HPFT

Medicines Policy

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Executive Lead	Executive Director Quality & Medical Leadership
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Target Audience	All staff involved in the prescribing, dispensing, ordering, supply, storage, transportation, administration and disposal of medicines.

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8.1	22.04.2018	22.11.20	Chief Pharmacist
Staff need to know about this policy because (complete in 50 words)	The Medicines Policy is the overarching policy with respect to medicines within the trust. It contains legislative, regulatory and best practice guidance with respect to medicines use.		
Staff are encouraged to read the whole policy but I (the Author) have chosen three key messages from the document to share:	1. Prescribe medicines legally and in line with GMC guidance 2. Ensure safe administration of medicines in line with NMC standards for medicines management 3. Ensure that service users are involved in the decision making when medicines are prescribed and administered		
Summary of significant changes from previous version are:	▪ The guidance around the management of controlled drugs has been removed and a separate policy on controlled drugs issued ▪ The references to a local standard operating procedure for the management of medicines have been removed as these documents contained significant overlap with the medicines policy. A new Pharmacy information folder has been created for each inpatient and community area that will contain key information on safe medicines use. ▪ Removed covert meds into a separate policy ▪ Medicines reconciliation section moved into a separate policy ▪ Simple linctus removed from the list of medicines that Nurses are able to administer at their discretionary in inpatient units ▪ Lactulose added to the list of medicines that Nurses are able to administer at their discretionary in inpatient units		

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PART 1 – Preliminary Issues:

1. Introduction

This policy provides the core standards and procedures to be followed by staff employed by Hertfordshire Partnership University NHS Foundation Trust (HPFT) with regards to the safe and effective use of medicines including the prescribing, dispensing, ordering, supply, storage, transportation, administration and disposal.

The policy has been developed in line with the standards and guidance set out by external agencies such as the CQC, Department of Health, Royal Pharmaceutical Society, General Medical Council, General Pharmaceutical Council, Nursing and Midwifery Council etc. The policy is also based on legislative documents such as The Medicines Act 1968, Mental Capacity Act 2005 and Misuse of Drugs Act 1971 etc.

The term service users and patients are used interchangeably in this policy.

2. Objectives

The objective of this policy is to ensure that the prescribing, dispensing, ordering, supply, storage, transportation, administration and disposal of medicines within the Trust follow legislative requirements and best practice.

There is a separate policy on the management of Controlled Drugs.

3. Scope

This policy details the processes for prescribing, dispensing, ordering, supply, storage, transportation, administration and disposal of medicines within all wards, units and services managed by HPFT.

4. Definitions

Dispensing - To supply and label from stock a clinically appropriate medicine to a patient/client/carer, usually against a written prescription, for self-administration or administration by another professional.

Medicines - are defined in the Medicines Act 1968 as '**pharmaceutical products in dosage form for administration to human beings**'. Medical gases, vaccines and preparations of human blood are included in this definition. Medicines are categorised as:

General Sales List Medicines (GSL) - These can be sold or supplied without pharmacist involvement, for example, small quantity pack of paracetamol tablets sold at a supermarket. GSL medicines can also be prescribed by a Dr, Dentist's or Non-Medical prescriber.

Patient/Service User/Client (will be used interchangeably in the policy) - a person receiving care form HPFT NHS Trust

Pharmacy Medicines (P) - These are only available from a pharmacy. P medicines can also be prescribed by a Dr, Dentist's or Non-Medical prescriber.

Prescription Only Medicines (POM) - These can only be obtained in accordance with a doctor's or dentist's or other authorised prescriber's prescription. Antibiotics and vaccines are examples of Prescription Only Medicines. POMs can only be supplied from a pharmacy or from a dispensing doctor. Controlled Drugs are a special category of Prescription Only Medicines, to which the Misuse of Drugs legislation applies.

Medicines Healthcare Products Regulatory Agency (MHRA) - A government agency responsible for regulating medicines and medical devices.

