Pennine Care NHS
NHS Foundation Trust

Policy Document Control Page

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- Midodrine removed as example, as it is now available as a licensed medicine
- Appendix 3. RCPCH Policy statement. Updated with most recent version (2013)
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Originator

Originated By: Lesley Smith

Designation: Chief Pharmacist

Equality Analysis Assessment (EAA) Process

Equality Relevance Assessment Undertaken by: Lesley Smith/ Robert Hallworth

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Where policy deemed relevant to equality-

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This policy is to be disseminated to all relevant staff. **This policy must be posted on the Intranet.** **Date Posted: 16th January 2017**

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1 TRUST STATEMENT

1.1 This document describes the Trust's Policy on the prescribing, supply and use of unlicensed medicines.

1.2 Unlicensed medicines must only be used when no pharmaceutically equivalent licensed product or suitable alternative licensed product is available for use at the time that the patient requires it. Such uses are informed and guided by respectable and responsible body or professional opinion. Products are considered pharmaceutically equivalent if they contain the same amount (or concentration) of the same active substance in the same dosage form, and meet the same or comparable standards considered in the light of clinical needs of the patient at the time of its use.

2 INTRODUCTION

2.1 For various reasons it is sometimes necessary to prescribe or use unlicensed medicines. Unlicensed medicines are defined as those not having a Product Licence (PL) in the United Kingdom (UK). Such unlicensed medicines include:

2.1.1 Items having PL equivalents in other countries, imported due to non-availability of the formulation in the UK, for example, levomepromazine suspension, Ritalin SR and naltrexone implants.

2.1.2 Items having PL equivalents in other countries, imported due to non-availability of the medicine in the UK, for example, pirenzepine.

2.1.3 Items without licences, for example, certain melatonin preparations (immediate release capsules),

2.1.4 Items prepared in the UK by manufacturers holding a "Specials" license, for example, melatonin liquid formulations.

2.2 This Policy is <u>NOT intended to cover:</u>

- Medicines used in Clinical Trials.
- Medicines which are prepared extemporaneously in response to a prescription.
- Products prepared under Sections 9, 10 or 11 of the Medicines Act 1968.

2.3 All unlicensed medicines used by the Trust will be procured, received, stored and supplied by the Pharmacy Departments/ Provider Services providing Pharmacy Services under the Service Level Agreement (SLA) in accordance with the Policy on the Use of Unlicensed Medicines of their own Trust/ Organisation and this Policy.

3 CONSENT OF PATIENTS OR CARERS

3.1 No additional measures beyond those taken to obtain informed consent when prescribing licensed medicines are required to prescribe and use unlicensed medicines.

3.2 Healthcare professionals must however respect the rights of patients and carers to participate in discussions regarding the health of the patient and to seek to ensure that these decisions are properly informed.

3.3 Out-patients and patients being discharged from hospital should receive a patient information leaflet (PIL), a model of which is given in Appendix 1, which explains why it is necessary to prescribe unlicensed medicines.

3.4 Children and their carers should receive a copy of a patient and carer information leaflet entitled unlicensed medicines published by the Royal College of Paediatrics and Child Health (RCPCH). The current version is shown in Appendix 2 and explains about the use of unlicensed medicines in children.

3.5 RCPCH has produced a policy statement: The use of unlicensed medicines or licensed Medicines for unlicensed applications in paediatric practice which may also be provided to patients and carers. The current version is shown in Appendix 3

3.6 For in-patients, medicines which are unlicensed because they are not available in the UK, should be named on the Section 58 treatment authorisation forms T2/ T3 when in use, with a specified maximum dose as they do not appear in the British National Formulary (BNF).

4 RESPONSIBILITY OF PRESCRIBERS

4.1 Before prescribing an unlicensed medicine, prescribers must be satisfied that an alternative, licensed medicine would not meet the patient"s needs. Prescribers of unlicensed medicines carry their own responsibility and are professionally accountable for their judgement in doing so.

4.2 Unlicensed medicines must not be prescribed without the permission of the patients Consultant or General Practitioner (GP).

4.3 Documentation supporting a decision to prescribe an unlicensed medicine should be made in the clinical notes by the prescriber and Consultant or GP.

4.4 Prescribers should discuss with patient and/or carer the reasons for prescribing an unlicensed medicine. In some cases there may be no Patient Information Leaflet (PIL) for the unlicensed medicine or it may be in a foreign language. Prescribers should make the patient and/or carer aware of this to avoid confusion.

