Medicines Management Policy

A Guide to the Safe and Secure Handling of Medicines

October 2011

<table>
<thead>
<tr>
<th>Responsible Director:</th>
<th>Director of Clinical and Operational Services</th>
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<tr>
<td>Committee:</td>
<td>Locala Medicines Management Committee</td>
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</tbody>
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NICE GUIDANCE

Once NICE guidance is published, health professionals are expected to take it fully into account when exercising their clinical judgment. However, NICE guidance does not override the individual responsibility of health professionals to make appropriate decisions according to the circumstances of the individual patient in consultation with the patient and/or their guardian or carer.
Version Control

Current versions of all policies can be found on the NHS Kirklees website under the Locala section. If printing a document, please check the internet for most up-to-date version.

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<thead>
<tr>
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<td>Restrictions:</td>
<td>This document is provided for use by Locala staff. Other healthcare professionals providing healthcare services within Locala geographical area may use this document as a source of guidance and reference to local practice and procedures.</td>
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</table>

Essential Standards of Quality and Safety, March 2010

<table>
<thead>
<tr>
<th>Section</th>
<th>Safeguarding and safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome 9</td>
<td>Management of medicines</td>
</tr>
<tr>
<td>Prompts for providers</td>
<td>1. Providing personalised care through the effective use of medicines 2. Manage risk through effective procedures about medicines handling 3. Promote rights and choices</td>
</tr>
</tbody>
</table>

Nurses working on the ward at Holme Valley Memorial Hospital (HVMH) should follow the basic principles in this policy, but for details of procedures to follow in the hospital, they should refer to The Holme Valley Memorial Hospital Medicines Code. This is available at: [http://www.kirklees.nhs.uk/your-health/medicines-management/locala-policiesguidelines/](http://www.kirklees.nhs.uk/your-health/medicines-management/locala-policiesguidelines/)
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>1</td>
</tr>
<tr>
<td>2. Associated Polices and Procedures</td>
<td>1</td>
</tr>
<tr>
<td>3. Aims and Objectives</td>
<td>1</td>
</tr>
<tr>
<td>4. Scope of the Policy</td>
<td>1</td>
</tr>
<tr>
<td>5. Accountabilities and Responsibilities</td>
<td>2</td>
</tr>
<tr>
<td>6. General Principles</td>
<td>2</td>
</tr>
<tr>
<td>7. PRESCRIBING</td>
<td>3</td>
</tr>
<tr>
<td>7.1 Doctors Information</td>
<td>3</td>
</tr>
<tr>
<td>7.2 Dental Practitioners Information</td>
<td>4</td>
</tr>
<tr>
<td>7.3 Independent Prescribing</td>
<td>4</td>
</tr>
<tr>
<td>7.4 Non-Medical Prescribing</td>
<td>4</td>
</tr>
<tr>
<td>7.5 Non-Medical Supplementary Prescribing</td>
<td>6</td>
</tr>
<tr>
<td>7.6 Prescribing for Self, Family and Friends</td>
<td>6</td>
</tr>
<tr>
<td>7.7 Shared Care and Shared Care Guidelines (Amber Drugs)</td>
<td>6</td>
</tr>
<tr>
<td>7.8 Communication</td>
<td>6</td>
</tr>
<tr>
<td>7.9 Prescription Forms</td>
<td>6</td>
</tr>
<tr>
<td>7.10 Handling and Security of Prescription Forms</td>
<td>7</td>
</tr>
<tr>
<td>7.11 Prescription Requirements</td>
<td>8</td>
</tr>
<tr>
<td>7.12 Documentation – Recording the Prescription</td>
<td>9</td>
</tr>
<tr>
<td>8. ADMINISTRATION OF MEDICINES</td>
<td>9</td>
</tr>
<tr>
<td>8.1 General Principles</td>
<td>10</td>
</tr>
<tr>
<td>8.2 Patient Group Directions</td>
<td>10</td>
</tr>
<tr>
<td>8.3 Patient Specific Directions</td>
<td>11</td>
</tr>
<tr>
<td>8.4 Administration of Medicines by Non-Medical Staff</td>
<td>11</td>
</tr>
<tr>
<td>8.5 Administration of Medicines by Practitioners in Training</td>
<td>12</td>
</tr>
<tr>
<td>8.6 Administration of Vaccines in a Community Setting</td>
<td>12</td>
</tr>
<tr>
<td>8.7 Non-Written Instructions to Administer Medicines (Verbal Orders)</td>
<td>12</td>
</tr>
<tr>
<td>8.8 Administration of Medicines in Schools</td>
<td>13</td>
</tr>
<tr>
<td>8.9 The Unlicensed Administration of Medicines</td>
<td>13</td>
</tr>
<tr>
<td>9. DISPENSING AND SUPPLY OF MEDICINES AND DRESSINGS</td>
<td>13</td>
</tr>
<tr>
<td>9.1 Dispensing</td>
<td>13</td>
</tr>
<tr>
<td>9.2 Dispensing of Medicines by Practitioners</td>
<td>14</td>
</tr>
<tr>
<td>9.3 Supply of Medicines</td>
<td>14</td>
</tr>
<tr>
<td>10. PROCUREMENT, TRANSPORT AND STORAGE OF MEDICINES</td>
<td>15</td>
</tr>
<tr>
<td>10.1 Procurement</td>
<td>15</td>
</tr>
<tr>
<td>10.2 Ordering of Medicines for Locala Service Centres</td>
<td>15</td>
</tr>
<tr>
<td>10.3 Transport and Receipt of Medicines</td>
<td>15</td>
</tr>
<tr>
<td>10.4 Storage of Medicines</td>
<td>16</td>
</tr>
<tr>
<td>10.5 Storage of Medicines in Community Clinics and Team Bases</td>
<td>16</td>
</tr>
<tr>
<td>10.6 Keys for Medicine Cupboards and Refrigerators</td>
<td>17</td>
</tr>
<tr>
<td>10.7 Medicines in Patient’s Homes</td>
<td>18</td>
</tr>
<tr>
<td>10.8 Medicines in Healthcare Professionals Bags</td>
<td>18</td>
</tr>
<tr>
<td>10.9 Security of Medicines and Controlled Stationary</td>
<td>19</td>
</tr>
<tr>
<td>11. DISPOSAL OF MEDICINES</td>
<td>19</td>
</tr>
</tbody>
</table>
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.1 Disposal of Patient’s Own Medicines</td>
<td>20</td>
</tr>
<tr>
<td>11.2 Disposal of Medicines by Locala Service Centres</td>
<td>20</td>
</tr>
<tr>
<td>11.3 Disposal of Medicines by Community Pharmacies</td>
<td>21</td>
</tr>
<tr>
<td>11.4 Disposal of Medicines by GP Practices</td>
<td>21</td>
</tr>
<tr>
<td>11.5 Diabetic Sharp Bins</td>
<td>21</td>
</tr>
<tr>
<td>12. RISK MANAGEMENT</td>
<td>21</td>
</tr>
<tr>
<td>12.1 Managing Errors and Incidents in the Use of Medicines</td>
<td>21</td>
</tr>
<tr>
<td>12.2 Serious Untoward Incidents</td>
<td>22</td>
</tr>
<tr>
<td>12.3 Adverse Drug Reaction Reporting</td>
<td>22</td>
</tr>
<tr>
<td>12.4 Medicine Defect Reporting</td>
<td>23</td>
</tr>
<tr>
<td>12.5 Incidents Involving Medical Devices</td>
<td>23</td>
</tr>
<tr>
<td>12.6 Healthcare Safety Alerts/Drug &amp; Device Recalls</td>
<td>24</td>
</tr>
<tr>
<td>12.7 COSHH</td>
<td>24</td>
</tr>
<tr>
<td>13. USE OF UNLICENSED MEDICINES</td>
<td>24</td>
</tr>
<tr>
<td>13.1 Unlicensed Medicines</td>
<td>25</td>
</tr>
<tr>
<td>13.2 Alternative and Complementary Medicines</td>
<td>25</td>
</tr>
<tr>
<td>14. LONG TERM CONDITIONS</td>
<td>25</td>
</tr>
<tr>
<td>15. CLINICAL TRIALS IN PRIMARY CARE</td>
<td>25</td>
</tr>
<tr>
<td>16. RELATIONS WITH THE PHARMACEUTICAL INDUSTRY AND COMMERCIAL SPONSORSHIP</td>
<td>26</td>
</tr>
<tr>
<td>17. AVAILABILITY OF MEDICINES OUT OF HOURS</td>
<td>26</td>
</tr>
<tr>
<td>18. CONSENT TO TREATMENT</td>
<td>26</td>
</tr>
<tr>
<td>19. ALCOHOL AND SUBSTANCE MISUSE IN THE WORKPLACE</td>
<td>27</td>
</tr>
<tr>
<td>20. TRAINING AND EDUCATION</td>
<td>28</td>
</tr>
<tr>
<td>20.1 Continuing Professional Development</td>
<td>28</td>
</tr>
<tr>
<td>21. AUDIT AND INSPECTION OF PREMISES</td>
<td>29</td>
</tr>
<tr>
<td>21.1 Introduction to Audit</td>
<td>29</td>
</tr>
<tr>
<td>21.2 Purpose of Audit</td>
<td>29</td>
</tr>
<tr>
<td>21.3 Audit and Medicines Management</td>
<td>29</td>
</tr>
<tr>
<td>21.4 Areas for Audit</td>
<td>30</td>
</tr>
<tr>
<td>21.5 Inspection of Locala Premises</td>
<td>31</td>
</tr>
<tr>
<td>22. Equality Impact Assessment</td>
<td>31</td>
</tr>
<tr>
<td>23. Training Needs Analysis</td>
<td>32</td>
</tr>
<tr>
<td>24. References and Acknowledgements</td>
<td>32</td>
</tr>
</tbody>
</table>

## Appendices

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Definitions</td>
<td>33</td>
</tr>
<tr>
<td>B</td>
<td>Key Stakeholders consulted/involved in the development of the policy/procedure</td>
<td>35</td>
</tr>
<tr>
<td>C</td>
<td>Equality Impact Assessment Tool</td>
<td>36</td>
</tr>
<tr>
<td>D</td>
<td>Terms of Reference and Membership Committee</td>
<td>37</td>
</tr>
<tr>
<td>E</td>
<td>Prescription Form Types</td>
<td>41</td>
</tr>
<tr>
<td>F</td>
<td>Good Practice Guidelines for the Safe and Secure Handling of Prescription Forms for Non-Medical Prescribers</td>
<td>42</td>
</tr>
<tr>
<td>G</td>
<td>Parenteral Administration</td>
<td>43</td>
</tr>
<tr>
<td>H</td>
<td>Prescribing of Unlicensed and Off Label Drugs</td>
<td>44</td>
</tr>
<tr>
<td>I</td>
<td>Unlicensed Methods of Administering Medicines</td>
<td>47</td>
</tr>
<tr>
<td>J</td>
<td>Long Term Conditions Documentation</td>
<td>49</td>
</tr>
</tbody>
</table>
POLICY STATEMENT

Locala Community Partnerships Community Interest Company (Locala) will endeavour to ensure the safe and secure handling of medicines to protect patients, staff and the public in accordance with current legislative requirements and best practice.

1. INTRODUCTION

The Department of Health requires that Healthcare Providers establish appropriate policies, procedures and quality assurance systems to ensure that medicines are prescribed, administered, stored and handled in a safe and secure manner in line with Risk Management Frameworks and Clinical Governance requirements.

Locala is committed to the safe, effective and efficient use of medicines to support the provision of high quality care to patients. The Medicines Management Policy ensures staff and contractors have access to information on the law, best practice and safe systems of working in relation to the management of medicines. This Policy includes guidance on the ordering, storage, prescribing and administration of medicines and is intended for use in conjunction with the current edition of the British National Formulary (BNF) and the references listed.

2. ASSOCIATED POLICIES AND PROCEDURES

This policy should be read in accordance with the following relevant policies, procedures and guidance, some of which include:

- Controlled Drugs (CD) Policy
- Cold Chain Policy
- Non Medical Prescribing Policy
- Patient Group Direction (PGD) Framework
- Consent Policy
- Handling and Administration of Cytotoxic Drugs
- Advanced Preparation of Insulin Syringes for Patients to Administer at Home
- Waste Management Guidelines
- Training, Education and Development Policy
- Health & Safety at work (incorporating COSHH)
- Code of Business Conduct
- Reporting of patient safety and non clinical incidents
- Serious Untoward Incident Procedure
- Policy on Alcohol and Substance Misuse in the Workplace

3. AIMS AND OBJECTIVES

The aim of this document is to provide guidance to all Locala staff who prescribe, administer, control, store or supply medicines as part of their role, on the safe and secure use of medicines and to ensure compliance with best practice and CQC outcomes.

4. SCOPE OF THE POLICY

This policy MUST be followed by all Locala employees who prescribe, administer, control, store or supply medicines as part of their role.

It MUST be followed by all staff working for Locala, including those on temporary or honorary contracts, bank staff and students.

Breaches of this policy may lead to disciplinary action being taken against the individual.
Independent Contractors are responsible for the development and management of their own procedural documents and for ensuring compliance with relevant legislation and best practice guidelines. Independent Contractors are encouraged to seek advice and support as required. It is recommended this policy should be used as guidance to ensure appropriate policies and procedures for the safe and secure handling of medicines within their area of practice are in place.

5. ACCOUNTABILITIES AND RESPONSIBILITIES

The Chief Executive has overall responsibility for the strategic and operational management of Locala, including ensuring that organisational policies comply with all legal, statutory and good practice guidance requirements.

The Director of Clinical and Operational Services has overall accountability for the safe and secure handling of medicines, supported by the Head of Medicines Management and the Medicines Management Committee. See appendix D for terms of reference/membership of the Medicines Management Committee.

All staff employed by Locala who are involved in any way with the use of medicines, must familiarise themselves with the correct procedures contained within this policy. Those in charge of services are responsible for ensuring that staff, in particular, new starters and locums, follows the procedures in this policy. Hard copies of the policy will be available to all staff through service leads and line managers. An electronic version will also be available on the NHS Kirklees website under the Locala section.

The procedures also apply to medical staff, nursing staff and other types of staff from other NHS Trusts or private practices, who are contracted to work for Locala on a sessional basis. Managers who contract for these services must make it explicit within the written contract that these sessional staff MUST follow the procedures described in this policy.