Trust – Trust in this document means "Hertfordshire Partnership University NHS Foundation NHS Trust".

5. Duties and Responsibilities

Executive Director Quality & Medical Leadership - is the lead director on medicines optimisation for the Trust and is the link to the Trust Executive

Chief Pharmacist - is responsible for ensuring that systems are established and maintained for the safe and effective use of medicines including the prescribing, dispensing, ordering, supply, storage, transportation, administration and disposal.

Service line leads and Heads of Nursing – are responsible for ensuring that all staff are aware and comply with the Medicines Policy

Pharmacy Staff – Support the implementation of the Medicines Policy

Prescribers (including Non-Medical Prescribers) – Ensure that medicines are prescribed in line with the guidance within this policy and in a evidence based, safe and cost - effective manner.

Registered Nurses - Ensure that medicines are administered in line with the guidance within this policy and NMC guidelines for the administration of medicines

Health Support Workers, Social Workers and Occupational Therapists – If administering medicines must follow the guidance in the Role of Unregistered Staff in the Administration of Medication Policy

Part 2 – What needs to be done and who by

6. Prescribing

6.1 Prescribing Guidance

All prescribing should be undertaken in an evidence based, cost-effective manner, safely and in line with the BNF, BNF for children, manufacturer's summary of product characteristics, Trust and/or external best practice guidelines etc.

The treatment is based, whenever possible, on the service user's awareness of the purpose of the treatment and their informed consent.

Only the following personnel can prescribe medicines within HPFT:

- HPFT employed medical staff (including locum cover)
- HPFT non-medical prescribers (See NMP policy for further details)
- General Practitioners that provide a service to HPFT under a SLA agreement

Medical students are NOT permitted to prescribe medicines.

Medicines must only be prescribed on:

- HPFT approved trust Drug Prescription and Administration Charts
- HPFT approved trust prescriptions e.g clozapine prescriptions, preformatted titration charts
- FP10(HP)

For supplying medicines under a Patient Group Direction, refer to the trust PGD Policy.

6.2 Prescription Standards

Prescriptions must be in writing, in the form of a prescription or medicine chart "Drug Chart".

In general when writing prescriptions (in-patient charts, outpatient (FP10), take home prescriptions, leave prescriptions) and additionally any communications to General Practitioners regarding medication the prescriber must ensure that the following principles are adhered to:

a) All prescriptions are written:
   - Clearly, legibly and indelibly in black or blue ink preferably in block capitals. The prescription will need to be of a quality that allows it to be photocopied, scanned and/or faxed.
   - Take home prescription forms should have only one item written on each line and additional prescription forms used if necessary
   - Any unused space on the prescription form should be scored through thus not allowing additional items to be written

b) Correct patient identification & details
   - The patient's full name, address, date of birth and NHS number must appear on all prescriptions. Paris number may also be included
   - Age and weight must be stated on all paediatric (under 12 years) prescriptions.

c) Allergy/sensitivity documentation

For medicines charts the allergy section must be completed, signed and dated. When an allergy or sensitivity is recorded, document as much information as possible regarding the details of the reaction. If the service user is confirmed to not have any known allergies/sensitivities the section should be completed as no known drug allergies (NKDA).

d) Drug Name

- The international approved drug name (rINN) must be printed clearly, legibly and indelibly so that each individual letter can be read.
- Do not use chemical descriptions or abbreviations for drug names as they increase the risk of medication errors (*e.g. FeSO4, ISMN are not acceptable)*
- The bioavailability of some medications may vary between different brands, and should be prescribed by brand name; these drugs include: a*nti-epileptics, ciclosporin, diltiazem long acting formulations, lithium, mycophenolate, nifedipine, theophylline modified release, tacrolimus. NB This list is not exhaustive*. *It will sometimes be appropriate to use the brand name, in addition to or instead of the approved name (examples include insulin, some combination products and opioids with particular emphasis on transdermal preparations).*

e) Formulation / Strength

Where different formulations and/or strengths of a preparation are available, it is important that details are correctly stated on the prescription e.g. modified release vs. immediate release tablets/capsules; transdermal opioid preparations.