5 RESPONSIBILITY OF PHARMACISTS

5.1 A pharmacist is designated (hereafter referred to as the designated pharmacist) for controlling the procurement and supply of unlicensed medicines from the pharmacy departments of the Acute Trusts providing pharmacy services to the Trust under SLA.

5.2 A pharmacist is designated for controlling the procurement and supply of unlicensed medicines from the dispensary of an external Provider providing pharmacy supply services to the Trust.

5.3 Clinical pharmacists employed by Pennine Care NHS Foundation Trust or by Acute Trusts providing pharmacy services under SLA will be responsible for ensuring that prescribers are aware that a medicine that they have requested is only available as an unlicensed product.

5.4 Clinical pharmacists employed by Pennine Care NHS Foundation Trust or by Acute Trusts providing pharmacy services under SLA will ensure that all the controls specified in this policy are applied including the keeping of appropriate records.

5.5 It is likely that several pharmacists may be involved in the decision making process around the use of an unlicensed medicine, for example, the clinical pharmacist, the designated pharmacist within an Acute Trust, the pharmacist employed by an external Provider and the Chief Pharmacist.

5.6 The Chief Pharmacist will maintain records of all requests to prescribe unlicensed medicines and other associated paper work.

5.7 Procurement and supply of unlicensed medicines will be in accordance with the Royal Pharmaceutical Society's document 'Professional Guidance for the Procurement and Supply of Specials'.
http://www.rpharms.com/support-pdfs/rps---specials-professional-guidance.pdf

6 AUTHORISATION

6.1 A Consultant wishing to prescribe an unlicensed medicine should contact the Chief Pharmacist of the Trust in the first instance, ideally in writing, stating the reason for the request and appropriate clinical details.

6.2 The Chief Pharmacist will discuss the application with the Medical Director where appropriate.

6.3 The Chief Pharmacist and Medical Director will review the clinical data and take a view on the likelihood of supply chain difficulties, the possibility of interruption to patient treatment and any other consequences of starting treatment with an unlicensed medicine.

6.4 A response to the Consultant will be made as soon as is practicable. A verbal response will be followed up in writing.

6.5 Where permission to prescribe an unlicensed medicine is given the response will include details of the Request and Risk Assessment form for Unlicensed Medicines of the Acute Trust pharmacy department or documentation used by an external Provider, for completion.

A copy of the response will also be sent directly to the designated pharmacist in the appropriate Acute Trust pharmacy department or dispensary of the external Provider by the Chief Pharmacist.

6.6 The Consultant must complete the Request and Risk Assessment form or documentation used by Lloyds Pharmacy of the Acute Trust pharmacy department following the relevant procedure. A copy of the completed documents should be sent to the Chief Pharmacist, Pennine Care as well as to the designated pharmacist in the Acute Trust pharmacy department or to the pharmacist of the external Provider.

6.7 In the case of urgent clinical need for an unlicensed medicine the Consultant and the designated pharmacist of the Acute Trust pharmacy department or pharmacist of the external Provider in consultation with the clinical pharmacist may start the process of obtaining a supply of an unlicensed medicine without prior reference to the Chief Pharmacist. The matter should be brought to the attention of the Chief Pharmacist as soon as is practicable following initiation.

7 RESPONSIBILITY OF THE DRUG & THERAPEUTICS COMMITTEE

7.1 The Drug & Therapeutics Committee (D&T Committee) is responsible for the approval for use of unlicensed medicines in the Trust.

7.2 When considering a request to approve use of an unlicensed medicine, the D&T Committee must be certain that there is no suitable licensed alternative available.

7.3 Ratification of initial approval by the Chief Pharmacist and the Medical Director may occur at the next D&T Committee meeting.

7.4 A list of unlicensed medicines that have been approved for use and details of usage will be maintained by the Chief Pharmacist.

8 EVALUATION OF UNLICENSED MEDICINES

8.1 The D&T Committee will have a monitoring role in the use of unlicensed medicines and will carry out periodic audit of the use of unlicensed medicines within the Trust.

8.2 The D&T Committee will review the list of unlicensed medicines in use annually. The review will include a re-assessment of the original clinical data, any new clinical data and any newly licensed products that may be more appropriate for use.