All professionals are required to work within their Professional Code of Practice and terms of service.

6. GENERAL PRINCIPLES

It is important that procedures listed in this policy apply to all medicines used within Locala. These include topical preparations (e.g. lotions), applications, subcutaneous/intravenous infusions, medicated dressings, diagnostic agents, and complementary medicines.

Medicines, whether for internal or external use, will be regarded for the purposes of this policy as comprising of the following categories:

- Controlled Drugs (CDs). These drugs are controlled under the provisions of the Misuse of Drugs Act, with stringent requirements for supply, storage and administration.
- All other medicines and medicinal products prepared for administration to patients that are controlled by the Medicines Act. This also includes many diagnostic agents, X-ray contrast agents and medical gases.
- All complementary medicines e.g. aromatherapy, herbal or homeopathic remedies. These products are used for therapeutic purposes and require the same safeguards as other medicines. Larvae are included in this category.
- Other pharmaceutical preparations including nutritional products.
- Disinfectants, reagents and other preparations not used directly to treat patients.
Some substances designated as Medical Devices under Medical Devices Directive (93/42/EEC) and the associated UK regulations implementing the directive (S1 1994 No 3017) but which are administered to patients as part of a medical or surgical procedure.

7. PREScribing

Prescribers are to follow ‘best practice’ and should choose those preparations which are efficacious, safe, and cost-effective.
National or local treatment guidelines/formularies (where available), which have been approved by Locala Medicines Management Committee or the South West Yorkshire Area Prescribing Committee should be followed.

7.1 Doctor’s Information

A document entitled ‘Good Practice in Prescribing Medicines 2006’ issued by the General Medical Council (GMC) gives comprehensive advice for doctors.
Fully Registered GPs may prescribe any medicine, but NOT those listed in Schedule 1 of the Misuse of Drugs Regulations 2001.

The following should also be noted:

- Blacklisted preparations are not available nationally on NHS prescriptions.
- All private CD prescribers MUST be registered with the NHS BSA by the CD Accountable Officer for Locala to receive a unique prescriber code, and will be required to write CDs on a FP10PCD prescription form.
- Prescribers are asked to be aware of the necessary monitoring and prescribing requirements for items on the RED and AMBER¹ list before considering issuing prescriptions for these items.
- Prescribers are asked to consider the GREY List, a locally-agreed list of medicines that are not recommended for use in normal practice and the BLACK list which contains drugs that commissioning organizations across the SWY APC boundaries have agreed with local hospital trusts that will not be commissioned locally.

Doctors employed or contracted by Locala MUST comply with relevant legislation and this policy. They should also prescribe within their limits of competence and experience. Doctors employed within a specialist service should confine their prescribing to that specialist area.

¹ Medicines classified as RED are prescribed in hospital only, and are maintained and monitored from the hospital. Primary Care prescribers are encouraged not to prescribe these drugs.

Medicines classified as AMBER are covered by shared care guideline agreements, produced following consultation between Secondary and Primary care, and approved by the South West Yorkshire Area Prescribing Committee.
A hospital consultant will initiate prescribing and undertake monitoring until stabilisation of treatment. Once the patient’s condition is stabilised the consultant will contact the GP to request agreement for the transfer of care in line with the approved shared care guideline.

Red, amber and black drugs lists are available from the web-formulary at: http://intranet.cht.nhs.uk/formulary/Web-Formulary_Files/Guidelines/APC/Main_Index.htm
7.2 Dental Practitioner's Information

NHS prescriptions can be issued by registered Dental Surgeons to treat oral and dental conditions ONLY. The prescribable items are listed in the Dental Practitioners Formulary, which can be found in the current edition of the BNF. Dentists are responsible for taking into account the patient's medical and dental condition, allergy status and contraindications or cautions for use of the medicine. They should prescribe within licensed indications wherever possible, and should prescribe within their scope of practice within their role. This also includes the issue of ‘To Take Out’ (TTO) packs and dental products sold to the general public.

Registered Dental Surgeons are independent prescribers and as such can prescribe any medicine on a private prescription, including controlled drugs. Dentists who wish to prescribe schedule 2 and 3 controlled drugs under private arrangements MUST be registered with the NHS BSA by the CD Accountable Officer for Locala to receive a unique prescriber code, and are required to write CDs on a FP10PCD prescription form.

Guidance on professional practice and general dental advice can be obtained from The British Dental Association and the General Dental Council.

Dentists employed or contracted by Locala must comply with relevant legislation/guidance and this policy.

7.3 Independent Prescribers

Independent prescribers take responsibility for the clinical assessment and management of a patient, establishing a diagnosis and prescribing appropriate treatment where necessary. Independent prescribers must only prescribe within their area of competence.

7.4 Non-Medical Prescribers

- Non-medical prescribing is the term used to describe prescribing by health care professionals other than doctors and dentists. Non-medical prescribers must comply with current legislation for prescribing and be accountable for that practice and to their registering professional body.

- Non Medical Prescribers include:
  - Community Nurse Practitioners
  - Nurse Independent Prescribers
  - Pharmacist Independent Prescribers
  - Supplementary Prescribers

- Practice nurse non-medical prescribers may only issue prescriptions for the patients of their practice. Locala employed non-medical prescribers’ usually only issue prescriptions for patients registered with GP practices within the Locala geographical area, unless they have a contract to provide services for a neighbouring organisation.

- From 21st December 2009 legislation changed to allow nurse and pharmacist independent prescribers to prescribe unlicensed medicines for their patients, on the same basis as doctors and dentists (and supplementary prescribers if part of a Clinical Management Plan).

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2 The status of unlicensed medicines must be recorded on the Clinical Management Plan.
Medicines prescribed should be licensed, and licensed for the indication for which they are to be prescribed. Prescribing an unlicensed medicine increases the clinical and legal liabilities on the prescriber. Before prescribing an unlicensed medicine the prescriber must ascertain that a reasonable body of medical opinion would support the use of the product in that way (or expert guidelines support its use), and that there is no suitable licensed alternative.

In all cases of “unlicensed” prescribing within Locala, the prescriber is fully accountable and liable for their actions and must be satisfied that:

- An alternative licensed treatment would not meet the patient’s needs.
- The prescribed drug and indication is within their area of competence.
- There is satisfactory evidence or experience of safety in prescribing the medication in the circumstances faced.
- The patient or carer understands that they are being prescribed an unlicensed medication, understands the implications of this, and gives consent.

Legal responsibility for any prescription lies with the person who signs the prescription. It is the responsibility of prescribers to be aware of the license status of products they prescribe.

Patients MUST be informed of the license status and their consent gained. This discussion must be documented in the patient’s record.

Nurse or pharmacist independent prescribers are able to prescribe products outside the terms of the manufacturer’s product licence (‘off-label’), but they must take full clinical and professional responsibility for their prescribing and should only prescribe in this manner when a reasonable body of medical opinion or expert guidelines support its use (refer to section 9 for further details).

**Important Note:**
In the case of both unlicensed and “off label” prescribing it is the personal responsibility of each prescriber to ensure they have a suitable level of indemnity protection for their prescribing practice.

- Community Practitioner Nurse Prescribers may only prescribe the dressings, appliances, and licensed medicines listed in the Nurse Prescribers’ Formulary for Community Practitioners.
- Community Practitioner Nurse Prescribers must not prescribe unlicensed or ‘off-label’ products with the exception of nystatin for neonates with a clear diagnosis of oral thrush at the dose recommended in the current BNF for Children. This exception is allowed on the basis that there is no systemic absorption of the product and the use of the product in treatment of oral thrush is long established. This should only be prescribed within the prescriber’s own competence and that they accept clinical and medico-legal responsibility for prescribing that medicine.
- Supplementary Prescribers may prescribe unlicensed medicines if the supervising doctor agrees and this has been documented within a Clinical Management Plan (CMP).
- Non-medical prescribers must not issue prescriptions on behalf of a health professional who is not a qualified prescriber.
Refer to Locala Non-Medical Prescribing Policy for further guidance. This can be accessed from the NHS Kirklees website under the Locala section.

7.5 Non-Medical Supplementary Prescribers

Non-medical supplementary prescribers take responsibility for implementing an agreed patient-specific Clinical Management Plan (CMP) which has been agreed between the patient, the independent prescriber (doctor or dentist), and the supplementary prescriber. The Supplementary prescriber must be a registered Nurse, Pharmacist or other Health care Professional as defined in Section 63 of the Health and Social Care Act 2001.

There are no legal restrictions on the clinical conditions that may be treated under supplementary prescribing, but it is generally expected to be used for the management of chronic medical conditions and health needs. Supplementary prescribers are able to prescribe all medicines that are prescribable by a doctor or dentist at NHS expense, provided they are referred to in the patient's Clinical Management Plan. This includes unlicensed drugs, use of off label indications and unlicensed drugs used in clinical trials. Controlled drugs can also be prescribed.

All prescribing MUST be within the Supplementary Prescribers area of expertise and competence.

Further information can be obtained from the Department of Health website at: http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/TheNon-MedicalPrescribingProgramme/index.htm

7.6 Prescribing for Self, Family and Friends

Prescribers are reminded that the General Medical Council, Nursing and Midwifery Council, and Royal Pharmaceutical Society of Great Britain, recommend that prescribers must not prescribe for themselves, members of their family, friends, or members of staff directly employed or working in the practice, unless the member of staff is a registered patient with the practice. If this situation arises it is good practice to refer the person to another prescriber or their own GP.

7.7 Shared Care/Shared Care Guidelines (Amber Drugs)

Prescribers are encouraged to only prescribe medicines classified as suitable for shared care (‘amber’ drugs) when the request is accompanied by a shared care guideline which has been approved by the South West Yorkshire Area Prescribing Committee. The most recent shared care classification list (the amber drugs list), together with copies of approved Shared Care Guidelines, are available from the web-formulary at: http://intranet.cht.nhs.uk/formulary/Web-Formulary_Files/Guidelines/APC/Main_Index.htm

7.8 Communication

Communication plays a key role in Medicines Management.

Guidance published by the BMA ‘Improving Communication, the Exchange of Information and Patient Care’, (which can be found at: http://www.bma.org.uk/ap.nsf/AttachmentsByTitle/PDFimprovecommunication/$FILE/Improvingcommunication1007.pdf), offers a number of suggestions to improve two-way communication between primary and secondary care practitioners. This guidance should be adopted as ‘best practice’ guidance as endorsed by Locala Medicines Management Committee and the South West Yorkshire Area Prescribing Committee.

7.9 Prescription Forms
A list of the types of current prescription forms can be found in Appendix E.

GP prescribers must prescribe drugs and substances prescribable under NHS Pharmaceutical Services for National Health Service patients using the standard FP10 form (green).

For prescribing drugs listed in Schedule 2 of the Misuse of Drugs Regulations and buprenorphine by instalment prescribing, prescribers should use form FP10MDA (blue).

Dentists must prescribe for NHS patients using FP10D (yellow).

District Nurse, Health Visitor and School Nurse Prescribers may only prescribe items from the Community Nurse Prescribers’ section of the BNF using the form FP10P (lilac) annotated ‘Community Practitioner Nurse Prescriber’.

Nurses or Pharmacists who have qualified as Independent/Supplementary Prescribers may prescribe from the BNF using the FP10P prescription form, which will be annotated with ‘Nurse Independent/Supplementary Prescriber’ or ‘Pharmacist Independent/Supplementary Prescriber’.

Practice nurses who work in more than one practice must have a separate prescription pad for each practice, with the correct practice information in the identification details area of the prescription form.

Loca employed non-medical prescribers who work across different practices can use one pad, but must complete the correct and relevant practice number for the patient on each prescription form. If a Loca employed non-medical prescriber works for more than one organisation, a separate pad would be required for each organisation. If a Loca employed non-medical prescriber also works as a practice nurse, they will require a separate prescription pad for the GP practice and for Loca.

Prescription pads are supplied on an individual basis to each prescriber with each form being individually numbered and identifiable.

It is recommended that independent prescribers should not use another prescriber’s pad. Non-medical prescribers MUST not use another prescriber’s pad.

Pads must be stored safely, e.g. in a locked drawer or cupboard.

7.10 Handling and Security of Prescription Forms

Prescription pads are controlled stationery and MUST be obtained, stored securely, and issued ONLY to the individual prescriber named on it.

All prescription forms MUST be handled securely and local policies should be established to ensure they cannot be misused or misappropriated.

It is advisable to only hold minimal stocks of prescription pads.

Individual prescribers must keep a record of the serial numbers of prescription pads received and issued. The first and last serial numbers of each pad must be recorded. It is also good practice to record the first and last serial number of an in-use pad at the end of the working day. Such steps will identify any prescriptions that are lost or stolen overnight.

Blank prescription forms must never be pre-signed.

It is the responsibility of each prescriber to ensure the security of his/her prescription pads at all times. When on duty, the prescriptions must remain in the possession of the prescriber at all times.
In the event of loss or suspected theft of prescriptions/pads medical prescribers must contact West Yorkshire Central Services Agency (WYCSA) on 01484 464000 and the police on 0845 606 0606. Community nurse prescribers must report immediately to the relevant Service Manager, who will inform WYCSA and the police (as above). Other Non-Medical prescribers must report immediately to their line manager, who will inform WYCSA and the police. Further information can be found in the Locala Non-Medical Prescribing policy.

A written report must be made by Locala staff using the incident reporting form (see section 12).

In the event of a non medical prescriber leaving employment, or who has been suspended from prescribing duties, it is the responsibility of the employer/line manager to:

- Ensure that no further prescription pads are ordered for the non-medical prescriber;
- Recover all unused prescription forms issued to that practitioner relating to that employment. (For Locala employed staff, all unused FP10s must be returned to the Service Manager’s PA or appropriate Locala Service secretary for recording and secure destruction. For practice employed staff unused prescription forms must be returned to the Practice Manager or Prescribing Lead GP).
- Notify the Locala Non-Medical Prescribing Lead or the Community Services Pharmacy Manager, so that the NHS Business Services Authority (BSA) can be informed and the non-medical prescriber can be removed from the Locala database of active non-medical prescribers.

Practice/Salaried GPs must inform WYCSA on 0113 2952515 when leaving their employment. All other medical prescribers must notify the Locala Non-Medical Prescribing Lead or the Community Services Pharmacy Manager on 01924 351525

Guidelines for Good Practice in the Safe and Secure Handling of Prescription Forms for Non Medical Prescribers are detailed in Appendix F.