f) Device

It is important to state the device required for medication such as insulin and inhalers to ensure the patient receives the correct product.

g) Drug Dose

- The dose must be stated on all prescriptions
- Avoid unnecessary use of decimal points. e.g. 3mg (*not 3.0mg*).
- Quantities of 1 gram or more must be written as grams e.g 2g, quantities less than 1 gram must be written in milligrams e.g. 500mg *(not 0.5g), q*uantities less than 1 milligram must be written in micrograms e.g. 100micrograms *(not 0.1mg)*
- When decimal points are unavoidable, a zero must be put in front of the decimal point where there is no other figure e.g. 0.5ml *(not .5ml)*
- Micrograms, nanograms and units must be written in full and not abbreviated however g (grams), mL (millilitres), and mg (milligrams) are acceptable abbreviations. Doses of liquid preparation MUST be written as mg, mcg etc unless there is no equivalent (e.g. lactulose).

h) Route

- Specify the route of administration. Take care when prescribing for different routes as doses may not be equivalent, in which case separate prescriptions for each route must

be written. (e.g. 10mg haloperidol oral dose is equivalent to 6mg haloperidol intramuscular therefore separate prescriptions are required)

- Acceptable abbreviations are: IV for intravenous, IM for intramuscular, SC for subcutaneous, PO for oral, S/L for sublingual, PR for rectal, PV for vaginal, Top for topical, INH for inhaled, NEB for nebulised etc.

i) Directions

- The dosage frequency must be stated on all prescriptions.

For *"as required" medications*, a minimum dose interval must be specified, and where appropriate a maximum dose (e.g. paracetamol 500mg tablets, one to two tablets every four to six hours when required, maximum 8 tablets in 24 hours, for the relief of pain or fever).

- The indication for any "as required" medication should also be stated.
- Directions should be in English without abbreviation; however the following Latin abbreviations are acceptable: *o.d for daily, o.m. or mane for in the morning , b.d. for twice daily, o.n. or nocte for at night , t.d.s. for three times daily, stat for immediately, q.d.s. for four times daily and p.r.n. for when required.*
- Where a limited course of treatment is required (e.g. steroids, antibiotics) this must be stated on the prescription.
- Particular care must be taken when prescribing medication to be taken weekly, monthly etc. It is good practice to cross through the administration boxes on the in-patient chart to emphasise that the dose must only be administered on certain days.
- When a drug is only administered monthly or 3 monthly, it is good practice to record when the last dose was given to ensure an accurate medicines trail.

j) Prescriber's Signature & Date

- All prescriptions must be signed and dated by the prescriber

6.3 Discharge Prescriptions, Medication for Leave and Visits (TTO/TTAs**)**

- Planning for a service user's discharge from a bedded unit (either to the crisis team or into the care of the GP), involves the preparation of a discharge prescription written by a doctor on the Trust's Transfer / Discharge Notification Form. The notification, by virtue of its duplicating design, enables copies to be made for the dispensing hospital pharmacy; the team; the service user's notes and a quick version for the GP ahead of the full discharge summary.

- Planning for a service user's short term leave from a bedded unit (either to the crisis team or normal place of residence), requires the preparation of short term leave medication. The short term leave prescription section of the drug chart should be used by a doctor to order the medication from the Pharmacy.

- Items supplied and labelled for inpatient use should not be issued for discharge, leave or visits. A TTO or short term leave prescription must be written and the supply received from pharmacy. In certain circumstances with agreement with the ward Pharmacist a FP10 prescription may be used.

- Fourteen days' supply is provided for on-going medication unless the duration of the treatment is less. Original packs should not be split if possible. Service users being treated for mental illness, with a history of self-harm in the last three months before discharge, or where there are concerns regarding medication abuse, must receive an appropriate length of supply of medication and should not cover more than two weeks.

