

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Unlicensed Medicines – Policy Document

Effective: January 2010

Review: January 2012

1. Introduction

In order to ensure that medicines are safe and effective the manufacture and sale or supply of medicinal products is controlled by national and EEC legislation (1,2). Accordingly no medicinal product may be placed on the market unless a Marketing Authorisation (Product Licence) has been issued.

The legislation gives some exemptions from full control to allow the use of medicinal products that are not licensed in order to fulfil special needs in individual patients on the direct personal responsibility of the prescribing clinician^a (doctor, dentist or non-medical supplementary prescriber).

Such unlicensed products are not subject to stringent control by the Licensing Authority (Medicines and Healthcare Products Regulatory Agency [MHRA]) and neither prescribers nor pharmacists can make the same assumptions of quality, safety and efficacy about unlicensed products as they do for licensed medicines.

For good clinical reasons the use of unlicensed medicines is widespread, particularly in teaching hospitals^b. Should their use be inappropriately curtailed the treatment of many patients would be impeded.

Guidance from the MHRA (3) requires NHS Trusts to develop policies on the use of unlicensed medicines.

The policy below is intended to satisfy this requirement. It has been prepared taking into account information and advice from many sources including:

- National and European legislation (1,2)
- Guidance from the Medicines Control Agency (3,4)
- Guidance from the NHS Pharmaceutical Quality Control Committee (5)
- The Royal College of Paediatrics and Child Health (6)
- The Newcastle Hospitals NHS Trust and the North of Tyne Area Prescribing Committee

References:

1. EEC Directive 65/65.
2. The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 [SI 1994/3144].
3. MHRA Guidance Note 14, The Supply of Unlicensed Relevant Medicinal Products for Individual Patients, January 2008.
4. Medicines Act Leaflet 81 (MAL81), The Medicines for Human Use (Marketing Authorisations Regulations 1994) S.I. 1994/3144.
5. Guidance for the Purchase and Supply of Unlicensed Medicinal Products, Notes for Prescribers and Pharmacists, NHS Pharmaceutical Quality Control Subcommittee, June 2001.
6. Royal College of Paediatrics and Child Health Policy statement on the use of Unlicensed Medicines or Licensed Medicines for Unlicensed Applications in Paediatric Practice, 2000.

^a These products are supplied in response to a bona fide unsolicited order, and are technically formulated in accordance with the specifications of an authorised health care professional.

^b Approximately 450 unlicensed medicinal products are currently used in Newcastle's Hospitals at a cost of about £3,050,000 per annum in 2009/2010.

2. Policy Statement

The use of unlicensed medicines within the Newcastle upon Tyne Hospitals is supported in accordance with the principles outlined below and any associated guidelines:

- 2.1. Unlicensed medicines should only be used if their use can be clearly justified clinically and/or pharmaceutically to meet the special needs of individual patients^c. An unlicensed product must not be used purely on the grounds of lower cost.
- 2.2. Those involved in the prescribing, distribution or administration of an unlicensed medicine must wherever possible be made aware of its unlicensed status and any known relevant risks associated with its use.
- 2.3. New unlicensed medicines must not be introduced into use without appropriate clinical and pharmaceutical scrutiny e.g. by the North of Tyne Area Prescribing Committee (APC). Their introduction should be subject to the same level of control and processes as that for licensed medicinal products^d, with particular attention being paid to any additional risks associated with their use.
- 2.4. Adequate records to an appropriate level must be kept with regard to the purchase and/or preparation and the supply of unlicensed medicines. These records will include details of the product supplied, batch number, quantity and patient's name for all unlicensed medicines except those placed in a 'low risk' category (see 'Additional Notes' and 'Notes for Pharmacy Staff').
- 2.5. Pharmacy staff issuing unlicensed medicines should ensure that they are labelled clearly in English and that the users have adequate information to use them properly.
- 2.6. Consultants and other clinicians^e must not ask others to prescribe unlicensed medicine without their agreement and must ensure that they are adequately informed about the medicine, how it is used and any risks involved.
- 2.7. Patients in general should be made aware that they may be prescribed an unlicensed medicine. Individual patients (and/or their parents/carers) should be given adequate information about any unlicensed medicines to ensure continuity of supply and appropriate awareness of problems that may be associated with their use. While it is not generally necessary to obtain informed consent to the use of an unlicensed medicine this may be advisable with new unlicensed medicines (as it is in clinical trials) and with those that carry a significant risk of causing serious adverse reactions, or have previously been withdrawn from the market because of serious toxicity problems.
- 2.8. To minimise the risks to other patients, problems with the use of an unlicensed medicine (e.g. product defects, problems with labelling/instructions) must be reported promptly to the hospital pharmacy. Adverse drug reactions should be

^c Examples of "special needs" include an intolerance or allergy to a particular ingredient, an inability to ingest solid oral dosage forms, or no sufficiently effective licensed medicine being available.