7.11 Prescription Requirements

Prescriptions must be in indelible ink (this includes typewritten and computer-generated) and once completed, must be signed in indelible ink by the practitioner giving the prescription.

The prescription must include:

- The name and contact number of the prescriber responsible for giving the prescription
- Identifiable prescriber code as appropriate.
- The Healthcare Organisations unique code.
- Date of issue.
- For dentists, GPs, & practice-employed non-medical prescribers include the name, address, and telephone number of the practice.
- In the case of Locala employed staff, include the address and telephone number of the individual prescriber’s base.
- Where applicable, for example prescriptions written by community nurses, insert the practice code for the practice at which the patient is registered.
- Such particulars as to indicate whether the practitioner is a doctor, dentist, or other type of prescriber.
- Full name of the patient, their address, and date of birth.
- Generic name of the medicine should be used except in the case of dressings, ostomy appliances or combinations of drugs where there is no generic name or where use of a generic name would result in confusion as to which product was required. Some preparations should be prescribed by brand where bioavailability differences would cause a problem e.g. lithium.
Further advice on this can be obtained from the Medicines Management Team on 01924 351525

- The full name of a drug and preparation must always be used. Unofficial abbreviations must NOT be used as they may be misinterpreted, and could result in patient misadventure.

- A clearly stated dose. Prescribers should specify the dose by using mg, micrograms, or nanograms. (Micrograms and nanograms should be written in full).

- The unnecessary use of decimal points should be avoided wherever possible, e.g. 3mg, NOT 3.0mg. Quantities of 1g or more should be written as 1g etc. Quantities less than 1g should be written in milligrams, e.g. 500mg NOT 0.5g Quantities less than 1mg should be written in micrograms, e.g. 100 micrograms, NOT 0.1mg. When decimals are unavoidable a zero should be written in front of the decimal point where there is no other figure, e.g. 0.5ml, NOT .5ml

- The quantity to be supplied.3

- Frequency of administration and route should be clearly stated. ‘As directed’, ‘as required’ or other non specific dosage instructions should not be used as standalone instructions.

- For topical preparations, the precise area to be covered should be specified e.g. face.

- Prescriptions for controlled drugs listed in schedule 2 or 3 of the Misuse of Drugs Regulations 2001 must be written in accordance with those regulations (refer to Locala Controlled Drugs policy).

Refer to ‘Prescription writing’ section in BNF for further information; Prescription writing: British National Formulary

7.12 Documentation: Recording the Prescription

- A record of any prescription written must be made in the patient’s clinical record as soon as possible and at least within 48 hours.

- The record must include the date, the name of the prescriber, the name of the item and quantity prescribed, the dose, indication, frequency, treatment duration and any other relevant details. The indication should be linked to a diagnosis, although in some circumstances it may be necessary to prescribe medicines whilst awaiting test results. In this situation medicines should not be continued indefinitely without a firm diagnosis.

- All current medication records should be available to a prescriber during consultation. This may be impractical in domiciliary settings. However where possible the prescriber should familiarise themselves with the patients medical record prior to making a domiciliary visit.

8. ADMINISTRATION OF MEDICINES

Prescription only medicines (POMs) may ONLY be supplied or administered under the:

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3The quantity supplied should be appropriate to the medical needs of each patient. For ongoing medical conditions where repeat prescriptions are issued, it is recommended that only one months supply is prescribed at a time. Greater quantities of this may be prescribed in some circumstances.
• Directions of an appropriate prescriber.
• Under the terms and conditions of a valid Patient Group Direction (PGD).
• Medicines Act Exemption (where they apply to health professionals).
• As an ‘emergency supply’ by a Community Pharmacy, OR
• When some medicines are used in an emergency for the purpose of saving life.

No one may administer a parenteral POM otherwise than to themselves, unless they are an appropriate practitioner or are acting in accordance with the directions of an appropriate practitioner. However, a number of medicines are exempt from this restriction when administered in an emergency for the purpose of saving a life. Refer to appendix G.

Pharmacy-only (P) and General Sales List (GSL) medicines must also be supplied or administered to individual patients only in accordance with the directions given by a doctor, dentist or appropriate non medical prescriber for that specific patient. This does NOT include patients own ‘over the counter’ medicines, which may have been supplied directly to the patient by a pharmacy (P or GSL), or other retail outlet (GSL medicines).

8.1 General Principles

• Medicines will be administered by appropriately qualified and competent persons with documented authority.

• Only medicines of assured quality, efficacy, and safety will be administered.

• All reasonable endeavours will be made to gain the patient’s consent before administration is undertaken in line with Locala’s Consent Policy.

• Each member of staff that administers a medicine that may cause anaphylaxis will have ready access to epinephrine (adrenaline) injection of the necessary strength and quantity, and have had appropriate training to assume competence in treating anaphylaxis.

• Special instructions for administering medicines must be read prior to administration. If in doubt about any route of administration the prescriber or a pharmacist should be contacted.

• Medicines for injection must always be freshly prepared at the time of administration by the health care professional.  

• The patient record must be completed immediately after a dose is given to the patient.

• Medicines must NOT be administered from a Monitored Dosage System (MDS) that has not been labelled and sealed by an appropriate professional.

• Where cytotoxic drugs are being administered, Locala employed staff must adhere to the Locala Cytotoxic Policy. This can be accessed via the Locala internet site.

8.2 Patient Group Directions (PGDs)

• A Patient Group Direction (PGD) is a written instruction for the supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment (HSC 2000/026)

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4 An exception to this is a medication prepared under the direction of a pharmacist from a Central Intravenous Additive Service which has been clearly labelled for that patient. Where the specific summary of product characteristic/patient information leaflet indicate it should be prepared in advance e.g. some chemotherapy treatments, it is acceptable to do so.

5 An appropriate professional refers to a Hospital/Community Pharmacist or accredited checking Pharmacy Technician.
The majority of clinical care should be provided on an individual, patient-specific basis. PGDs should be reserved for those limited situations where there is an advantage for patient care without compromising patient safety.

Only registered Health Care Professionals (as listed in HSC 2000/026) and as updated by the Dept of Health, may supply and/or administer medicines under the terms and conditions of a valid PGD. This responsibility CANNOT be delegated to others. The registered health care professional must be adequately trained (all PGDs authorised for use indicate the qualifications required to work under them), and be authorised by their manager/clinical lead to work under the PGD.

Guidance as provided in the Locala PGD Policy must be used to prepare PGDs.

PGDs must be reviewed every 2 years.

PGDs for unlicensed medicines are not allowed.

In special circumstances the following medicines can be included in a PGD:

- Recently licensed drugs under intensive monitoring and subject to special adverse drug reaction reporting requirements (“Black Triangle Drugs”)
- Medicines used outside the terms of their license (Off Label use)

In both of the above cases such use is exceptional, and should be justified by current best practice e.g. NICE guidance, or recommendations of the Joint Committee on Vaccination and Immunisation (JCVI) for vaccine use. Each PGD should clearly state when the product is being used outside the terms of the Summary of Product Characteristics (SPC) and documentation should include the reasons why such use is necessary.

8.3 Patient Specific Directions

A patient specific direction (PSD) is used once a patient has been assessed by an independent prescriber, and that prescriber, (doctor, dentist, independent nurse or independent pharmacist prescriber), instructs another health care professional in writing to supply or administer a medicine directly to that named patient or to several named patients.

This could be demonstrated by a simple request in the patient’s notes or an entry on the patients’ drug chart. It may also take the form of a list of patients’ names and addresses attached to a direction to supply or administer a certain medicine, e.g. patients on a clinic list.

Generally speaking, patient specific directions are a direct instruction and do not require an assessment of the patient by the health care professional instructed to supply and/or administer the medicine, unlike a PGD. Full responsibility and accountability lies with the independent prescriber who has written the instruction.

8.4 Administration of Medicines by Non Medical Staff

Staff other than nursing and medical may be authorised practitioners, (e.g. members of intermediate care teams or night care staff) who are engaged in handling or administering specific medicines. They must be deemed competent to do so by the appropriate manager, must have undertaken the required training and must adhere to a local written and approved protocol. They

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6 Health Service Circular 2000/026: Patient Group Directions is available on the Department of Health website.
7 Further guidance on PGDs and PSDs can be found in the Department of Health document, ‘Medicines Matter’.
must not be involved in the administration of medicines, which are not defined within their local service policy.

8.5 Administration of Medicines by Practitioners in Training

Practitioners in training must be given every opportunity to become competent in medicines related activities under appropriate supervision. The supervising practitioner has responsibility for medicines procedures at such times.

Student practitioners who are not registered in their own right must not administer medicines without supervision. They must only administer medicines under the direct supervision of a suitable registered practitioner (this includes all medicines administered by any route), and the details of each occasion should be recorded.

8.6 Administration of Vaccines in a Community Setting

Nurses participating in vaccine programmes must be presented with specific named prescriptions, a patient specific direction, or be covered by a patient group direction, setting out the arrangements within which substances can be administered to certain categories of persons who meet the stated criteria.

8.7 Non-Written Instructions to Administer Medicines (“Verbal Orders”)

The Medicines Act does not specify that the directions of a prescriber must be in writing. Nevertheless, instruction by telephone to a practitioner to administer a previously unprescribed substance must NOT be accepted.

An exception would be the administration of medicines to manage an emergency which otherwise endangers life or might result in serious harm.

In exceptional circumstances, where medication (NOT including Controlled Drugs) has been previously prescribed and the prescriber is unable to issue a new prescription, but where changes to the dose are considered necessary, the use of information technology (such as fax or email)\(^8\) may be used, but this must be followed up by a new prescription signed by the prescriber who sent the fax/email confirming the changes within a maximum of 24 hours. (72 hours maximum for bank holidays and weekends).

The practitioner receiving such a message must take reasonable steps to ensure that it is genuine and that the person sending the message is authorised to do so; that is, the person must either be a prescriber authorised to prescribe the medicine or be following a protocol or similar instruction specified for that patient by an authorised prescriber. Since faxes and emails can be sent several times, the practitioner should ensure that he or she is not duplicating the actions of another in following the directions in the fax or email.

If there is no alternative but to follow a verbal order, the practitioner must make strenuous efforts to avoid any error. This may include repeating back the message, spelling out drug names, etc. The practitioner has the right to refuse a verbal order, having considered the risks of not accepting the instruction against the risks of following it. In all instances the instruction must be fully documented, dated with times, and signed (ideally with a witness).

\(^8\) Email should ONLY be used over a secure network (i.e. via NHS mail).

A fax or email is not a legally valid prescription as it is not written in indelible ink and has not been signed by the prescriber. A fax does indicate that at the time of receipt, a valid prescription is in existence. A fax or email might also constitute a direction by a prescriber.
8.8 Administration of Medicines in Schools

Patients own medicines should only be taken to school or settings when essential; that is where it would be detrimental to a child’s health if the medicine were not administered during the school day. Schools and settings should only accept patients own medicines that have been prescribed by a doctor, dentist, nurse prescriber or pharmacist prescriber, and are provided in the original container (as dispensed by a pharmacist) and include the prescribers instructions for administration. Doses administered must be recorded.

Each school and setting should have in place its own policy on the management of medicines in the school setting. Further advice and a Kirklees Local Authority guidance document is available from Kirklees Education Authority.

Advice for school nurses can be found at:  

8.9 The Unlicensed Administration of Medicines

The Summary of Product Characteristics (SPC) for licensed medicines includes the storage and administration recommendations for that product. Deviations from the SPC makes the product ‘off label' or unlicensed. Refer to section 13 for further information.

Examples of this are crushing tablets, cutting un-scored tablets, cutting patches, opening capsules, adding liquid medicines to food or drink, adding thickening agents to liquid medicines and giving medicines by un-licensed routes such as giving intravenous fluids by a subcutaneous route.

There are legal, professional and clinical considerations to be made when administering medicines using an unlicensed method. (Refer to appendix H)

Advice on crushing solid dose forms of medicine prior to administering can be found in Appendix I.

9. DISPENSING AND SUPPLY OF MEDICINES AND DRESSINGS

Dispensing of medicines is distinguished from administration of medicines if the patient or carer is intended to use the medicine other than under the direct supervision of the practitioner. Clear procedures agreed with the Head of Medicines Management must be in place in any setting where dispensing occurs.

For most patients medicines are obtained by means of a prescription, which has been issued by an appropriate prescriber for the medical treatment of that individual. The prescription is then dispensed by, (or under the supervision of), a pharmacist or dispensing doctor, according to national legislation before being supplied to that patient.

9.1 Dispensing

Dispensing includes such activities as checking the validity of the prescription, appropriateness of the medicine for an individual patient, and the assembly and labelling of the product (including the addition of appropriate cautions, providing information leaflets and necessary counselling for the patient).

All dispensing procedures must comply with the Medicines Act 1968 and EEC Directive 92/27 with regard to their packaging, labelling and package leaflets. Handling of medicines must comply with any relevant COSHH risk assessment.
Dispensing is the prime responsibility of the Pharmacist, or in certain situations the Dispensing Doctor.  

9.2 Dispensing of Medicines by Practitioners

Patients have the right to expect that dispensing will be carried out with the same care and to the same standard they might reasonably expect if it was carried out by, or under, the supervision of a pharmacist. In particular:

- There must be Standard Operating Procedures (SOPs) in place covering all aspects of dispensing which all staff should follow.
- Medicines must be supplied as original manufacturer packs or in pre-packs prepared under the supervision of a pharmacist.
- The medicines must have a sufficiently long expiry date to cover the course of treatment.
- Medicines supplied must be labelled according to the requirements of the Medicines Act and European Directives and must specify:
  - The patient’s name
  - The date of supply
  - The name and address of the supplying service or clinic
  - The phrase “Keep out of sight and reach of children”
  - The phrase “For external use only” if appropriate
  - Directions for use
  - Quantity supplied
- The patient or carer must be supplied with the manufacturers information leaflet and provided with counselling where necessary. Any information provided to patients should be in a format that the patient can understand.
- There must also be arrangements in place for collection of fees payable under regulation 5 (1) of the National Health Service, (Charges for Drugs and Appliances), Regulations 2000 (as amended).