- The pharmacy should be given as much as advance notice as possible of the discharge/short term leave medication requirement

- Before returning the service users' own drugs on discharge they should be returned to Pharmacy for checking with the TTO.

- Drugs for service users on bedded units to take on a visit including investigation/treatment appointment such as Electro-Convulsive Therapy (ECT), day surgery etc. should be specifically dispensed by the pharmacy for that purpose. The Transfer/ Discharge Notification Form should not be used for the purposes of short-leaves: the "short leave regular medication TTA" column inside the 4- and 12-week medication charts is used for this purpose.

6.4 Community based treatment teams and prescribing on FP10 (HP) prescriptions

- Prescribing in out-patient departments must be documented in the EPR.
- Prescriptions for out-patient users are generally prescribed on FP10 prescriptions to be dispensed by community pharmacists (Chemist)
- The duration of treatment prescribed should generally be fourteen days' supply with further supplies by the General Practitioner. If there is concern that the service user may be unable to obtain further supplies from the GP within 14 days then additional quantities should be prescribed although generally not longer than one month's supply.
- The prescriber should record details of the prescription in the EPR.
- An FP10 (HP) prescription should not be used if the medicine is not on the Trust Formulary, unless approved through the non-formulary request process
- The FP10 (HP) prescription pads may be subject to misuse and are classed as controlled stationery for security purposes. The pads must be locked away after use and a record maintained of the prescription issued. **If prescription forms are found to have been lost or stolen the prescriber must contact the Pharmacy department at the earliest opportunity**

6.5 Private prescriptions or prescribing

- FP10 (HP) must not be used for personal prescriptions for medical staff or for private service users, under any circumstance.
- Prescribers must not order medication through the Trust for their own use
- Private prescriptions should not be written for NHS service users
- For the purposes of clozapine dispensing by Lloyds Pharmacy under the service level agreement a prescription template is utilised for ordering clozapine

6.6 Supply or administration of medicines through Patient Group Directions

Patient Group Directions (PGD) must comply with legal requirements, and the guidance set out in Health Service Circular 2000/026. For further information refer to the trust policy on *Patient Group Directions (PGDs).* The Chief Pharmacist may be contacted for further advice.

6.7 Prescribing supplying medicines for overseas travel

For patients who wish to have extended vacations or for other reasons wish to travel abroad for an extended period the prescriber and the patient need to be aware of the constraints on taking medicines abroad. The Trust will not normally provide medicines for a period of significant absence (more than 8 weeks) unless agreed with the Chief Pharmacist.

6.8 Prescription Review

Inpatients:

- All inpatient prescription charts must be clinically reviewed by the ward Pharmacist as per the clinical pharmacy standards. Once clinically reviewed the pharmacist will endorse the medication chart in green pen.
- It is good practice to review PRN medication at every medical review. Consideration should be given to a PRN prescription if it is thought that a drug may be required e.g. anti-muscarinic drugs.
- If the BNF/BNFC dose of the PRN medication is exceeded in 24 hours, and the service user requires further treatment, the doctor must be called to review the PRN medication
- All medication should be reviewed and re-written at least every three months

Community based teams:

- Service users using the community/outpatient service should normally have their medicines reviewed at least annually by the medical practitioner or during the Care Programme Approach review meeting whichever is earliest
- Service users on clozapine, depot injections and any other medicines requiring closer monitoring should be reviewed by a clinician / nurse at least monthly and by a doctor or NMP at least 6 monthly
- Pharmacy support to community based teams is provided on a as requested/query answering basis

6.9 Adverse Drug Reactions/Side effects

An adverse drug reaction (ADR) is a reaction which is harmful and unintended, experienced by a patient treated with a medicinal product at doses normally used for diagnosis, prophylaxis or treatment of disease, and where the reporter suspects that there is a possible association between the medicinal product taken and the reaction experienced

Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these are of vital importance. Please report to the MHRA:

- All suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- All suspected ADRs associated with new drugs and vaccines (identified by the black triangle symbol in the BNF or manufacturer's summary of product characteristics: ▼)

Any healthcare professional or member of the public may submit a report to the MHRA. The form to report adverse drug reaction is called a Yellow Card and can be found at the back of the British National Formulary or can be downloaded from MHRA website. The completed form can be posted to MHRA free of cost by just writing "FREEPOST YELLOW CARD" (no other address details necessary) on the envelope. It can also be reported electronically by logging on at www.yellowcard.gov.uk.

