Cheshire and Wirral Partnership NHS
NHS Foundation Trust

Document level: Trustwide (TW)
Code: MP9
Issue number: 3

Policy for the initiation and maintenance of prescribing medicines for "off-label" indications (licensed medicines for unlicensed indications)

Lead executive	Medical Director
Author and contact number	Chief Pharmacist – 01244 397 379

Type of document	Policy
Target audience	All clinical staff
Document purpose	Defines off-label medicines. Outlines the responsibilities of the prescriber initiating treatment and for continued treatment in primary care. Includes signposting to leaflets for patients and carers.

Document consultation	Trust staff via Clinical Directors, Medical Directors, General Managers, Director & Deputy Director of Nursing, Clinical Governance Lead and PCTs via Medicines Management Group	
Approving meeting	Medicines Management Group	10-Feb-11
Ratification	Document Quality Group (DQG)	8-Jun-11
Original issue date	Aug-6	
Implementation date	Jun-11	
Review date	Jun-16	

CWP documents to be read in conjunction with	HR6 MP1 MP18	Trust-wide learning and development requirements including the training needs analysis (TNA) Medicines policy High Dose Antipsychotic Therapy (HDAT) guidelines Patient advice leaflets on the CWP intranet / choice and medication website

Training requirements	There **are no** specific training requirements for this document.

Financial resource implications	No

Equality Impact Assessment (EIA)

Initial assessment	Yes/No	Comments
Does this document affect one group less or more favourably than another on the basis of:		
• 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 disabilities, physical disability, sensory impairment and mental health problems	No	

Is there any evidence that some groups are affected differently?	No	
If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable? N/A		
Is the impact of the document likely to be negative? • If so can the impact be avoided? • What alternatives are there to achieving the document without the impact? • Can we reduce the impact by taking different action?	No N/A N/A N/A	
Where an adverse or negative impact on equality group(s) has been identified during the initial screening process a full EIA assessment should be conducted.		

If you have identified a potential discriminatory impact of this procedural document, please refer it to the human resource department together with any suggestions as to the action required to avoid / reduce this impact.

For advice in respect of answering the above questions, please contact the human resource department.

Was a full impact assessment required?	No	
What is the level of impact?	Low	

Monitoring compliance with the processes outlined within this document

Is this document linked to the NHS litigation authority (NHSLA) risk management standards assessment?	No NB - The standards in bold above are those standards which are assessed at the level 2 and 3 NHSLA accreditation.

Who is responsible for undertaking the monitoring?	The Trust Medicines Management Group
How are they going to monitor the document?	Monitored as part of the annual medicines management audit cycle.
What are they going to monitor within the document?	The adherence to the standards outlined in section 3 for the prescribing of off-label medicines.
Where will the results be reviewed?	Annual audit report on medicines management from the clinical audit team.
When will this be monitored and how often?	As part of the audit cycle as stated above and as a minimum every two years
If deficiencies are identified how will these be dealt with?	Via the medicines management action plan from the annual audit which is overseen by the MMG. This action plan is disseminated to clinical directors to action within their service units and give assurance to the MMG that actions have been implemented.
Who and where will the findings be communicated to?	Via the medicines management action plan from the annual audit which is overseen by the MMG. This action plan is disseminated to clinical directors to action within their service units and give assurance to the MMG that actions have been implemented.
How does learning occur?	Via each clinical service unit
How are the board of directors assured?	Annual medicines management report to the Board of directors summarises all issues from that financial year.

Document change history

Changes made with rationale and impact on practice
1. Added 'Off-label medicines should not be used if there is a suitable alternative licensed product is available.' 2. Deleted 'Appendix2' Leaflet - Added' Trust leaflet on Intranet' 3. Deleted 'In the case of antipsychotics the Royal College of Psychiatrists guidelines on

prescribing' Added 'the MP18 High Dose Antipsychotic Therapy (HDAT) Guidelines'
4. Removed 'UKPPG leaflets on medicines (on Trust Internet/ Intranet).' Added 'Leaflet from the choiceandmedication website (link on the pharmacy and medicines page of the Trust intranet site)'
5. Remove appendix 1 Royal College of Psychiatrist Guidelines
6. Remove leaflet (to be saved on intranet with Trust leaflets)
7. Changed from Guidelines to Policy in title
8. Updated links to GMC and RCPCH
9. Deleted See unlicensed medicines policy

External references

References

1. Nunn, T (2002) Using unlicensed and ''off-label'' medicines; Pharmacy Management; Vol. 18, p.64-67.
2. Miller, H. E. J; Simpson, N; Foster, S. E. (1997) Psychotropic medication in learning disabilities: audit as an alternative to legislation; Psychiatric Bulletin; Vol. 21; p.286-289.
3. A position statement prepared on behalf of the Association for Palliative Medicine and The Pain Society (2001) The use of Drugs beyond licence in Palliative Care and Pain Management.
4. RCPCH Unlicensed Medicines Statement (Revised November 2010) http://www.rcpch.ac.uk/Research/Research-Activity/Medicines-projects
5. GMC Good practice in prescribing medicines (Nov 2010) - guidance for doctors http://www.gmc-uk.org/guidance/ethical_guidance/prescriptions_faqs.asp

Content

1. Introduction

The Medicines and Healthcare Products Regulatory Agency (MHRA) grant marketing authorisations (previously 'product licences') for medicines in the UK. Medicines must meet standards of safety, quality and efficacy before they are granted this authorisation. The authorisation covers all the main activities associated with the marketing of a medicinal product.