9.3 Supply of Medicines

- For most patients, medicines are obtained by means of an individual prescription for a named patient. (See above).
- In some situations medicines may be supplied by Patient Group Direction (PGD) or Patient Specific Direction (PSD).
- Where a supply of medicines is made to an individual who is not exempt from prescription charges, arrangements must be made to collect the national prescription charge. This also applies to medicines supplied under a Patient Group Direction. The Department of Health leaflets HC11 and HC12 provide guidance on exemptions and help with health costs. These are available to download from the Department of Health website at http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Abouthealthcosts.aspx

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9 The Royal Pharmaceutical Society’s document ‘Professional Standards and Guidance for the Sale and Supply of Medicines’ provides advice on the legal requirements, mandatory professional standards and accepted best practice guidance for Pharmacists and Pharmacy Technicians.
• Patients who are not exempt must pay the national prescription fee for any medicine supplied from a Walk-in Centre. Walk-in Centre patients who are exempt from prescription fees must state this on a signed declaration form.

• Practitioners should not supply oils for baby massage nor give samples or materials received from pharmaceutical companies to patients/clients. This includes dressings, nutritional supplements, medicines, devices, etc. All such products should be obtained through the standard ordering process (refer to section 10). Any variation from this must be specifically approved and agreed with the Head of Medicines Management. This is primarily because of the liabilities relating to product quality. There are also issues relating to probity and transparency in the selection of products. There have also been occasions when issue of samples has compromised the planned care pathway for patients.

10. PROCUREMENT, TRANSPORT AND STORAGE OF MEDICINES

10.1 Procurement

• Procurement covers the activities through which medicines are acquired for or on behalf of Locala

• All medicines must be sourced from Locala approved suppliers and be appropriate and legitimate for their intended use.

• The Department of Health document ‘Commercial Sponsorship: ethical standards for the NHS’, the APBI code of conduct, and Locala Code of Business Conduct should be consulted when procuring medicines.

10.2 Ordering of Medicines for Locala Service Centres

Only a designated professional or authorised designated person may order medicines for their service. The Pharmacy Distribution Centres based at Huddersfield Royal Infirmary and Dewsbury District Hospital will ONLY accept orders from these designated signatories.

For Huddersfield based services, the correct stock list must be completed, signed, and sent either by post or in a sealed tamper evident orange bag to the Pharmacy Distribution Centre at Huddersfield Royal Infirmary (HRI).

For services based in North Kirklees, the correct stock list must be completed, signed, and sent by post, fax, or in a locked/sealed pharmacy box to Pharmacy Stores at Dewsbury District Hospital (DDH).

Variations to stock list orders must be agreed with the Head of Medicines Management. The Medicines Management Team is responsible for updating and amending stock lists

Order books and requisition forms should be treated as controlled stationary and kept in a locked location.

NB: In the near future an e-procurement system will be introduced and therefore processes for ordering medicines from suppliers will change.

10.3 Transport and Receipt of Medicines

• Transport includes the transfer of medicines between sites within Locala geographical area e.g. between clinics, between Locala sites and an outside location e.g. a patient’s home.

• Staff engaged in transportation of medicines should be identified, authorised, and appropriately trained.
• All medicines must be transported in a securely sealed or tamper evident container. Refer to Generic Risk Assessment Hazardous waste (COSHH). Policy Refs 6.5.3

• Items requiring refrigerated storage, such as vaccines, should be transported in separate containers (validated cool bags/boxes) to maintain the cold chain. (Refer to the Locala Cold Chain policy for further information).

• Staff in receipt of drugs requiring refrigeration must ensure that cold chain requirements have been complied with during delivery, and must ensure that the items are unpacked, checked and placed **immediately** in the designated medicines fridge.

• Staff in receipt of drugs must sign the appropriate notice to acknowledge receipt of the delivered goods.

• Staff signing for deliveries must ensure that the delivery has not been tampered with or damaged in transit.

• Medicines must be unpacked and stored in a secure environment as soon as possible after receipt.

• Staff unpacking orders must ensure that the delivery note has not been tampered with.

• Medicines will be checked against the order requisition and delivery note for:
  - Correct drug
  - Correct formulation
  - Correct strength
  - Correct quantity
  - Shelf life of product

  Also check for:
  - Storage requirements
  - Good condition of the product
  - Requirements for safe handling

• Any discrepancies must be reported immediately to the supplier. (For Huddersfield based services this will be HRI Pharmacy Stores on 01484 342724. For services based in North Kirklees this will be DDH Pharmacy Stores on 01924 816054).

• The delivery note must be signed and kept for 2 years as a record that supply was complete.

• The delivery driver is responsible for the safe delivery of the goods to the correct location.

**10.4 Storage of Medicines**

Medicines must be stored securely in either a lockable cupboard, or a medicine trolley, which can be secured to a wall when not in use. Further guidance can be obtained from Royal Pharmaceutical Society’s Document ‘The Safe and Secure Handling of Medicines – a Team Approach’, often referred to as the Duthie Report.

**10.5 Storage of Medicines at Community Clinics and Team Bases**

• The practitioner in charge is responsible at all times for the safekeeping and secure storage of medicines in their service, and ensuring that all medicines are stored according to national legislation and local policy.
• Medicines will be stored in an approved, secure location and there will be a reasonable need for the medicine in that location.

• This safe and secure storage also applies to prescription pads and stationery used to order medicines

• Access to medicines will only be by authorised personnel.

• All internal and external medicines, disinfectants and reagents must be stored in locked cupboards, fridges, trolleys or other secure cabinets – all reserved solely for medicinal products. The only exceptions to this requirement are medicines for clinical emergencies, intravenous fluids, sterile topical fluids, nutritional products and some bulky medicated dressings, which because of their bulk can be stored in a secure clean area, to which the general public does not have access. Under no circumstances should products be placed on the floor.

• Internal medicines must be stored separately from medicines for external use. Under no circumstances should medicines be transferred from one container to another, nor must they be taken out of their original container and left loose. All medicines in transit must be stored in a sealed tamper evident container.

• Cupboards or refrigerators for the storage of medicines must be sited where they are convenient for staff, allow adequate space to permit surveillance and afford maximum security against unauthorised entry. Medicine cupboards should generally be sited in a clean utility room to which unauthorised persons do not have access. Cupboards must not be sited where they may be subject to higher than average humidity or temperature. Reagent cupboards must be sited in areas where testing is carried out.

• Medicines and vaccines that require refrigeration MUST be stored in an approved dedicated medicines fridge that is temperature monitored to maintain the stability of the medicines. Medicines are not to be stored together with food or pathological specimens, but in a separate locked fridge. The fridge should be of a suitable size, which is dependent on the volume of refrigerated medicines to be stored. (Refer to Locala Cold Chain policy).

• Controlled drugs (CDs) should be kept in a locked cupboard, solely for the storage of CDs, which must be secured to the wall. Refer to Locala CD Policy.

• Advice regarding the storage of flammable liquids, gases and aerosols should be obtained from the Health and Safety Advisor based in the Governance and Quality Team

• Drugs for emergency use should be stored in a tamper evident container, in an easily accessible location, (NOT a locked cupboard), when clinical procedures are taking place. At the end of each clinic day they must be stored away securely.

10.6 Keys for Medicine Cupboards and Refrigerators

• The keys for the controlled drug cupboard, medicine cupboard, internal medicine cupboard, medicine trolley, medicine refrigerator and pharmacy transport box must be kept together on one key ring reserved solely for these keys. The keys must be clearly identified.

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10 Advice on the suitability of storage and types of medicine refrigerators can be obtained from the Community Services Pharmacy Manager on 01924 351525

11 Refrigerated medicines should be stored on the shelves, NOT on the floor of the unit or in the door of the fridge. Medicines must not touch the freezing compartment, cooling element or back of the fridge where ice may form.
• The keys must be kept on the person of the designated practitioner during working hours and stored securely when the clinic or base is closed.

• In the event of no designated practitioner being on duty in a ward or department, the keys should be handed to the practitioner in charge.

• At bases where a number of designated practitioners may require access to the medicine cupboards at different times a secure system must be agreed. Where keys are issued to staff it is good practice to maintain a control log to record when the keys were issued, to whom and when they have been returned.

10.7 Medicines in Patients’ Homes

• Although patients or their carers are responsible for storage of their drugs in their homes, every effort should be made to encourage patients to store drugs in a safe place. This is particularly important if there are children in the household or likely to visit. If the practitioner has concerns about medicine storage in the patient’s home they should undertake a risk assessment, which should be recorded in the patient’s notes. Medicines prescribed for an individual are legally the property of that individual and consent should be sought prior to removal for safe disposal. An exemption to this would be where medicines pose an immediate risk to patients or the public. Where medicines are removed, this must be clearly documented and signed by the patient. (see Appendix J)

• In addition, drugs should be stored under appropriate conditions e.g. refrigerator where required. Storage should not be near a radiator nor in warm, damp places e.g. kitchen or bathroom, and away from direct sunlight. Medicines should be kept in the original container that they were dispensed in.

• Patients/carers should be advised to take any unwanted medicines back to a community pharmacy for safe disposal.

10.8 Medicines in HealthCare Professionals Bags

The medicines contained in HealthCare Professionals bags MUST be stored securely and within the recommended temperature limits. Good practice would suggest:

• The bag must be lockable and not left unattended.

• Most medicines should be stored between 4°C and 25°C. Consideration should be given to the type of bag used to keep drugs within recommended temperatures.

• Consider keeping a maximum-minimum thermometer in the bag to record extremes of temperature. A car boot may reach sub zero temperatures in winter which may freeze liquid medicines or very high temperatures in summer, which may cause degradation of medicines.

• Bright lights may inactivate some drugs so keep the bag closed when not in use.

• Lock the bag out of sight in the boot if not required on a visit. The HealthCare Professionals bag must NOT be left overnight, or for prolonged periods in the car boot. It must be removed and placed in a secure place either at home (overnight), or in the health premises in which the individual is working.

• Use a non loose-leaf notebook to record the origin, expiry date and batch numbers of all drugs administered. Advice on controlled drugs registers can be obtained from Locala CD Accountable Officer. Contact the Medicines Management Team on 01924 351525
• Check monthly that drugs are in date and are usable. Discard and replace any that have nearly expired. (Refer to the Locala Controlled Drugs Policy where applicable).

• If oxygen is carried, the car should be labelled with the correct ‘Hazchem’ sticker and appropriate measures taken to secure the canister.

• Patients given more than immediate treatment should also be supplied with a patient information leaflet. (See section 9.2)

10.9 Security of Medicines and Controlled Stationery

• When medicines are transported by staff it becomes the responsibility of that person to ensure safe custody as far as is practically possible. Medication should not be left unattended in a car (see 10.8)

• When a medicine or chemical has been removed from its storage facility/packaging for use, it must remain under the direct supervision of the person who has been delegated to use the agent concerned, and it is the responsibility of that person to ensure continued safe custody.

• Prescription pads are controlled stationery and their security is the responsibility of the individual prescriber. Prescription pads must be kept in a secure place when stored on Locala premises. See Appendix 4 and refer to the Locala Non-Medical Prescribing Policy for further guidance.

• Order books and requisition forms must be treated as controlled stationary and kept under lock and key by a designated person in the service centre.

Further information can be found in ‘The Duthie Report’.

11. DISPOSAL OF MEDICINES

Medicinal waste encompasses licensed medicinal products of any type and residuals in bottles, vials and ampoules that are not sharp.

• Under the Hazardous Waste Directives, only cytotoxic or cytostatic medicines are classified as hazardous waste.

• Cytotoxic and cytostatic medicines are defined as any medicinal product that has one or more of the following hazardous properties:
  ❖ Toxic,
  ❖ Carcinogenic
  ❖ Mutagenic
  ❖ Toxic for reproduction.

Refer to the Locala Waste Management Guideline, (‘classification of medicinal waste’), for a list of cytotoxic and cytostatic medicines. It should be noted that this is provided as a guide only and is not a comprehensive list. Further guidance can be sought from the Locala Medicines Management Team or the supplier from where the medicine was sourced.

• The Hazardous Waste Regulations 2005 prohibit the mixing of hazardous waste with non hazardous waste. This means that cytotoxic and cytostatic waste medicines and any sharps or containers contaminated with these products need to be placed in separate containers from all other medicines.
A yellow bin with a purple lid (leak proof container) must be used for all cytotoxic/cytostatic drugs. Solid and liquid medicines must be separated. Therefore there should be one container for solid medicines and one for liquid medicines. The container for liquid medicines must have an absorbent pad. These containers are not the same as those that should be used for sharps waste.¹²

Any other medicines must be placed in a yellow bin with a blue lid (leak proof container). Again solid and liquid medicines must be separated; therefore one container for solid medicines and one for liquid medicines should be available. The container for the liquid medicines must have an absorbent pad.

Medicinally contaminated syringes, needles and broken glass medicinal ampoules are considered to be sharps and need to be disposed of in a yellow sharps bin. For sharps that have been in contact with cytotoxic/cytostatic drugs a yellow bin with a purple lid (UN 3291 approved) must be used. For sharps that have been in contact/used for administering all other drugs a yellow sharps bin with a yellow lid (UN 3291 approved) must be used.

Pharmaceuticals should never be placed for disposal in a refuse bin.

For information on the disposal of controlled drugs refer to the Locala Controlled Drugs Policy.

Refer to the Locala Waste Management Policy for further information.

### 11.1 Disposal of Patient’s Own Medication

Medicines obtained for a patient on a prescription are the property of the patient.

In most situations, if they are no longer required, the patient or patient’s agent should be encouraged to return them to a Community Pharmacy for safe disposal. However, in situations where this cannot take place, the Health Care Worker can accept them but must place them in the correct waste stream (as described above) at the GP practice/health centre, or take them to the local Community Pharmacy. Medicines should never be disposed of in a refuse bin. (See also 10.7)

Medicines that have been issued to a patient must not be put back into stock or used for any other patient.

Disposal of patient’s own controlled drugs is discussed in the Locala Controlled Drugs policy. This can be found on the NHS Kirklees website under the Locala section.

### 11.2 Disposal of Medicines by Locala Service Centres

Service centres should NOT accept unwanted or out of date medication from the public. They should advise people to take them to their Community Pharmacy for destruction. Pharmaceutical waste bins MUST be available in each centre for waste generated by staff within that centre. Medicines must be segregated prior to placing in the pharmaceutical waste bin. Cytotoxic and cytostatic medicines MUST be placed in a separate pharmaceutical waste container (see above) from unwanted or expired stock medicines. The containers will be collected and emptied on a regular basis.