^d Utilising current Drug and Therapeutics Committee and Corporate Governance arrangements

^e Unlicensed medicines can legally be prescribed by doctors, dentists and non-medical supplementary prescribers, but cannot be prescribed by non-medical independent prescribers.

reported to the MHRA^f using the yellow card scheme with a copy of the report being sent to the hospital pharmacy.

3. Notes for Prescribers

3.1. Indications for use

Unlicensed medicines should only be used where their use is clearly justified and their clinical/pharmaceutical benefits are considered to outweigh the risks involved.

3.2. Introduction of New Unlicensed Products

The introduction of new unlicensed medicines into hospital practice is subject to the same process as for licensed medicines.

3.3. General Responsibilities

Whenever an unlicensed medicine is prescribed, the prescriber is professionally accountable for his judgement in so doing, and may be called upon to justify his actions. A pharmacist who manufactures or prepares an unlicensed medicine in response to a prescription is professionally accountable for any harm caused by a defect in the medicine which is attributable to his own actions or omissions.

Other hospital staff involved in the treatment of a patient with an unlicensed medicine should, where appropriate, be:

- made aware of its unlicensed status.
- informed of any problems/risks involved and how to deal with them.
- be given sufficient information to administer/use the product safely and correctly.

3.4. Information to patients (including parents, carers etc. where appropriate).

Patients have the right to participate in the making of properly informed decisions on their health care. In normal 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. However, because of the greater risks and potential problems associated with the use of unlicensed medicines:

- Individual patients should be given adequate information about any unlicensed medicines to ensure continuity of supply and appropriate awareness of problems that may be associated with their use.
- Clinicians should consider obtaining informed consent to the use of an unlicensed medicine where this involves a new or experimental treatment (as in clinical trials) and with unlicensed medicines that carry a significant risk of causing serious adverse reactions (including those that have previously been withdrawn from the market because of serious toxicity problems). Inadequate provision of information may increase the clinician's or trust's liability in the event of a mishap that results in a complaint and possible litigation.

Patient information leaflets explaining why it may be necessary to prescribe unlicensed medicines or to use licensed medicines for unlicensed applications are available for use.

^f Using a Yellow Card form or an electronic Yellow Card (found at <http://www.yellowcard.gov.uk>), stating the manufacturer and indicating that the product is unlicensed.

3.5. Referral to General Practitioners

General Practitioners must not be asked to prescribe any unlicensed medicines containing drugs that are not licensed for any indication in the U.K. (unless they are included in the BNF, BNF for Children or North of The Formulary^g). They may however be asked to prescribe other unlicensed products e.g. unlicensed oral liquid preparations in patients where licensed tablets cannot be given, or unlicensed preservative free eye drops, but this should only be with the agreement of the GP.

If a GP agrees to prescribe an unlicensed medicine he/she must be given sufficient information about the product and its availability.

3.6. Adverse Reaction Reporting

All significant adverse reactions to an unlicensed medicine should be reported to the MHRA (preferably via the hospital pharmacy) as with black triangle (◻) drugs^h.

4. Notes for Nursing staff

Nursing staff should:

- Be aware of the unlicensed status of any medicines they are using.
- Notify pharmacy staff and/or the doctor looking after the patient, as appropriate :
 - If the labelling/any instructions supplied with the medicines are unclear.
 - They are unsure about any aspects involved in the use/administration of the medicine, its quality, likely side effects or patient monitoring required.
 - The patient experiences any serious or unexpected adverse reactions.

5. Notes for Pharmacy staff

5.1 General

A senior pharmacist should be designated as having overall responsibility for controlling the procurement and supply of unlicensed medicines in each of the main hospital unitsⁱ (although many pharmacy staff will be involved in the process and have responsibilities for specific aspects).

5.2 New Requests

Pharmacy staff should ensure, as far as is practicable, that before a new unlicensed medicine is introduced into use:

- a. There is no suitable licensed alternative.
- b. There is no equivalent or better unlicensed alternative already available within the Trust.
- c. That the use is approved by the chair of the Trust's Drug and Therapeutics Panel or the North Tyne Area Prescribing Committee, as appropriate.
- d. The prescriber is aware that a medicine he/she has requested is only available as an unlicensed product.

A nominated pharmacist must be involved in assessing the evidence for the product in the APC evaluation process. This pharmacist will confirm which junior

^g Unlicensed medicines included in the North of Tyne Formulary are marked with the suffix ^u and have been approved by the APC. Those unsuitable for prescribing by GPs are marked as 'RED' or hospital only drugs.

^h Using a Yellow Card form or an electronic Yellow Card (found at <http://www.yellowcard.gov.uk>), stating the manufacturer and indicating that the product is unlicensed.

ⁱ This will be the Director of the Pharmacy Services, Mr N. Watson.

medical staff, if any, should be permitted to prescribe the product if this is not clear when a request is submitted for discussion by the APC and its Formulary Subcommittee.

5.3 Records

Pharmacy staff must keep purchasing and general issue records of all unlicensed medicines for a period of at least 5 years (2,3). Patient specific records will however only be maintained for unlicensed medicines that come into a 'high risk' category i.e.

