two respected texts are at the bottom of the page.

Only prescribe special-order medicines if there is no suitable licensed medicine available that meets the patient's needs.

It may be appropriate to use a licensed medicine in an unlicensed way.

References:

- UKMi. Medicines Q&A 294.1a: Therapeutic options for patients unable to take solid oral dosage forms. December 2009 (partial revision January 2010). Available online at: www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Therapeutic-options-for-patients-unable-to-take-solid-oral-dosage-forms/
- White R and Bradnam V. Handbook of drug administration via enteral feeding tubes. London: RPS Publishing; 2007.
- Smyth J. The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties. Wrexham: North East Wales NHS Trust; 2006.

Date of preparation: January 2010

APPENDIX F -REFLECTIVE ACTION PLAN

(REMINDER - YOU MAY WANT TO CONSIDER THIS AUDIT ACTIVITY AS AN ENTRY IN YOUR RPSGB CPD PORTFOLIO)

Identify areas in your practice where you can make changes to help ensure:-

- Unlicensed products are only used where necessary,
- Guidance (RPSGB & MHRA) covering the supply of unlicensed medicines is fully adopted
- Treatment adherence is improved through better patient understanding,
- Appropriate use of NHS resources

What changes will you make in the future?

- Set practice guidelines
- Outline at least 3 action points to achieve agreed practice standards
- Set a date for a re-audit and compare results to standards

Practice standard	Action points

Did you identify areas in the practice of others e.g. GPs, nurses or hospital Drs /Nurses or Pharmacists, where they can make changes to help meet the guidance?

Yes No

If yes, how will you communicate this to them?

What help if any do you need from NHS Sheffield to achieve this? (The summarised results of the audit will be circulated to pharmacists and GPs after amalgamation for information and consideration)