9 ADVERSE DRUG REACTIONS

9.1 Suspected adverse drug reactions to unlicensed medicines are handled in the same way as licensed medicines. Doctors, Pharmacists, Nurses or patients should report suspected adverse drug reactions to the Medicines and Healthcare Regulatory Agency (MHRA) via the Yellow Card reporting system. This may be using the Yellow Card System. Copies of Yellow Cards are available in the BNF and reports may also be submitted electronically at http://yellowcard.mhra.gov.uk

9.2 Copies of ALL adverse drug reaction reports (Yellow Cards) to unlicensed medicines should be submitted to the D&T Committee via the Chief Pharmacist.

10 DEFECTIVE PRODUCTS

Reporting a defective unlicensed medicine is handled in the same way as a licensed medicine. Suspected defects should be reported to the Pharmacy department of the Acute Trust providing Pharmacy Services under SLA, the pharmacist of the external Provider or the Chief Pharmacist.

11 CONTINUING SUPPLIES OF UNLICENSED MEDICINES

There is no expectation that GPs will continue the prescribing of unlicensed medicines for discharged patients or out-patients except where this has been previously agreed between the D&T Committee and the Clinical Commissioning Group (CCG). There may also be circumstances in which arrangements for unlicensed medicines to be prescribed in primary care are agreed between individual Consultants and GP.

12 RELATED POLICIES

This Policy should be read in conjunction with:

Medicines Policy (CL15)

The use of licensed medicines outside the conditions of their Product Licence Policy (CL17)

Guidelines for the reporting of suspected Adverse Drug Reactions (MM038)

13 IMPLEMENTATION AND TRAINING

The Trust will ensure that the policy on the prescribing, supply and use of unlicensed medicines has been issued and implemented as follows:

13.1 Issue and Implementation

A variety of dissemination methods are in place to make sure that all staff are aware of, have access to and comply with, the policy on the prescribing, supply and use of unlicensed medicines.

Lists of all new policies are published in the Trust‟s Corporate Brief including a brief description and its intended audience.

All policies are held on the Trust‟s intranet, to which all staff have access. Staff should always consult the intranet for the latest version.

Where a hard copy is kept on a ward/clinical area, it is the responsibility of the Ward Manager/Team Leader to ensure that the current version is on file.

Following approval, the Chief Pharmacist is responsible for cascading details of the latest version of all policies to all healthcare professionals.

Ward and team managers are responsible for ensuring staff in their area of managerial control are fully aware of the content of policy on the prescribing, supply and use of unlicensed medicines and to act accordingly.

All healthcare staff are responsible for ensuring they understand the content of the policy on the prescribing, supply and use of unlicensed medicines and to act accordingly.

13.2 Training

Training in medicines management and in relation to the policy on the prescribing, supply and use of unlicensed medicines, forms part of the Trust's mandatory and essential training programme for identified staff groups.

The format of the mandatory medicines management training is described as per the Trust Training Needs Analysis.

Checking and monitoring of non-completion of mandatory medicines management training is undertaken by the Organisational Development (OD) team

Where pharmacy staff provide additional training on medicines on an ad hoc basis or at the request of managers within the Trust, attendance records will be completed and forwarded to the (OD) Team for inclusion on the Training database.

Pharmacy staff input on an ongoing basis to the induction programme of junior medical staff.

Further training will be made available when necessary to support initiatives of the National Reporting and Learning System (NRLS) and /or NICE.

Medicines management training needs in relation to the policy on the prescribing, supply and use of unlicensed medicines should be identified through the Individual Performance and Development Review (IPDR) process and feed into the Trust Training Needs Analysis (TNA).

Training required for individual members of staff is identified through the Trust's IPDR process and arranged as appropriate. Any non- attendance is reported via e-mail from the OD Team to the individual's authorising manager for action and future attendance to be arranged.

14 AUDIT AND MONITORING OF COMPLIANCE

14.1 Audit

Audit in relation to the policy on the prescribing, supply and use of unlicensed medicines will be carried out as part of the Trust's clinical audit programme and in accordance with the annual audit calendar.

14.2 Monitoring

Compliance with this policy will be monitored using an analysis of incidents and complaints, by the Managing Prescribing Risk group on a quarterly basis, where there has been a failure to follow procedure.

Quarterly medication error/incident reports (Safeguard) prepared and reviewed by Managing Prescribing Risk Sub Group. Analysis allows identification of trends and themes.

Action plans to manage improvement in compliance will be developed by the Managing Prescribing Risk group on a quarterly basis where necessary.

Key findings of both audit and monitoring of compliance will be reported to the Drugs and Therapeutics Committee.