- Products containing drugs that have never been licensed in the U.K.
- Products containing drugs that have been withdrawn because of safety concerns.
- Products that are obtained through a specialist import company (e.g. IDIS) or through sources other than a U.K. Specials manufacturer, or an NHS pharmacy manufacturing unit, unless specifically assigned to a low risk category by the Trust's Drug and Therapeutics Panel.

Pharmacists should also participate in the notification of the licensing authority of any suspected adverse reaction.

5.4 Monitoring

Pharmacy staff should:

- Monitor the usage of unlicensed medicines, confirming that continuing use remains as originally agreed. The more unlicensed medicines are used, the greater the risk that control of their use will be reduced.
- Notify clinicians of licensed alternative products becoming available where appropriate.
- Notify appropriate clinicians of any serious problems that they are alerted to with individual unlicensed medicines.
- Report any defects in unlicensed products to the regional quality assurance pharmacist.

5.5 Quality Assurance

During the procurement/supply process pharmacy staff should ensure that:

- The manufacturer holds the appropriate licence.
- As far as practicable the product:
 - Complies with an agreed/adopted specification.
 - Is manufactured in an appropriate environment.
 - Has a validated shelf life.
 - Is quarantined on receipt until it has been formally checked and cleared for use by a pharmacy quality assurance officer or a nominated deputy.
 - Is labelled in English and where appropriate supplied with information in English to allow its use in a safe manner (arranging for over-labelling and for translations to be prepared/obtained if necessary).
 - Any 'high risk' item issued for inpatient use is labelled to indicate that it is unlicensed and is only authorised for use by a named doctor (or group of doctors) in the treatment of a named patient or specified group of patients.

6. Additional Notes

Within the Newcastle Hospitals unlicensed medicines have been categorised into two main groups, to avoid the need for a lot of unnecessary work and record keeping:

Higher Risk Group

These products will be labelled as unlicensed when issued to wards for inpatient use and full records of issues, including patient names, will be retained in the hospital pharmacies for at least 5 years. This group comprises of the following categories:

- Products that are imported e.g. through companies such as IDIS and Durbin (unless specifically classified as low risk by the Trust's Drug and Therapeutics Panel).
- Products that are supplied by manufacturers on an individual patient basis, e.g. prior to a product licence being granted.
- Products containing drug substances that have never been marketed in the UK.
- Products where there are concerns with regard to their pharmacological or pharmaceutical safety.

Lower Risk Group

These products will not be specifically labelled as unlicensed and full details of patients to whom they are given will not be recorded in the pharmacy. However, as with licensed medicines, pharmacy computer records of issues, batch numbers stocked will be kept for at least 5 years and copies of prescriptions etc. will be kept for a period of at least 2 years in order to provide an audit trail should a need to refer to past issues be necessary.

This group of products consists of a range of products that meet all of the following criteria:

- a) Have a good clinical safety record - these generally contain active drugs that have been marketed in the UK and/or are included in the current or previous editions of the British National Formulary, excluding agents that have been withdrawn from the market because of safety concerns.
- b) Are manufactured in NHS hospitals or other premises licensed by the MCA as Specials Manufacturers.
or
Products labelled in English that are licensed for use in other mutually recognised countries in the EU^j, USA, Canada, Australia, New Zealand, Japan or Switzerland and that have been specifically classified as Low Risk by the Trust's Drug and Therapeutics Panel.
- c) Are considered to be of a suitable pharmaceutical quality.

In most cases these products will not be specifically labelled as being unlicensed, but an indication of their unlicensed status is given in the North of Tyne Formulary and on a list accessible via the Newcastle Hospitals NHS Trust's Intranet pages.

^j France, Germany, The Netherlands, Belgium, Greece, Ireland, Luxemburg, Sweden, Spain, Portugal, Denmark, Austria, Finland, Italy

THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
IMPACT ASSESSMENT – SCREENING FORM A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy Title:	Unlicensed Medicines – Policy Document	Policy Author:	Ian Campbell
		Yes/No?	You must provide evidence to support your response:
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:	No	This policy does not discriminate against any group or individual on the basis of race, ethnicity, nationality, gender, culture religion or belief, sexual orientation, age or disability.
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems.	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4(a).	Is the impact of the policy/guidance likely to be negative? <i>(If “yes”, please answer sections 4(b) to 4(d)).</i>	No	
4(b).	If so can the impact be avoided?	N/A	
4(c).	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
4(d)	Can we reduce the impact by taking different action?	N/A	

Comments:	Action Plan due (or Not Applicable):

Name and Designation of Person responsible for completion of this form: Ian Campbell, Asst. Director Medicine Management
 Date: 08/04/2010

Names & Designations of those involved in the impact assessment screening process: Ian Campbell, Asst. Director Medicine Management
 Neil Watson Director of Pharmacy

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)

For advice on answering the above questions please contact Helen Lamont, Director of Nursing, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) steven.stoker@nuth.nhs.uk together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation, with relevant stakeholders, to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker within six weeks of the completion of this form.