7. Service User Medicines Information

When medication has been prescribed, the service user or carer will need to know the following information:

- The name, form and strength of the medication
- The reason for using it
- When and how to take it
- How to know if it is effective and what to do if it isn't
- What to do if one or more doses are missed
- How long to continue taking it
- The risk of stopping it
- The most likely side effects, those unlikely but important and what to do if they occur
- Whether other medicines can be taken at the same time
- Whether other remedies alter the effect of the medicines prescribed
- What foods or drink, e.g. alcohol, should be avoided while taking the medication
- Any lifestyle changes e.g. smoking that may affect the medication
- Advice on how to get repeat prescriptions

A good source of information about mental health medicines is the "Choice and Medication" website which can be accessed via useful links on Trust website or Trust space or it can be accessed online by typing
http://www.choiceandmedication.org/hertfordshire/

It is a legal requirement to issue a patient information leaflet (PIL) with every dispensed medicine. These are supplied within the pack of medicines by the pharmaceutical companies and distributed by the pharmacy. Information leaflets for service users are also available from www.medicines.org.uk. Please note that the information in the PIL will only detail licensed uses of the medicine, so if the medicine is not being used for a licensed indication, further explanation and consent of the patient will be needed.

8. Consent to Treatment

Consent has been defined as voluntary and continuing agreement to a proposed course of action, which may be an examination, a diagnostic investigation or a treatment.

8.1 Informed Consent

Under English Law, Consent is only valid if the following criteria are fulfilled:

- The service user providing consent has the **capacity** to do so
- The service user's decision is **voluntary and definite**, made without coercion, undue influence or deceit.

- The service user has received or been offered the opportunity to receive **sufficient information**, in a way that he/she can understand, about the treatment options available, the nature and effect of the clinician's recommended treatment and substantial risks associated with it. This includes any adverse outcome or side effects and where there may be significant consequences for the service user's employment, social or personal life.

Entries must be made in the EPR detailing the information given and the response of the service user.

HPFT expects all staff to operate a policy of informed consent unless it can be demonstrated that the service user does not have the capacity to consent.

8.2 Capacity to Consent to Treatment

A service user will be judged to have capacity to consent, if, in the opinion of the health professional, he/she has the ability at that time:

- To understand in simple language (including non-verbal means if necessary) what the proposed treatment is; its purpose and why it is being proposed.
- To understand its principal benefits, risks and alternatives.
- To understand in broad terms what the consequences would be of not receiving the proper treatment.
- To retain the information for long enough to make an effective decision.

All discussions with regard to consent and capacity including conversations with service users, relatives and carers/relatives must be recorded in the EPR.

Refer to Trust Policy "Consent to Examination, Care and Treatment Including ECT, Guidance and Procedure".

8.3 The service user who lacks capacity

The Mental Capacity Act (MCA) 2005 provides a legal framework for acting and making decisions on behalf of individuals who lack the mental capacity to make particular decisions themselves. Everyone working with and/or caring for an adult who may lack capacity to make specific decisions must comply with this Act when making decisions or acting for that person,. The same rules apply whether the decisions are life changing events or everyday matters. Refer to the MCA Code of Practice and the Trust policy on "Mental Capacity Act" for further information.

It is the individual professional's duty to act in the best interests of the service user. It is also a doctor's or registered nurse's common law duty to give urgent medical treatment in the best interest to an adult service user unable to consent at the time.

A full discussion should take place within the multi-disciplinary team and a record of discussions and decisions must be made in the EPR. The MDT discussion should include relatives and carers and their wishes and views must also be recorded in the EPR.