¹²Medicines may have a range of hazardous properties, but only those with one of the hazardous properties denoted by ‘H codes’ will be classified as a hazardous waste: H6 (toxic); H7 (carcinogenic); H10 (toxic for reproduction), and H11 (mutagenic). Other medicines are not hazardous within the meaning of the legislation. Diabetic patients who manage their care at home are the exception as they are able to mix both sharps and liquid and solid medicines together.
For advice relating to disposal of specific medicinal items, please contact the Medicines Management Team on 01924 351525

To request additional collections please contact NHS Kirklees Estates and Facilities Team on 01924 351470.

This procedure does not cover the disposal of stock Controlled Drugs (CDs).
If a service needs to dispose of schedule 2 or 3 CD stock (misuse of drugs regulations 2001) contact Locala Medicines Management Team on 01924 351525.

11.3 Disposal of Medicines by Community Pharmacies

Disposal of unwanted medicines is classed as an essential service under the community pharmacy contract. The aim of this service is to ensure that the public can easily and safely dispose of unwanted medicines. Community Pharmacies should accept unwanted and out of date medicines for disposal from patients’ homes and residential homes only.

Waste medicines from Care Homes with Nursing are classified as industrial clinical waste and cannot normally be accepted by Community Pharmacies. Care Homes with Nursing MUST make arrangements for pharmaceutical waste to be collected directly from their premises.

11.4 Disposal of Medicines at GP Practices

Each GP practice MUST arrange for the appropriate pharmaceutical waste containers to be available on the premises. These are to be used for the disposal of the practices own stocks of out of date or unwanted medicines only. Sharps bins issued on prescription by the practice should be accepted from patients for disposal if necessary.

11.5 Diabetic Sharps Bins

These may be returned to the prescribing GP practice for disposal if necessary. Kirklees Council will collect sharps bins from housebound patients on request from a practitioner. A request can be made by telephoning the 24 hour Cleansing Service Clinical Waste Collection answer phone 01484 223148.

12. RISK MANAGEMENT

12.1 Managing Errors or Incidents in the Use of Medicines

- A medication error is a preventable incident associated with the use of medicines that has resulted in harm or potential for harm to a patient. Such incidents may be related to any step in the medicines use process. This includes the prescribing, dispensing, storage and administration of medicines as well as the transfer of information.

- Following an incident, individuals should immediately report the incident to their line manager and complete an incident report form. These are available via the Locala internet

- The well being of the patient is of prime importance following a medicine incident. The incident must be reported as soon as possible to an appropriate member of medical staff who will decide whether any further action is needed.

- Potential safeguarding implications must be given due consideration when an incident involves a child or a vulnerable adult.
Incidents involving the administration of medicines require thorough and careful investigation, which takes full account of the circumstances and context of the event and the position of the practitioner involved. Where an administration error has occurred the patient/carer and the GP in charge of the patient must be informed.

All nursing staff must be familiar with the Nursing and Midwifery Council guidelines for the management of errors and incidents in the administration of medicines (Guidelines for the Administration of Medicines NMC 2010).

Other registering professional bodies also provide guidance to their members on managing incidents. This is available from the GMC, the GDC, the GPhC and the Health Professions Council.

Locala staff must follow the procedure as stated in the Locala Patient Safety and Non Clinical Incident Reporting procedure. Staff should adopt fair blame policies for recording medication errors, which are designed to protect staff, patients, and the organisation. The incident reporting policy encourages the reporting of all medication incidents or near misses. This is to allow incidents to be investigated and any risk to be assessed. Any learning, (which is anonymised), is shared with colleagues and action plans can then be implemented to prevent future recurrences.

Locala encourages contractors to report any incidents or near misses, which would benefit patient safety as a whole, through the local reporting procedure.

For more information please consult the Locala Patient Safety and Non Clinical Incident Reporting procedure for the initial management and reporting of incidents and near misses.

12.2 Serious Untoward Incident (SUI)

Any incident of a serious nature i.e. those involving fatalities, significant injury and/or dangerous occurrences must be reported under the Locala Serious Untoward Incident Procedure in addition to normal incident reporting procedures.

For more information please consult Locala Serious Untoward Incident Procedure

12.3 Adverse Drug Reaction Reporting

Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance.

Prompt reporting should be carried out for any suspected adverse reactions to new drugs and vaccines under intense surveillance. To aid this distinction, drugs under intense surveillance are given the symbol of an inverted black triangle (▼). Reporting should also be undertaken for unlicensed drugs and for any serious or unusual reactions to established products. Reporting should be carried out for both prescribed drugs and those medicines obtained by patients over the counter and herbal medicines.

If a severe or unexpected drug reaction to a prescribed medicine occurs, the prescriber should, if appropriate, use the Adverse Drug Reaction (ADR) Reporting Form or ‘yellow card scheme’ to report this to the Medicines and Healthcare Products Regulatory Authority (MHRA).

All health professionals are urged to help by reporting suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA)

patients should also be encouraged to self-report.
Alternatively a paper copy can be found in the BNF.

- All staff should also report any adverse drug reactions through the Locala incident reporting procedure.
- The patient’s GP must be informed of any adverse reaction to a drug or dressing prescribed by a non-medical prescriber.
- Further guidance on reporting ‘reactions’ can be found in the BNF.

12.4 Medicine Defect Reporting

A defect is present if the product, as supplied by the manufacturer, is not of the expected standard. Defects may involve inadequate or incorrect labelling, ineffective packaging, contamination, discoloration, breakage, and incorrect contents.

When a defect is found or suspected in a medicine:

- If the medicine is a stock item in a service centre, inform Pharmacy Distribution Centre at Huddersfield Royal Infirmary on 01484 342724 (for Huddersfield based services). For North Kirklees based services contact Pharmacy Stores at Dewsbury District Hospital on 01924 816054. Otherwise inform the community pharmacy from which the medicines were obtained. They will advise and implement any necessary reporting, recording and investigation of the defect.
- The defect, or the reporting of it to the pharmacy, should also be reported to Locala Head of Medicines Management.
- Retain and quarantine any remaining product and associated products or equipment.
- Record the details of the product and the defect.
- If the product has been administered to a patient, inform the doctor responsible for the patient and record the defects in the patient’s notes.

Report the incident using the Incident Reporting System. For more information please consult Locala Reporting of patient safety and non clinical incidents procedure.

Adverse incidents arising from the use of a medicinal product or medical device thought to be defective should also be reported to the Medicines and Health Care Regulatory Agency via the yellow card system (see section 12.3 above – ‘Adverse Drug Reaction Reporting’)

12.5 Incidents Involving Medical Devices

Advice can be obtained from the Locala Governance and Quality Team (01924 351674). Withdraw the item from service (where possible) and label accordingly. Record full details, e.g. serial/batch number, manufacturer, and model number.
If it is not possible to withdraw a particular medical device, ensure it is checked by the Medical Physics Department at Mid Yorkshire Trust (01924 541050), or the manufacturer, before it is used again.
An incident reporting form must be completed and returned following the Locala Patient Safety and Non Clinical Incident Reporting procedure.
12.6 Healthcare Safety Alerts & Drug/Device Recalls

Any necessary recall of products is the responsibility of the license holder. When defects represent a significant hazard to health, The Medicines and Healthcare Products Regulatory Authority (MHRA) may issue a “drug alert” letter, which provides 4 categories of urgency for recall or caution in use.

Nursing staff, Community Pharmacists and GP Practices will be alerted to a product recall through the cascade process co-coordinated by the West Yorkshire Central Services Agency (WYCSA) and MUST take the appropriate action as detailed within the alert.

12.7 Control of Substances Hazardous to Health Regulations (COSHH)

The Control of Substances Hazardous to Health Regulations, known as COSHH, is the UK legislation on chemical hazards at work. The main legal duties of employers under COSHH are contained in Regulations 6-12, which cover risk assessment, prevention or control of exposure, use and maintenance of controls, monitoring exposure, health surveillance, and provision of information and training.

Some medicines are, by their nature, hazardous. It is the responsibility of the senior clinic nurse for a community clinic or practice manager within a GP practice to perform an assessment of hazard and risk of medicines kept in the clinic or practice.

13. USE OF UNLICENSED MEDICINES

In the UK a medicine cannot be marketed for human use without a Product License (PL) granted by the Licensing Authority. The PL specifies the indications for which a product may be used and also the dose, route of administration etc. Licensing arrangements are determined by the Medicines Act 1968 and implemented through the Medicines and Healthcare Products Regulatory Authority (MHRA).

It is important to distinguish between use of unlicensed medicines (i.e., medicines which are not licensed for any purpose in UK), and use of licensed medicines for unlicensed purposes. In this policy this is referred to as off-label use. (Refer to appendix H for further information).

- Medicines prescribed should be licensed, and licensed for the indication for which they are to be prescribed. Prescribing an unlicensed medicine, or a licensed medicine off-label, increases the clinical and legal liabilities on the prescriber.

- Before prescribing an unlicensed medicine, or a licensed medicine off-label, the prescriber must ascertain that a reasonable body of medical opinion would support the use of the product in that way (or expert guidelines support its use), and that there is no suitable licensed alternative.

- It is recognised that many medicines are used outside their terms of PL in paediatric practice but the same principles still apply. The current edition of BNF for Children is an essential resource for paediatric prescribing.

Legal responsibility for any prescription lies with the person who signs the prescription. It is the responsibility of prescribers to be aware of the license status of products they prescribe. Patients MUST be informed of the license status and the implications of this, and the patients consent to this prescription gained. This discussion must be documented in the patient’s record. Patients could decide not to consent to treatment with an unlicensed medicine or a licensed medicine prescribed off-label.
13.1 Unlicensed Medicines

Practitioners who prescribe unlicensed products take complete responsibility and liability for any adverse reactions, which may occur, and may be called upon to justify their actions.

All unlicensed medicines initiated by hospital prescribers are classified as ‘red drugs’ and should be prescribed by a hospital specialist only.

Generally Locala employed practitioners should not prescribe unlicensed medicines. However on occasions, an unlicensed product in the UK may be substituted for a licensed product with the sanction of the Department of Health.

Such products may be prescribed and administered either under a Patient Specific Direction or an agreed protocol. This will have been authorised by Locala Medicines Management Committee.

Special circumstances apply to use of medicines in clinical trials, and exceptions may be made for some unlicensed indications or complementary medicines (see below)

- Nurse or pharmacist independent prescribers are able to prescribe products outside the terms of the manufacturer’s product licence (‘off-label’), but they must take full clinical and professional responsibility for their prescribing and should only prescribe in this manner when a reasonable body of medical opinion or expert guidelines support its use (refer to section 9 for further details).

- From 21st December 2009 legislation changed to allow nurse and pharmacist independent prescribers to prescribe unlicensed medicines for their patients, on the same basis as doctors and dentists (and supplementary prescribers if part of a Clinical Management Plan) Prescribing an unlicensed medicine increases the clinical and legal liabilities on the prescriber. Before prescribing an unlicensed medicine the prescriber must ascertain that a reasonable body of medical opinion would support the use of the product in that way (or expert guidelines support its use), and that there is no suitable licensed alternative.

See appendices H and I for further information on the prescribing of unlicensed and off-label drugs.

13.2 Alternative and Complementary Medicines

Most alternative and complementary medicines do not hold marketing authorisations and the principles above apply to these medicines as well as to the “orthodox” medicines. Exceptions may be made to the prohibition on use of unlicensed medicines, for example, use of essential oils for aromatherapy. However these will take into account the source of the alternative medicine, including its quality, the intended use and the expertise of the practitioner. These exceptions must be agreed with Locala Medicines Management Committee.

14. LONG TERM CONDITIONS DOCUMENTATION

To support the process of Pharmaceutical Assessment in the Long Term Conditions (LTC) Service key documents have been developed. These have been integrated with existing LTC documentation as part of the overall care package. See Appendix J

15. CLINICAL TRIALS IN PRIMARY CARE

- All clinical trials in the UK are governed by the Medicines for Human Use (Clinical Trials) Regulations 2004.

- For any clinical trials local organisational approval should be obtained via the Research and Development Department at Huddersfield Royal Infirmary. Contact details are 01484 347007 or by email at r&d@cht.nhs.uk
Members of staff involved in the prescribing or administration of clinical trial medicines to patients / clients must be provided with sufficient information and training by the trial co-coordinator to ensure that patient care is not compromised.

Further guidance and information can be found by accessing www.dh.gov.uk and search for ‘Research Governance’ this will ensure the most current information is accessed.

16. RELATIONS WITH THE PHARMACEUTICAL INDUSTRY AND COMMERCIAL SPONSORSHIP

There are many sources of funds available to primary care to support prescribing-related activities. Whilst it is desirable to seek additional resources to fund NHS activities, for the overall benefit of patients, it is imperative that confidentiality of patient records and probity in the use of NHS resources are both maintained. Sponsorship should not be accepted for activities that will place pressure on prescribers to compromise patient safety, efficacy, or cost effectiveness in the prescribing of medicines.

Refer to Local Code of Business Conduct.

17. AVAILABILITY OF MEDICINES OUT OF HOURS

Medicines required by patients out of hours can be obtained via a number of routes depending upon the circumstances. Locala holds a list of pharmacy contractors together with hours of business, who provide pharmaceutical services in the area. Further information is available via the NHS Choices website.

In the eventuality that an urgent prescription is needed out of hours and cannot wait until the next day, Local Care Direct should be contacted on 0845 1207066. Where it is not possible for the patient to access the medicine via the available pharmaceutical services, Local Care Direct will issue, (if stocked), the complete course of the medicine to the patient.

A local Community Palliative Care Scheme which guarantees provision of an agreed list of palliative care drugs from some Community Pharmacies is also in operation. Information relating to the participating community pharmacies and the medicines stocked is available via a link from the NHS Kirklees intranet pages.

18. CONSENT TO TREATMENT

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients.

The possible side effects and complications, as well as benefits of the medicines, should be discussed with the patient. The discussion should be carried out in such a way that the patient is able to express agreement or disagreement with the proposed treatment. Any information provided to patients about their medicines should be in a format that the patient can understand.

Only people with ‘parental responsibility’ are entitled to give consent on behalf of their children. Not all parents have parental responsibility for their children. If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check.
Once children reach the age of 16 they are presumed in law to be competent to give consent for themselves. This means that they are able to sign their own consent form for example. However it is good practice to encourage competent children to involve their family in decision-making.