The authorisation does not restrict the prescription of the medicine by properly qualified medical practitioners. Licensed medicines can be used legally in clinical situations which fall outside of the remit of the licence: for example a different age groups, dose, indication, route or method of administration. Manufacturers may not have sought to extend the licence for commercial reasons where costs are likely to exceed the financial return. It is possible for the same medicine from different sources to have different indications depending on the decision of the manufacturer.

The use of medicines ''off-label'' should be seen as a legitimate aspect of clinical practice. The use of medicines ''off-label'' is often necessary and is common in many areas of medicine, for example palliative care, paediatrics and psychiatry. Off-label medicines should not be used if there is a suitable alternative licensed product is available.

Recommendations from bodies such as the General Medical Council and the Medical Defence Organisations place a duty on doctors to act responsibly and to provide information to patients on the nature and associated risk of any treatment, including ''off-label'' and unlicensed medicines.

The choice of treatment requires partnership between patients and healthcare professionals and informed consent should be obtained wherever possible before prescribing any medicines. Patients should be informed of identifiable risks and details of information given should be recorded. Usually no additional steps to obtain consent are required beyond those for licensed medicines.

2. Definition of 'off-label' medicines

The Summary of Product Characteristics (SPC) lists:

- Indications;
- Dose ranges;
- Methods of administration;
- Age restrictions.

As granted by the marketing authorisation for each medicine licensed for use within the UK.

Any use not in accordance with the SPC is considered 'off-label', or an unlicensed use.

2.1 Definition of unlicensed medicines

A medicine that has not been granted a marketing authorisation (product license) for use within the UK.

3. Clinical standards for prescribing 'off-label' medicines

In addition to usual clinical standards for prescribing medicines points 1-3 should be recorded in the patients' case notes:

1. Where appropriate a generic leaflet about off label use will be provided in addition to clinical information and to complement verbal explanation (see CWP website);
2. The indication for the prescription and the treatment plan should be recorded;
3. The treatment should be reviewed at least every 12 months;
4. Where a consultant recommends to a GP the prescription of a medicine for an 'off-label' indication, based on the consultant's assessment of the individual, the consultant should explain the rationale for such a treatment recommendation in the GP letter. If the GP is unhappy to initiate such a treatment then a dialogue needs to take place between the consultant and GP to decide on the most appropriate treatment options.

3.1 Patient information on "off-label" indications

By law patient information leaflets (PILs) must be supplied to the patient with their dispensed medication. The leaflets will contain information relating to the UK licensed indications of the product.

The consultant initiating treatment for an "off-label " indication should make the patient aware of this and document that additional verbal / written information has / will be provided to the patient on such a use of the medicine.

Pharmacy / nursing staff should document in the case notes that counselling / provision of additional information has been provided on this medicine when it has been carried out.

Not providing such additional information and raising awareness of this with the patient may lead to poor concordance with medication regimens. Patients should be counselled on the difference between their regimen and the information leaflet, where possible additional written information should be given on the use of the medicine for the 'off-label' indication. Leaflets from the choice and medication website (http://www.choiceandmedication.org.uk/cheshire-and-wirral/) may be helpful.

4. Duties and responsibilities

4.1 Cheshire and Wirral Partnership NHS Foundation Trust (CWP)

CWP will support the use of medicines 'off-label' provided:

- The use is in accordance with a responsible body of professional opinion in the appropriate specialty;
- The use is in accordance with evidence based practice where available;
- The use is necessary for the specific clinical need of the individual patient.

4.2 Prescribers

Involved in prescribing, dispensing and administering medicines 'off-label' should:

- Select the medicine which offers the best balance of benefit against harm for any particular patient;
- Inform, change and monitor their practice with regard to medicines used 'off-label' in the light of evidence from audit and published research and local policy guidelines;
- Be aware that clinical responsibility for prescribing lies with the prescriber who signs the prescription;
- Have access to information on any product, to enable informed discussion with the patient;
- Remember that prescribing above the current British National Formulary (BNF) dose is also off label prescribing. In the case of antipsychotics prescribed above the BNF maximum the High Dose Antipsychotic Therapy (HDAT) Guidelines should be adhered to and the treatment plan documented.

4.3 Community Mental Health Teams and Clinical Pharmacy Team

Staff caring for patients receiving off-label medicines should:

- Have access to information on any product, to enable informed discussion with the patient;
- Record any additional information to that given by the prescriber.