Training required for individual members of staff is identified through the Trust's IPDR process and arranged as appropriate. Any non-attendance is reported to the individual's Service Manager.

15 REVIEW

The D&T Committee will review the policy on the prescribing, supply and use of unlicensed medicines every three years.

Appendix 1 ***[Insert name of trust]***

[MODEL] PATIENT INFORMATION LEAFLET FOR UNLICENSED MEDICINES

You have been given this leaflet because the medicine you have been prescribed is „unlicensed". Pharmaceutical companies must hold a marketing authorisation for each medicine that they sell in the United Kingdom. The Medicine and Healthcare Regulatory Agency (MHRA) issue these licences only after they have assessed information on the quality, safety and efficacy of the medicine.

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

- The medicine is being tested in a clinical trial and/or awaiting the granting of a Product Licence from the Government.
- Usage of the medicine is low and therefore it is uneconomical for the manufacturers to get the medicine approved, or difficult to get enough patients to perform a clinical trial.
- The medicine is not commercially available as a liquid/cream and has to be made specially in a different form.
- The medicine has to be imported as it is not available in the UK.

You have been prescribed an unlicensed medicine because no suitable licensed alternative is available to treat your condition. Please be reassured that the person treating you will have thought very carefully about prescribing the most appropriate medicine for you.
If you have any concerns regarding this medicine please contact your Doctor or Pharmacy.

HOW TO OBTAIN A FURTHER SUPPLY

If you require a further supply of this medicine please:

□ Go to your GP to obtain a prescription and take it to your local Pharmacy along with this leaflet.

□ Return to the Hospital Pharmacy for a further supply.

You will probably need to give the Pharmacy one or two weeks' notice to obtain the supply for you. You should bear this in mind if you need to get a repeat prescription from your Doctor/GP.

Appendix 2

Medicines for Children information for parents and carers

Unlicensed medicines

Most medicines used in the UK have a licence that says exactly how the medicine can be used. However, this licence may not include use in children or in a particular illness or condition.

This leaflet explains what we mean by the unlicensed use of a medicine, why the use of many medicines in children is unlicensed, and why this is safe and acceptable.

This leaflet has been written specifically about medicines in children. Please read this leaflet carefully. Keep it somewhere safe so that you can read it again.

Most medicines used in the UK have a licence that says exactly how the medicine can be used. However, this licence may not include use in children or in a particular illness or condition.

The term medicine refers to any substance used to prevent or treat a medical condition: tablets, capsules, liquid medicine, liquid given by injection, inhalers, suppositories, creams, ointments and patches.

What is a licence?

A drug company must have a licence to advertise and sell a medicine. The licence states which illness the medicine can be used for, what doses (how much) can be used, how the medicine should be given (e.g. by mouth, by injection) and which group of patients it can be used for – this is usually adults.

To get a licence, the drug company must prove that the drug works and that it is safe to use, which is done during clinical trials. Trials are usually done in adults but may be done in children if a medicine is to be used for them.

What do we mean by unlicensed use?

When doctors know more about how a medicine works and its possible side-effects (unwanted effects), they may then want to try using it for other illnesses or conditions, or in other groups of patients, such as elderly patients or children.

If a medicine is used in a way that does not meet the strict rules set out in the licence, this is described as 'unlicensed use' (it may also be called off-label or off-licence use). This includes giving a medicine in a way that is different from that described in the licence.

Here are some examples of unlicensed uses:

- use of a licensed medicine for an illness that is not covered by the licence
- use of a medicine that is only available from abroad and has to be imported (it may have a licence in other countries)
- a medicine that needs to be made specially because it cannot be obtained easily; for example, a patient may not be able to swallow a (licensed) tablet or capsule and would prefer a liquid (unlicensed) version of the medicine.

Many medicines that are widely used in children's hospitals and neonatal units are unlicensed. This gives doctors more choice about which medicine to use than if they could only use licensed medicines.

Why is use in children often unlicensed?

To get a licence to use a medicine in children, the drug company would have to do clinical trials in children. This can be difficult, especially for a rare illness.

Once a medicine is widely used, the drug company may do clinical trials in children. This allows them to get a licence so that they can market the medicine for this age group.

Is it OK to use an unlicensed medicine?

Most medicines that are prescribed for a child will have a licence for use in adults, and so clinical trials have been done to prove that it is OK to use in adults.

Your doctor will only suggest using a medicine for your child if he or she thinks that it is the best thing to help your child. Your doctor will tell you about any side-effects that your child may get.