Children/young people are not automatically presumed to be legally competent to make decisions about consent for themselves. However, the courts have stated that under 16’s are competent to give valid informed consent if they have sufficient understanding and intelligence to enable them to understand fully what is proposed (Gillick/Fraser competent).

Refer to Locala Consent policy

19. POLICY ON ALCOHOL AND SUBSTANCE MISUSE IN THE WORKPLACE

For Staff

Refer to Locala’s Policy on Alcohol and Substance Misuse in the Workplace.

For Clients or Visitors

If staff suspect any client or visitor of misusing substances whilst on Locala premises they should recommend the client or visitor speak to their GP in the first instance or contact:

Lifeline Dewsbury (Drugs support)
Address: 3 Wellington Street
Dewsbury
WF3 1LY

OR

Lifeline Huddersfield (Drugs Support)
Address: Lifeline Huddersfield Office,
12 Station Street Buildings,
Station Street,
Huddersfield,
HD1 1LZ

OR

On TRAK Dewsbury (Alcohol Service)
Address: 13 Union Street
Dewsbury
WF13 1BG

OR

On TRAK Huddersfield (Alcohol Service)
Address: 2 St Peters Street
Huddersfield
HD1 1RA

In the event of a client or visitor dealing illicit substances whilst on Locala premises, Security or the Police must be called.
20. TRAINING AND EDUCATION

All staff involved in the handling of medicines should be appropriately trained with regard to safety and security of medicines and with regard to safeguarding themselves and those under their supervision from any risks posed by products. They should also be trained to ensure understanding of the need for risk management in relation to drug products and procedures.

All staff should understand their scope of practice and work within it.

Practitioners must work within their own level of professional knowledge and competence and are accountable for their own actions.

Nurses and Midwives must act according to the:


Nursing and Midwifery Council (2008) Standards of Proficiency for Nurse and Midwife Prescribers


Pharmacists and Pharmacy technicians must act according to the:

The General Pharmaceutical Councils Standards for Pharmacists and Pharmacy Technicians (2011)

Allied Health Professionals must act according to the:


Furthermore Allied Health Professionals must abide by their respective Standards of Proficiency as thus:

Physiotherapists

Podiatrists

Radiographers

As appropriate to their role, staff should ensure that the following training is kept updated:

- Anaphylaxis (Mandatory – and must be undertaken annually)
- Immunisation & Vaccination Update (Compulsory for staff carrying out imms and vacs). This should be updated on an annual basis. Newly qualified staff should have completed the 2 day university course before undertaking imms and vacs for the first time.
- Cold Chain Training (Compulsory for staff who are responsible for storing vaccines and monitoring/recording fridge temperatures at their base of work). This should be updated on an annual basis.
• Medicines Management Training (Mandatory for clinical staff)

**Continuing Professional Development**

The requirements for the safe and secure handling of medicines may change over time. It is therefore essential that all practitioners keep up to date with current practice. This involves continuing learning i.e. continuing professional development (CPD).

CPD is an essential element in improving service quality on the delivery of health care services and staff should be encouraged to maintain their CPD portfolio.

For registered practitioners the respective regulatory bodies all stipulate CPD requirements and practitioners MUST fulfil these obligations.

**21. AUDIT AND PREMISES INSPECTIONS**

**21.1 Introduction**

• Audit is a key component in the delivery of Clinical and Corporate Governance.

• The most commonly quoted definition of clinical audit is an adaptation of that originally put forward by the Department of Health in working paper 6 (Medical Audit) of the White Paper 'Working for Patients', in 1989: *Clinical audit is the systematic and critical analysis of the quality of clinical care, including the procedures used for diagnosis, treatment and care, the associated use of resources and the resulting outcome and quality of life for the patient.*

• Opportunities to promote best practice throughout the organisation, whether from audit, research, service evaluation, development projects or other sources will be facilitated by the organisation.

• In relation to Medicines Management, audit in broader terms encompasses all aspects of medicines handling, storage, distribution, administration, and waste disposal within the organisation, its constituent contractors and patients.

**21.2 Purpose of Audit**

• Audit is a powerful tool for determining compliance against agreed standards, and for identifying areas where improvements in practice are required. Audit is a means of providing:
  o Support for health professionals / admin staff
  o Information to assist the improvement of patient care / processes
  o Benchmarking of practice
  o Evidence of need for service development / change in practice
  o Support for rational prescribing
  o Support for cost effective use of resources
  o Confidence

• It is important that the purpose of any audit is made clear to all those who are involved in it, whether it be clinical or not in nature. Through understanding its purpose, the outcome of audit is more likely to be positive. More detailed information on audit can be accessed through Locala Governance and Quality Team.

**21.3 Audit and Medicines Management**

Medicines management and prescribing are major aspects of service delivery in both primary and secondary care. It is important therefore that the medicines we use and how we use them in clinical
practice, as well as the underlying processes that govern how we handle medicines, are audited against accepted best practice to ensure the end user, the patient, derives maximum benefit from limited resources. It is therefore important that medicines management and prescribing initiatives embrace clinical audit and use it as a means of improving patient care and service delivery and to verify the use of best practice.

21.4 Areas for Review/Audit

The following checklist highlights areas that each service/department should consider in relation to medicines management. This should include whether there is a policy or procedure that covers the items listed and relevant adherence:

(1) Medicines Systems and Processes
- Procurement
- Ordering
- Delivery
- Storage (including cold chain/ Controlled drugs/dressings etc) - Includes:
  - Appropriate lockable cupboards
  - Freezers/fridges
  - Temperature recording
- Distribution
- Lockable/sealable security containers for transport
- Dispensing
- Issue
- Supply
- Administration
- Waste disposal
- Prescription charges including:
  - Prescriptions dispensed at Pharmacies
  - Personally administered items
  - Medicines supplied under Patient Group Directions
- COSHH assessment
- Expiry dates

(2) Legal and Professional
Prescription, supply and administration of medicines:

a) Comply with legislation
   - Controlled Drugs
   - Independent/ supplementary prescribers
   - Patient Group Directions
   - Use of Unlicensed medicines
   - Clinical Trials

b) Are undertaken by qualified, competent staff including:
   - Independent prescribers (Doctors/Dentists/Nurses/Pharmacists)
   - Supplementary prescribers
   - Community Nurse Prescribers
   - Health professionals under the directions of a Doctor
   - National Patient Safety Alerts implemented as appropriate
   - MHRA alerts
   - Yellow card reporting scheme
   - Adverse incidents reporting

(3) Security
- Lockable cupboards/fridges/freezers.
• Medicines cupboards to Safe and Secure Handling of Medicines report standards
• Lockable, security sealed containers for transport of medicines.
• Entrances to Pharmacies or other controlled areas should have solid doors fitted with security locks and alarms.
• Stationery (Requisition books, order books, blank prescription forms) to be kept in a locked cupboard.

(4) Training and Education
• CPD
• Nurses – includes:
  o Imms and Vaccs
  o Cold Chain
  o Medicines Management
  o Patient Group Directions
  o Cytotoxics

(5) Records
• Controlled Drugs
• Treatment notes
• Medical Notes
• Prescribed medicines
• Prescriptions log for order/ receipt/ use of blank prescriptions
• Training

(6) Risk Management
• Incident reporting system in operation
• Risk register
• Risk treatment plans

The above list is not exhaustive, but covers the main areas that should be considered for audit.

21.5 Inspection of Locala Premises

All Locala premises (community clinics, team bases and other service centres), will be inspected by a member of the Medicines Management Team usually on a bi-annual basis.

The purposes of these inspections are to:

• Ensure the safety of patients.
• Provide information on the standards required for satisfactory performance and compliance with legislation relating to the control and use of medicines.
• Establish safe and efficient systems for medicines control and use within Locala
• Reduce risks in the day-to-day operation of the components of medicines control and use.
• Ensure that the quality of prescribing, recording, administration, storage, disposal and monitoring of medicines is of the required standards.
• Support medical, nursing, pharmacy, dental and other staff dealing with all aspects of medicines whilst delivering safe, appropriate care with medicines for patients.
• Achieve continual improvement in the use of medicines in Locala by promoting effective risk management.
• To ensure that the standards laid out by the Care Quality Commission are met.

22. Equality Impact Assessment

All public bodies have a statutory duty under the Race Relation (Amendment) Act 2000 to “set out arrangements to assess and consult on how their policies and functions impact on race equality.”
This obligation has been increased to include equality and human rights with regard to disability age and gender. The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

In order to meet these requirements, a single equality impact assessment is used to assess all its policies/guidelines and practices. This policy was found to be compliant with this philosophy (see appendix C).

23. Training Needs Analysis

In order to ensure that policies, guidelines and protocols are introduced and work effectively, there is a need to provide adequate training and instruction. As a result, the author of this document has carried out a training needs analysis which has identified the staff who require training, the methodology of training delivery and the frequency that the training will be provided. The policy author must ensure that the details of this training are passed to the Education and Training Department and where necessary, this will then be included in the Locala Training Prospectus.

24. References

This Policy recognises the following statutory and advisory publications concerning the safe and secure handling of medicines and should be read in conjunction with:

- NMC Standards for Medicines Management 2008
- The Code of Professional Conduct NMC 2008
- The Medicines Act 1968
- The Misuse of Drugs Act 1971
- The Misuse of Drugs Regulations 2001
- The Controlled Drugs (Supervision and Management of Use) Regulations 2006
- Medicines for Human Use (Marketing Authorisations etc) Regulations 1994
- Building a Safer NHS: Improving Medication Safety Department of Health 2004
- The Safe and Secure Handling of Medicines (Revision of Duthie Report 1988) 2005
- The Health Act 2006
- Patient Group Directions Health Services Circular 2000/026
- Medicine Matters Department of Health 2006
- Control of Substances Hazardous to Health (COSHH) Regulations 1999
- Department of Health Safe Management of Healthcare Waste 2011

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We would like to thank NHS Kirklees for sharing their Medicines Management policy which has been amended and reviewed for use within Locala.
DEFINITIONS

Administer
To give a medicine by either introduction in to the body (e.g. orally or by injection) or by external application (e.g. cream or ointment).

Head of Medicines Management
The lead Pharmacist for medicines management who provides pharmaceutical advice on the management of medicines within Locala, including establishing, monitoring and reporting on systems that ensure the safe and secure handling of medicines.

Community Nurse Prescriber
Nurse prescribers are registered nurses, district nurses, health visitors, school nurses or registered midwives who have successfully completed an accredited nurse prescribers’ training course and who are recorded with the Nursing & Midwifery Council (NMC) as a Nurse Prescriber. Nurse prescribers may prescribe from within the appropriate section of the Nurse Prescribers Formulary (NPF)

Controlled Drugs (CD)
Controlled drug means a drug in Schedule 1, 2, 3, 4 or 5 of the Misuse of Drugs Regulations 2001

CD Accountable Officer
The person within a healthcare organisation who takes formal responsibility for all controlled drug handling and governance issues in their organisation. The Locala appointed CD Accountable Officer has responsibility for ensuring the safe, effective use and management of CDs within the organisation

Dentist
A dentist fully registered with the General Dental Council

Dietary Product
A product included in the list of foods in Appendix 7 of the BNF

Dispense
To prepare a clinically appropriate medicine for a patient to self-administer or for administration by another. This function must be performed under the supervision of a pharmacist or dispensing doctor.

Doctor/General Practitioner (GP)
A doctor registered in the UK with the General Medical Council.

General Sales List Medicines (GSL)
A licensed product on the general sales list that can, with reasonable safety, be sold or supplied otherwise than under the supervision of a pharmacist.

Medicine
A substance, which may be administered for the purpose of diagnosis or for preventing or treating disease.

Medical Independent Prescriber
A UK registered doctor or a dentist (prescribing from the Dental Formulary)

Non-Medical Prescribing
Non-medical prescribing is the term used to describe any prescribing that takes place by another professional other than a doctor or dentist
Non-Medical Independent Prescriber A first level registered nurse, registered midwife or pharmacist who has completed the independent/supplementary" prescribing” course and has this recorded with the Nursing & Midwifery Council or Royal Pharmaceutical Society of Great Britain. Independent prescribers may prescribe from within the BNF restricted by their area of professional competence and with limitation on some controlled drugs.

Nurse
A nurse fully registered with the Nursing and Midwifery Council

Locala Employed Community Nurse/Practice Nurse
Includes School Nurses, District Nurses, Health Visitors, Practice Nurses and Nurse Practitioners employed by the organisation, public health nurses, palliative care specialist nurses, and other Specialist Nurses.

Podiatrist
A person who is registered in the register established and maintained under Section 2 (1) of the Professions Supplementary to Medicines Act 1960 by the Chiropodists Board.

Practitioner
Practitioner is a term used to describe a registered medical practitioner, registered nurse, pharmacist, dentist or other authorised healthcare employee.

Prescribe
To authorise in writing the supply or administration of a medicine.

Prescription Only Medicine (POM)
Medicines which may be sold or supplied from pharmacies in accordance with a prescription from a practitioner who is authorised to prescribe them, and which are specified in the Prescription Only Order.

Pharmacy Medicine (P)
Any product which is not a prescription-only medicine (POM) or a general sale list medicine (GSL) is a pharmacy medicine. Pharmacy medicines must be supplied by or under the supervision of a pharmacist from a registered pharmacy but can be supplied without a prescription.

Pharmacist
A pharmacist fully registered with the General Pharmaceutical Council (GPhC)

Pharmacist Supplementary Prescriber
A registered pharmacist who has completed an accredited training course and is registered as a pharmacist supplementary prescriber with the General Pharmaceutical Council (GPhC)

Supplementary Prescriber
A supplementary prescriber is an allied health professional who has completed an accredited training course in supplementary prescribing and has this recorded with their professional body, Nursing & Midwifery Council (NMC) or the General Pharmaceutical Council (GPhC)

Supply
To supply a medicine to a professional, patient or carer for administration

Service Centre
A location from which healthcare is provided or which serves as a base for peripatetic practitioners. The term is used to include community clinics, adult training centres, special schools, walk-in centres; Locala led Personal Medical Services (PMS) practice surgeries etc.

WYCSA West Yorkshire Central Services Agency
# Key Stakeholders Consulted/Involved in the Development of the Policy/Procedure

<table>
<thead>
<tr>
<th>Stakeholders name and designation</th>
<th>Key Participant Yes/No</th>
<th>Feedback requested Yes/No</th>
<th>Feedback accepted Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines Management Committee - Locala</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Lucianne Ricketts – Head of Medicines Management - Locala</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Medicines Management Team - Locala</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Service Managers – Locala (T30)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Clinical Leads - Locala</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Team leaders – Locala (T60)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Senior Management Team – Locala (Temporary T7)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Karen Poole – Clinical Development Manager, Children and Families, NHS Kirklees</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Jane O’Donnell – Deputy Director of Infection Control, NHS Kirklees</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Karen McClean (WYCSA)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Equality Impact Assessment Tool

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

<table>
<thead>
<tr>
<th>Insert Name of Policy / Procedure</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines Management Policy – A Guide to the Safe and Secure Handling of Medicines</td>
<td>Yes/No</td>
<td>Comments</td>
</tr>
</tbody>
</table>

1. **Does the policy/guidance affect one group less or more favourably than another on the basis of:**

   - Race
   - Ethnic origins (including gypsies and travellers)
   - Nationality
   - Gender
   - Culture
   - Religion or belief
   - Sexual orientation including lesbian, gay and bisexual people
   - Age
   - Disability - learning disabilities, physical disability, sensory impairment and mental health problems

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?**

   - NA

4. **Is the impact of the policy/guidance likely to be negative?**

   - No

5. **If so can the impact be avoided?**

   - NA

6. **What alternatives are there to achieving the policy/guidance without the impact?**

   - NA

7. **Can we reduce the impact by taking different action?**

   - NA
1. BACKGROUND

All providers of NHS services have a statutory duty, in accordance with Regulation 13 of the Health and Social care Act 2008 (Regulated Activities) Regulations 2010, to ensure that they protect service users against the risks associated with the unsafe use and management of medicines. The Medicines Management Committee is a sub-committee of the Board, which assures appropriate arrangements for obtaining, recording, handling, using, safekeeping, dispensing, safe administration and disposal of medicines are in place. The committee has authority to act in independence and to pursue any area within its terms of reference. The Medicines Management Committee reports to the Board via the Executive Management Group (EMG).

2. PURPOSE OF THE COMMITTEE

The Committee will steer and support systems and processes to ensure decisions and advice (Including guidelines, policy, PGDs etc) relating to medicines and medicines management are cost effective, safe and evidence based to assure positive patient outcomes.

3. OBJECTIVES

- To support clinical governance in Locala through effective policies that assure best practice in prescribing, supplying (procurement, storage, dispensing, safe handling and distribution), administering and monitoring of medicines and compliance with any regulatory requirements, including NICE guidance, MHRA and NPSA.

- To advise the Board via EMG on all aspects regarding policy and practice for supply of medicines.

- To provide assurance that actions in relation to medicines management have been implemented in a safe manner with ongoing monitoring and review.

- To work with external organisations to facilitate seamless care across the interface in relation to prescribing and medicines management.

- Through peer review and with consideration to safety, efficacy and cost-effectiveness, make recommendations regarding the introduction of medicinal products, medical devices and products used to administer drugs that are new to Locala. This will be done in liaison with relevant external medicines committees as necessary.

- To ratify and register all unlicensed medicinal products supplied or administered throughout Locala.

- To review, approve, provide, promote and encourage adherence to both national and local prescribing guidelines or formularies and encourage and support the development and implementation of formularies as required for individual service units in accordance with evidence based medicine and best practice.
To discuss and endorse advice and education on developments in health care (particularly for new medicines) and legal obligations in relation to statutory guidance, for our prescribers and health professionals handling medicines.

To authorise documentation associated with the prescribing and administration of medicines. This includes that which may form part of Locala policies, standard operating procedures or guidance that is primarily the responsibility of other Board sub committees to ratify.

To monitor and review medicines related incident reports and develop appropriate action plans to reduce risk and share learning amongst staff.

To ratify and approve Patient Group Directions which enable appropriately trained Locala staff to supply and administer medicines. In exceptional circumstances Patient Group Directions can be approved in between the Medicines management committee meetings via Chairman’s action. Formal approval of the PGD will take place at the next available committee meeting.

Via the Key Objectives, Risks and Opportunities (KORS) plan ensure the Board and EMG are appraised appropriately of ongoing areas of work, any areas of concern/risk and areas of achievement and provide advice on financial issues relating to medicines and service developments

To ensure patient / public involvement in the use of medicines within Locala.

To monitor compliance with the Risk Management Standards for Primary Care Organisations Clinical Care, Medicines Management; 1.4.6, 2.4.6 and 3.4.6.

To monitor compliance with Care Quality Commission ‘ Essential Standards of Quality and Safety’ Outcome:9 Management of Medicine

To explore Strategic Service developments and new ways of providing medicines management services to patients.

To discuss potential QIPP areas in relation to prescribing, and agree which initiatives should be implemented to improve the cost efficiency and cost-effectiveness of prescribing locally, including ongoing monitoring of performance against agreed QIPP area targets, and identification of areas where achievement is not in line with agreed QIPP financial efficiency plans, and to agree necessary actions to address any such concern areas

**NON MEDICAL PRESCRIBING**

To inform and provide the strategic direction for the development of non-medical prescribing within NHS Kirklees and Locala, maximising the benefits for the patient, employer and workforce, whilst managing and minimising the risks associated with non medical prescribing.

To promote safe, cost effective and appropriate prescribing competence amongst qualified non-medical prescribers within NHS Kirklees and Locala and provide ongoing support and leadership.

To explore Strategic Service developments and new ways of providing services to patients via the non medical prescribing route.
4. ORGANISATION OF THE AGENDA & REPORTS

The agenda will be organised to:
- Include appropriate standing agenda items
- Facilitate engagement
- Include local, regional and national priorities
- Highlight Key opportunities, risks and successes to the Board via EMG.

5. REPORTING

The Medicines Management Committee will report to the Board via the EMG for required ratification of any decision made by the Medicines Management Committee. The minutes of the meeting with the KORS information sheet will form the basis of this report.

6. MEMBERSHIP

Core membership:
- Director of Clinical and Operational Services (Chair)
- Head of medicines management (Deputy Chair)
- Medical Lead
- Non Medical Prescriber representatives (Community matron, District nurse, Health visitor, nurse practitioner, Allied health professional)
- Head of Integrated Governance
- Informatics lead
- Medicines Management Team representatives
- Patient representative
- Administrative support

Core members are asked to nominate a deputy with appropriate decision making authority.

Co-opted members
- University of Huddersfield non medical prescribing lead

Other people will be co-opted as necessary.

Groups/committees reporting to the Medicines Management Committee:
- Patient Group Directions Group

Relationship with NHS Kirklees:
- Locala will maintain attendance to the NHS Kirklees Medicines management committee or subsequent replacement committees and will have the same level of membership as local hospital trusts.
- Applicable portions of the minutes are to be shared with NHS Kirklees via the Head of Medicines Management.
- Applicable portions of the minutes will go to the South West Yorkshire Area Prescribing Committee via the Head of Medicines Management.

NB: When sharing minutes of meetings commercially sensitive information will be removed.

Key external committee links
- NHS Kirklees Medicines Management Committee or subsequent replacement committee(s)
- South West Yorkshire Area Prescribing Committee
- South West Yorkshire Area Wound formulary sub group
6. **QUORUM**

In order for the meeting to be quorate a minimum of 5 people must be in attendance, including the chair or vice chair and at least 2 non medical prescribers.

7. **FREQUENCY OF MEETINGS**

Meetings of the Medicines Management Committee will be formal. The committee will meet every 2 months, on a specified day during normal office hours.

8. **SUPPORT TO THE COMMITTEE**

The Group will receive administrative support in agenda setting, distribution of all relevant papers and minutes from the Medicines Management Team administrative support.

10. **CONDUCT OF BUSINESS**

1. Agendas and papers will be circulated to committee members at least 3 working days before the meeting.
2. Minutes of the meeting and the KORS plan will be circulated no later than 7 working days after the meeting to gain members informal approval that they are a correct representation of the meeting before being forwarded to EMG. Minutes will be formally ratified at the next medicines management committee meeting.
3. This committee will operate in accordance with Locala’s guidance for Chairs and Minute Takers.
4. All members must declare any conflict of interest they may have regarding an agenda item at the start of the meeting.

11. **REVIEW DATE**

These Terms of Reference will be reviewed on an annual basis. The review will include a thorough assessment of how each objective has been met during the past year and whether each one is to remain, be amended or deleted from the terms of reference if no longer appropriate/applicable.

*Approved by Board: October 2011*
*Review Date: October 2012*
## PRESCRIPTION FORM TYPES (updated October 2006)

<table>
<thead>
<tr>
<th>Paper type</th>
<th>Colour</th>
<th>Purpose</th>
<th>Order code and format</th>
</tr>
</thead>
</table>
| FP10NC     | Green  | Hand-written prescription – prescriber details, address etc. printed by manufacturer. For use by GPs + Hospitals | FP10NC – GPs - Glued at top 50-form pad  
FP10HNC – Hospitals - Glued at top 50-form pad |
| FP10SS     | Green  | Computer single sheet prescription - prescription & prescriber name, address etc printed by computer prescribing system. For use by GPs (and hospital/ supplementary prescribers using accredited systems) | Single sheet printer forms  
Box 2000 forms  
Also used by services eg. Deputising where the form is part printed and then the patient's prescribers details are entered onto the prescription when the patient is seen |
| FP10MDA    | Blue   | Drug Mis-use instalment prescription can be either –  
Pre-printed with prescriber name, address etc. printed by manufacturer - occasional use” form for GPs, hospitals and supplementary prescribers or  
Single sheet blank forms with prescriber name, address etc printed by prescriber’s computer prescribing system. For use by GPs, hospitals and supplementary prescribers | All products A4 width  
FP10MDA-S – GPs - Glued pad of 10 forms  
FP10HMDA-S – Hospitals Glued pad of 50 forms  
FP10MDA-SP – Supplementary prescribers - Glued pad of 10 forms  
FP10MDA-SS - GPs, hospitals and supplementary prescribers – box of 500 forms |
| FP10P      | Lilac  | Hand-written prescription pad. Prescriber name, address etc & type of prescriber eg. “Extended Formulary Nurse” printed by manufacturer. For use by nurse, supplementary/additional prescribers and Out of Hours Centres | FP10PN – Practice nurses - Glued pad of 50 forms  
FP10CN – Community nurses - Glued pad of 50 forms  
FP10SP – Supplementary prescribers - Glued pad of 50 forms  
FP10P-Rec – Out of Hours Centres - Glued pad of 50 forms |
| FP10D      | Yellow | Community Dentist prescription | Glued pad of 50 forms |
| FP10PCDSS  | Pink   | Private Controlled Drug Single Sheet prescription. For use when prescribing controlled drugs in a private environment only | Box of 500 forms |
GOOD PRACTICE GUIDELINES FOR THE SAFE AND SECURE HANDLING OF PRESCRIPTION FORMS FOR NON-MEDICAL PRESCRIBERS

1. Responsibility of the Individual Prescriber

Treat the prescription pad as you would a cheque book:

DO

• Keep the pad with you in your bag or on your person whilst out of the office.
• Consider only taking one or two prescriptions out with you.
• Secure the pad in a locked drawer in your place of practice when not in use.
• Record the number of the first and last prescription in each pad, and the date on which they were used. This can be done in your work diary.
• Notify your manager immediately if any forms or the pad go astray.
• Return all unused prescriptions to your manager if leaving Locala.
• Only use your own prescription pad, and check it’s yours before writing on it.

DON’T

• Pre-sign blank prescription forms.
• Leave the prescription pad in your car - 80% of GP pads that go missing are stolen from cars
• Leave the pad unattended on your desk.
• Have more than one prescription pad in use at any one time.
• Let any other practitioner use your prescription pad.
• Use any other pad except your own - if you run out of prescriptions you will not be able to prescribe until you get another pad!

2. Responsibility of Locala or Practice Base

• Provide secure, lockable storage for prescription pads.
• Ensure the provision of new prescription pads as required.
• Minimise the risk of fraud by recording the numbers of the first and last prescription in each pad at the central and local distribution centres.
• Inform the Non Medical Prescribing lead or the Community Services pharmacy manager with details of practitioners leaving Locala.
• Retrieve unused prescription pads from non-medical prescribers leaving Locala, or when prescription pads are no longer required (ie. moving to a non-prescribing role). ALL prescription pads MUST be returned to the Service Managers PA for secure destruction. They should be annotated as returned on the individual non medical prescribers prescription record log and signed out of the log when shredded.
Appendix G

PARENTERAL ADMINISTRATION

Legislation provides that no one may administer a parenteral Prescription Only Medicine otherwise than to himself, unless he is a practitioner or is acting in accordance with the directions of a practitioner.

The following list of medicines for use by parenteral administration is exempt from this restriction when administered for the purpose of saving life in an emergency.

Adrenaline Injection (1 in 1000)
Atropine Sulphate Injection
Atropine Sulphate and Obidoxime Chloride Injection
Atropine Sulphate and Pralidoxime Chloride Injection
Atropine Sulphate, Pralidoxime Mesilate and Avizafone Injection
Chlorphenamine Injection
Dicobalt Edetate Injection
Glucagon Injection
Glucose Injection 50%
Hydrocortisone Injection
Naloxone Hydrochloride
Pralidoxime Chloride Injection
Pralidoxime Mesilate Injection
Promethazine Hydrochloride Injection
Snake Venom Antiserum
Sodium Nitrite Injection
Sodium Thiosulphate Injection
Sterile Pralidoxime
Prescribing of Unlicensed & Off-Label Drugs

Information relating to the issues surrounding the prescribing of unlicensed drugs and licensed drugs for unlicensed uses (off-label) by nurse prescribers.

What’s in a Licence?

Licenses cover the whole product not just the active ingredient. UK product licences are awarded by Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMEA).

A product license will cover all of the following:

- The indication for the product (and sometimes its place in therapy)
- The patient group for which the product is to be used.
- The name, strength and dose of the product
- The product's formulation
- The products method of administration

What is an Unlicensed Product?

Quite simply it is a medicinal product intended to diagnose, prevent or treat disease that has not been awarded a licence to be marketed in the UK.

Some products may have been granted licences in other countries, such as the USA, but they are still classed as unlicensed in the UK. Some products are produced routinely by “specials manufacturers” in unlicensed formulations. E.g. Spironolactone solution from Rosemont. This is an example of a product made “under licence” but which itself does not hold a licence. This means that the manufacturer is a quality organisation and you will get what is says on the bottle, but that the effectiveness of the contents cannot be vouched for.