It is important to understand that if your doctor prescribes a medicine for your child, it is because they think that the benefit of taking the medicine will be greater than the risk of not treating your child's illness.

How do I know whether my child's medicine is unlicensed?

Your doctor or pharmacist may tell you that the medicine is not licensed for use in children. The leaflet that comes with the medicine may not say anything about its use in children, or may say that the medicine is not suitable for children.

This **does not** mean that it cannot be used safely in children – it means that the drug company does not have a licence for use in children and so is not allowed to recommend this use.

Where can I get information about unlicensed medicines?

Your doctor or pharmacist will be able to tell you more about the medicine. Medicines for Children produces leaflets that are written specially for parents and carers.

Many of these are about medicines that are unlicensed for use in children. You can get the leaflets from our website, www.medicinesforchildren.org.uk

You will probably get an information leaflet with your child's medicine, which describes what the medicine is used for, how to take it, and any side-effects. This information may have been written about use of the medicine in adults. However, a lot of it will be relevant to children and useful to parents/ carers, although the doses recommended in this leaflet may not be right for children.

⚠ You should always follow your doctor's instructions about how much to give.

Remember, your doctor will never prescribe a medicine that is not thought to be safe.

www.medicinesforchildren.org.uk

The primary source for the information in this leaflet is the British National Formulary for Children. For details on any other sources used for this leaflet, please contact us through our website, www.medicinesforchildren.org.uk

We take great care to make sure that the information in this leaflet is correct and up-to-date. However, medicines can be used in different ways for different patients. It is important that you ask the advice of your doctor or pharmacist if you are not sure about something. This leaflet is about the use of these medicines in the UK, and may not apply to other countries. The Royal College of Paediatrics and Child Health (RCPCH), the Neonatal and Paediatric Pharmacists Group (NPPG), WellChild and the contributors and editors cannot be held responsible for the accuracy of information, omissions of information, or any actions that may be taken as a consequence of reading this leaflet.

Appendix 3

THE USE OF UNLICENSED MEDICINES OR LICENSED MEDICINES FOR UNLICENSED APPLICATIONS IN PAEDIATRIC PRACTICE

Policy statement produced by the joint RCPCH/NPPG Standing Committee on Medicines

This statement, originally produced in 2000, has been updated by the Joint Standing Committee on Medicines, a committee of the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists Group. The update reflects changes in European (including UK) law that aim to facilitate the development of more licensed medicines for children. The purpose of the statement is to inform and guide health professionals, health service managers, parents and carers who prescribe, dispense, administer or have responsibility for medicines for children.

Summary

Those who prescribe for a child should choose the medicine which offers the best prospect for that child, aware that such prescribing may be constrained by the availability of resources. Children should be able to receive medicines that are safe, effective, appropriate for their condition, palatable and available with minimal clinical risk.

The informed use of some unlicensed medicines or licensed medicines for unlicensed applications is necessary in paediatric practice.

Health professionals should have access to reliable and up-to-date information where possible on any medicine they prescribe, dispense or administer, and on its availability.

In general, it is not necessary to take additional steps, beyond those taken when prescribing licensed medicines, to obtain the consent of parents, carers and child patients to prescribe or administer unlicensed medicines or licensed medicines for unlicensed applications.

NHS Trusts and Health Authorities should support therapeutic practices that are advocated by a respectable, responsible body of professional opinion.

Where available an appropriate licensed preparation should be prescribed and supplied in preference to an unlicensed preparation.

Licensing

12 For a medicine to be marketed in the United Kingdom it must have received a Marketing Authorisation and is then said to be licensed. Many medicines that are given to children are not licensed for the particular indication, the age of the child or for the route of administration. Additionally they may not be in a suitable formulation. This position has arisen when a pharmaceutical company has made an application to the Licensing Authority for a Marketing Authorisation for use of the medicine in adults, but had chosen not to make an application for the use of that medicine in particular ways in children. Certain medicines that are given to children have not received a licence for any indication, and are said to be unlicensed.

In 2007, European (including UK) law introduced a requirement for pharmaceutical companies to undertake studies in children as part of the development plan for most new medicines. Over time, it is anticipated that the number of medicines licensed for use in children will increase. When a licensed medicine becomes available it should, therefore, be prescribed and supplied in preference to an unlicensed preparation.

13 The use of unlicensed medicines or licensed medicines for unlicensed applications is necessary in paediatric practice when there is no suitable alternative. Such uses are usually informed and guided by a respectable and responsible body of professional opinion.