When is a Product “Off-Label”?

When there is any deviation from the details of the licence in the way a product is used, it is referred to as off-label.

Off-label use can be:

- A product that has a licence for another age group e.g. Methylphenidate used for ADHD in a child under 6 years old.
- A product used for an indication outside of the licence e.g. Metformin for polycystic ovary syndrome
- A product used in an unlicensed route e.g. Glucose 5% iv solution used s.c for dehydration
- A product that is prepared in some manner not included in the licence e.g thiamine tablets crushed and mixed with water and put down a PEG tube.
- A product used in a dose for which it is not licensed.

Informed Consent

Patients expect top quality healthcare that is assured by legal frameworks, clinical excellence and high-powered regulation. They also expect failures in healthcare to be the result of justifiable risks.
In the UK the quality of drugs is regulated by the MHRA (Medicines and Healthcare products Regulatory Agency; see MHRA – Medicines and Healthcare products Regulatory Agency - Home page). Unlicensed drugs and drugs used off label do not have the backing of the UK regulator so their use must be based on robust legal frameworks and the best clinical evidence.

Before prescribing unlicensed or off-label drugs, the patient must be informed that the products are not endorsed by the UK regulator. This must be documented in the patient’s record together with confirmation that the patient has consented to an unlicensed treatment being used.

**Licensing & Best Practice**

In some circumstances excellent clinical practice requires the use of an unlicensed or off label drug. A drug licence is a product of commercial pressures as only drug manufactures apply for licenses. Where there is no commercial advantage to obtaining a licence there is no imperative for a manufacturer to do so. For unlicensed or off label drugs confidence in prescribing relies on the available evidence rather than the product licence.

All prescribing of unlicensed or off-label drugs should be justified by reference to best practice. The evidence used in deciding whether or not to prescribe must enable the prescriber to weigh the risks against the potential benefits.

The more licence infringements included in the selection of the product to be prescribed off-label, the less likely it is that selection of the off-label drug can be justified.

**Legal Considerations.**

Unlicensed products are not quality assured. As the prescriber it is your responsibility to ensure that your patient receives the drug you intended. The best way of doing this is to prescribe a licensed product. The next best is to prescribe a product manufactured “under licence” by a quality manufacturer. Lastly you can prescribe a product that you are happy with the active ingredient but rely on it being manufactured as a “special”. In rare circumstances "specials" might be prepared in a pharmacy.

You will be entirely responsible for all the effects the unlicensed or off label drug has on your patient, both good and bad.

**Competence & Professional Considerations**

A nurse must only prescribe within their field of competence. To prescribe a drug competently the nurse must know:

- The indication for the drug and its place in therapy
- The drug’s effects.
- The drug’s side effect profile
- The dose of the drug
- The drug’s method of administration

For more information see the [NPC Competency Framework for Nurse Prescribers](#)

Nurses are professionally obliged to be familiar with the potential side-effects of any medication they prescribe. When prescribing an unlicensed or off-label drug the listed side-effects of the medicine cannot be relied upon. For this reason any prescriber seeking to prescribe an unlicensed or off label drug should seek advice from the drug manufacturers or a pharmacist on what side effects might be anticipated.
### Legal Framework for Nurse Prescribers

<table>
<thead>
<tr>
<th></th>
<th>Community Nurse Prescribers</th>
<th>Supplementary Prescribers</th>
<th>Independent Nurse Prescribers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dressings &amp; Appliances</strong></td>
<td>Can prescribe products in the Drug Tariff NPF. Prescribing must be in accordance with ‘best practice’.</td>
<td>All Drug Tariff dressings and appliances can be prescribed in accordance with ‘best practice’ if included in a Clinical Management Plan.</td>
<td>All Drug Tariff dressings and appliances can be prescribed in accordance with ‘best practice.’</td>
</tr>
<tr>
<td><strong>Unlicensed Drugs</strong></td>
<td>NONE on the NPF</td>
<td>Allowed if included in a Clinical Management Plan.</td>
<td>Can prescribe unlicensed medicines for their patients, on the same basis as doctors, provided that they are competent and take responsibility for doing so.</td>
</tr>
<tr>
<td><strong>Off-Label Drugs</strong></td>
<td>Only Nystatin Oral Suspension</td>
<td>Allowed if included in a Clinical Management Plan.</td>
<td>Can prescribe medicines ‘off-label’ or ‘off-license’. However, Nurse Independent Prescribers must take full clinical and professional responsibility for their prescribing and should only prescribe ‘off-label’ where it is best practice to do so.</td>
</tr>
</tbody>
</table>
UNLICENSED METHODS OF ADMINISTERING MEDICINES

Introduction

Unlicensed methods of administering medicines are ways in which a licensed medicine might be prepared immediately before administering, which are not specifically described within the manufacturer’s Summary of Product Characteristics.

Examples of this are crushing tablets, cutting un-scored tablets, cutting patches, opening capsules, adding liquid medicines to food or drink, adding thickening agents to liquid medicines and giving medicines by un-licensed routes.

There are legal, professional and clinical considerations to be made when administering using an unlicensed method.

The Bottom Line

Prior to administering a medicine by an unlicensed method, the prescriber should be contacted to consider changing to a medicine that will provide the same treatment but that is available in a formulation that is licensed for the intended method or route.

If such a licensed formulation is not available or is not suitable, the nurse should get written authorisation from the prescriber to administer the medicines by the unlicensed method. In addition to this the nurse should seek advice from a pharmacist on the suitability of the prescribed drug for administering by the unlicensed method. The pharmacist should also be asked if the unlicensed method of administering can be expected to affect the efficacy or side-effect profile of the medicine. The pharmacist’s advice should be documented by the nurse.

Choosing the Most Appropriate Formulation

Every effort should be made to use medicines by their licensed method of administration. This may mean changing a prescription to a different formulation or even prescribing a similar drug that is available in the formulation that is needed. For instance a patient with swallowing difficulties may be prescribed tetracycline for an infection. This is only available in tablet form and would require crushing. Changing this prescription to doxycycline, a similar antibiotic, would allow the prescribing of a dispersible tablet.

Advice on suitable substitutions should be sought from a pharmacist.

Clinical Considerations

The effects of a medicine administered by an unlicensed method may be different from those normally expected. This can be due to changes in the amount of medicines released from the preparation or the speed the medicine is released. Some formulations are designed to reduce or eliminate some side-effects or to release the active ingredients at a particular site or under particular conditions. For this reason any nurse who has been authorised to administer a medicine by an unlicensed method should seek advice from a pharmacist on whether the unlicensed method will be safe and effective for the patient. This advice can be taken from any pharmacist but the nurse should make a record of the name of the pharmacist and where they were contacted.

Professional Considerations

Nurses are professionally obliged to be familiar with the potential side-effects of any medication they administer. When administering using an un-licensed method the listed side-effects of the medicine
cannot be relied upon. For this reason any nurse who has been authorised to administer a medicine by an unlicensed method should seek advice from the drug manufacturers or a pharmacist on what side-effects might be anticipated.

Legal Considerations

Manufacturers are not liable for any adverse incident that arises from a medicine that is administered by an unlicensed method. This is because unlicensed methods of administering have not been properly studied or evaluated. This means that the responsibility for the effects of the medicines rests with the health professionals involved.

Any doctor prescribing a medication to be given by an unlicensed method, or any nurse administering a medication by an unlicensed method, is liable for the side effects it causes regardless of whether these might have been predicted. For this reason nurses must get written authorisation from the prescriber that an unlicensed method of administration should be used. This can be on the prescription, the dispensing label or by a separate letter, e-mail or fax.
GUIDELINES FOR COMMUNITY MATRON REFERRAL FOR A PHARMACEUTICAL ASSESSMENT BY THE SPECIALIST PHARMACIST FOR LONG TERM CONDITIONS.

Objectives:
- To provide Community Matrons and other Health Care professionals in the Long Term Conditions Service with a co-ordinated system to identify the need for a Pharmaceutical Assessment for their patients/clients.
- To provide a method for referral.

Rationale:
To develop and implement a tool by which staff in the Long Term Conditions (LTC) Team/Service can identify pharmaceutical needs in individual patients/clients.

Responsibilities
Where appropriate the member of staff who makes a referral for a Pharmaceutical Assessment is responsible for:
- Gaining and recording the patient’s consent for a Pharmaceutical Assessment. This is especially important if a home visit is requested.
- Referring the request for a Pharmaceutical Assessment to the Specialist Pharmacist for Long Term Conditions in a timely manner.

Process Stages:
- Any member of staff in the Long Term Conditions Service may make a referral for a Pharmaceutical Assessment by the Specialist Pharmacist for Long Term Conditions.
- The member of staff considering referral should complete the Pharmaceutical Needs Assessment part of the Community Matron Assessment template on SystmOne.
- If the answer to any of the questions is: Yes, then the referring member of staff should ask the patient if they agree to a Pharmacist from the Long Term Conditions Team carrying out a Pharmaceutical Assessment with the patient.
- The referring member of staff should then phone or task the pharmacist for the Longterm conditions team to ask them to visit the patient.
- The pharmacist will document the outcome of the visit for the medication review/pharmaceutical assessment on SystmOne and complete the medication review level 2 or 3 documentation on SystmOne and send a copy of this to relevant healthcare professionals if necessary. Consent will be obtained from the patient/carer.
- Following the review the pharmacist will liaise with the relevant people. A patient medication information chart may be provided.
PROCEDURE FOR REMOVAL OF MEDICATION FROM A PATIENT’S HOME BY A LONG TERM CONDITIONS HEALTHCARE PROFESSIONAL

Objectives:
- To return all unsuitable or unwanted medicines to the Community Pharmacy for appropriate destruction if the patient or their carer is unable to arrange for this safely and in a suitable time frame.
- To undertake this process and record the name, form, strength and quantity of medicines that are removed.
- To gain approval from the patient to remove unsuitable or unwanted medicines from their home.

Rationale:
To reduce the risks from unsuitable and unwanted medicines stored in the patients’ home and ensure they will be safely disposed of.

Responsibilities:
The professional removing any medicines is responsible for:
- Gaining the patient’s permission.
- Completing the medication removal form.
- Returning all unwanted or out of date medicines to an appropriate Community Pharmacy for destruction.

Process Stages:
- The need to remove any medicines from the patient’s home should be identified during the review process at the home visit.
- Permission should then be gained, from the patient, to remove any unsuitable or unwanted medication from their home.
- A medication removal form should be completed and filed in the case folder held by the relevant professional. You may wish to take a photocopy back at base for the patient’s home file should they request one.
- The unsuitable or unwanted medicines should then be returned to the Community Pharmacy, for appropriate destruction.

Produced by Laura Gardiner Specialist Pharmacist for Long Term Conditions, Medicines Management Team
Date of issue October 2011
Medication Removal Form

Ideally, unwanted medication will be returned to the Community Pharmacy from which the patient obtains their regular medication by the patient/carer liaising directly with that Pharmacy. This form is to be used if a health care professional is removing medication from the patient’s home for safety reasons.

Patient Name: .................................................. Address: ........................................................................

The above patient has been visited at home.

<table>
<thead>
<tr>
<th>Name of Assessor</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role/Profession</td>
<td>Date of Review/Visit</td>
</tr>
</tbody>
</table>

During the review the following medicines were found to be no longer required and have been removed with the patient’s permission for safety reasons.

<table>
<thead>
<tr>
<th>Drug name, form and strength</th>
<th>Total Quantity</th>
<th>Reason for removal*</th>
</tr>
</thead>
<tbody>
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* Reason for removal
  1. Out of date
  2. Stopped
  3. Inappropriate re-ordering
  4. Started on a compliance aid (existing medication is excess to requirements)
  5. If it is for another reason please state the reason

These medicines have been returned to the following Community Pharmacy for appropriate destruction.

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>Telephone Number</td>
<td></td>
</tr>
<tr>
<td>Signature of the Community Pharmacist /Member of staff receiving the medication</td>
<td></td>
</tr>
</tbody>
</table>

I give my permission for the above medicines to be returned to the Pharmacy.

Patient’s/Carer’s Signature and Date.

Please retain this form with the patient’s records held at base and make a photocopy for the patient’s home file to be taken on the next visit.
Each of your medicines has been individually prescribed for you.

At your medication review you have the chance to ask for information about your medication or talk about any concerns.

It is important that you take your medication as you have agreed with the healthcare professional who prescribed it for you.

Tell your doctor, nurse or pharmacist as soon as possible if you think any problems you have could be due to your medication.

Take your medicines as shown on the label. Ask your pharmacist if you are not sure how to take them.

Take only medicines that are part of your current treatment.

Keep them in the container they come in and store them in a cool dry place.

Take any medicines you do not use to your local pharmacy for safe disposal as soon as possible.

Keep medicines out of sight and of reach of children.

Name……………………………….……
Address……………………………….…
………………………………………………
………………………………………………
HEALTHCARE CONTACTS
GP……………………………………....
Tel……………………………………....
Nurse/Matron……………………
Tel:…………………………………………
Local Pharmacy……………………
Address:………………………………..
Tel…………………………………..…..

PLEASE TAKE THIS CARD WITH YOU EACH TIME YOU VISIT YOUR DOCTOR, NURSE OR PHARMACIST.
Name of Patient:

<table>
<thead>
<tr>
<th>Name, form and strength of medicine</th>
<th>How much to take and when</th>
<th>What it is for?</th>
<th>Other useful information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Breakfast</td>
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<tr>
<td></td>
<td>Lunch</td>
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<td>Teatime</td>
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<td></td>
<td>Bedtime</td>
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</tbody>
</table>

Regular medication is recorded on this chart. The names of medicines only taken 'when required' can be listed on the chart with the 'when required' instructions being listed in the other useful information box.

Produced by: 

Job Title: 

Date Produced:

53
Long Term Conditions
Address:

**GP Communication Sheet**

<table>
<thead>
<tr>
<th>To:</th>
<th>From:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref:</td>
<td>Position: Community Matron/ Case Manager/Specialist Pharmacist Long Term Conditions</td>
</tr>
<tr>
<td>Surgery:</td>
<td>Tel: Mobile:</td>
</tr>
<tr>
<td></td>
<td>Fax:</td>
</tr>
</tbody>
</table>

Patient Name:
Date of birth:
Address:
Message:

**Important:** this transmission is only intended for the above addressee. It contains private and confidential information. If you are not the intended recipient, please return to sender. Thank you.