14 The Medicines Act and Regulations (which incorporate the relevant EC directives) provide exemptions which enable prescribers to:

- prescribe unlicensed medicines;
- use clinical trials medicines which are not yet authorised to be marketed.
- use or advise on the use of licensed medicines for indications, or in doses, or by routes of administration, outside the recommendations of the licence;
- override the warnings and the precautions given in the licence.

15 In each case, the prescriber has to be able to justify the action taken as being in accordance with a respectable, responsible body of professional opinion.

Sources of information

16 Although the choice of a medicine is not necessarily determined by its licence status, it will take account of information made available as a consequence of licensing and contained in the marketing authorisation. When the Marketing Authorisation does not include indications for use in children, the licence is of limited help. When the medicine is unlicensed, the necessary information must be sought elsewhere. It often is available, though might not be readily accessible.

17 The British National Formulary for Children (BNF-C) provides reliable and up-to-date information and guidance on medicines for children.

Information for other health professionals and the public

18 Parents, patients and teachers, and others *in loco parentis*, require information about medicines. The information must be given in a way they can understand, and be accurate and consistent. This is particularly important when the specialist who has advised the use of unlicensed medicines or licensed medicines for unlicensed applications, hands over the care of the patient and responsibility for the

administration of the medicine to someone else. Given the complexity of therapeutic and pharmacological information, and the burdens upon those giving and receiving it, the need is for sound, practical and sensible arrangements for communication, supplemented by readily available sources of reference.

It is essential that health professionals should have ready access to sound information on any medicine they prescribe, dispense or administer, and on its availability. The BNF-C fulfils most of these roles.

Consent of parents, carers and patients

19 Health professionals respect the right of children and their parents to participate in decisions on the health care of the child, and seek to ensure that those decisions are properly informed. In normal paediatric practice no additional steps, beyond those taken when prescribing licensed medicines, are required to obtain the consent of patients and parents / carers for the use of unlicensed medicines.

20 Prescribers are anxious that the licence status of a drug should not be perceived as reflecting what is or is not best for the child. They are mindful of a possible impact upon the confidence of parents and patients who might then be reluctant to accept advice, with consequences for a child who might not receive a medicine that offers benefit.

10. Most licensed medicines are dispensed in standard packages together with a Patient Information Leaflet (PIL) approved by the Licensing Authority. When the licence does not include indications for children, the PIL may caution against such use. Naturally, this may undermine confidence in the advice given by health professionals, besides provoking a call for explanation. The Committee working in partnership with the WellChild charity has produced leaflets on medicines, including one on Unlicensed Medicines which explains why it may be necessary to prescribe unlicensed medicines or to use licensed medicines for unlicensed applications. This leaflet will be made widely available to all, especially parents/carers, hospitals and pharmacies via the website www.medicinesforchildren.org.uk where Medicines for Children: Information for Parents/Carers leaflets are freely available to download.

- There are circumstances when a clinician may decide to give fuller information than is usually judged necessary. These may arise when a medicine is new or experimental; or when the balance of risk versus benefit is less clear or when the concerns of some parents, carers or patients suggest a more detailed discussion is needed.

Policies of NHS Provider Organisations

- Some NHS Provider Organisations have suggested that a clinician should not use an unlicensed medicine, or a licensed medicine for unlicensed application. In 1993 the Department of Health stated that it would not expect that a health authority would seek to fetter a prescriber's freedom to prescribe by expressly directing its medical staff against prescribing unlicensed products or licensed products for unlicensed purposes. The Department of Health also stated that, should a health authority so direct its medical staff, a court would be reluctant to support the authority in those circumstances.

- However the emphasis on risk management and evidence-based medicine in Clinical Governance framework implies that Trusts may be encouraged to introduce systems and protocols to monitor, and even direct, the use of both licensed and unlicensed medicines. We understand that, because the Medicines Act (1968) exemptions remain current, the courts would not hold the prescription of an unlicensed medicine to be a breach of the duty of care, if that treatment was supported by a respected body of medical opinion. The best evidence available should always inform the prescription of medicines for children.

We consider that NHS Provider Organisations should support therapeutic practices that are advocated by a respectable, responsible body of professional opinion.

Updated authors

Dr Andy Fox
Dr Helen Sammons 06th

December 2013

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Royal College of Paediatrics and Child Health 5-11
Theobalds Road
London WC1X 8SH
www.rcpch.ac.uk
Registered Charity 1057744

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