The formalisation of the Advanced Directive in the Mental Capacity Act 2005 permits a service user to agree not to have a specific treatment when they become unwell. In all situations where informed discussion and consent is not possible advance directives should be taken fully into account and the individual's advocate and/or carer should be consulted.

Mental capacity decisions should be reviewed at regular intervals, appropriate to the clinical picture of the individual

Consent should be reviewed when:

- medication is changed
- the dose of medication is reviewed.
- renewal of detention under the Mental Health Act 1983

8.4 Children and Young Persons Consent to Treatment

The GMC advises that registrants must decide whether a young person is able to understand the nature, purpose and possible consequences of investigations or treatments proposed, as well as the consequences of not having treatment. Only if they are able to understand, retain, use and weigh this information, and communicate their decision to others can they consent to that investigation or treatment. That means the registrant must make sure that all relevant information has been provided and thoroughly discussed before deciding whether or not a child or young person has the capacity to consent.

The capacity to consent depends more on young people's ability to understand and weigh up options than on age. When assessing a young person's capacity to consent, the registrant should bear in mind that:

- at 16 a young person can be presumed to have the capacity to consent
- a young person under 16 may have the capacity to consent, depending on their maturity and ability to understand what is involved.

If the child or young person lacks the capacity to consent a person with parental responsibility will normally give consent except where the interests of that person and the young person are not compatible.

8.5 Consent and service users detained under the Mental Health Act

For the purposes of the Mental Health Act 1983, medical treatment includes the administration of drugs by all routes. Medical treatment under the act does not include treatment for physical disorders unless that disorder is a symptom or underlying cause of the mental disorder. For further information refer to the Trust Policy on "Mental Health Act".

8.6 Written Consent

It is not required to seek written consent, but it is good practice to do so if any of the following circumstances apply:

- the procedure involves general/regional anaesthesia or sedation
- the treatment is part of a project or programme of research approved by Hertfordshire Partnership University NHS Foundation Trust, e.g. clinical trials

8.7 Refusal of Treatment

After discussion of possible treatment options if a service user refuses treatment, this fact should be clearly documented on the medication chart using the appropriate code and in their EPR. If the service user has already signed a consent form, but then changes their mind, the doctor (and where possible the service user) should note this on the form.

Where a service user has refused a particular intervention, the health care professional must continue to provide any other appropriate care to which they have consented. The service user should be advised they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

Within Mental Health/Learning Disability Services, any refusal of current treatment may need to inform the CPA process.

The situation is different for people detained under the Mental Health Act 1983 with regard to treatment for mental illness and the Trust Policy "Mental Health Act" must be followed.

9. Unlicensed / Off-label Medicines Prescribing

Unlicensed prescribing is defined as prescribing a medication without a current United Kingdom marketing authorisation (formerly known as product licence). These medicinal products tend to be imported, or alternatively manufactured from the raw ingredients also known as "Specials" in the UK by large reputable companies, small independent companies or within hospital pharmacies.

For example:

Example : Pipotiazine depot injection imported from France as no longer commercially available in the UK

In the remainder of the policy "unlicensed medicinal products" will be referred to as UMP or UMPs

Off label prescribing is defined as prescribing a drug that has a UK marketing authorisation but for an indication or at a dose outside the terms of its marketing authorisation. Off label prescribing tends to happen where there is a reasonable evidence base or sufficient experience to use the medicinal product outside the terms of their marketing authorisation.

Examples- *Olanzapine prescribed in excess of the maximum licensed dose of 20mg per day*
Hyoscine hydrobromide "Kwells" for clozapine induced hypersalivation
Lamotrigine in bipolar disorder
Antidepressant prescribing in children

In the remainder of the policy "off label medicinal products" will be referred to as OLMP or OLMPs

When prescribing unlicensed medicines or off label, the manufacturer carries no legal liability for the prescribing outcomes unless harm results form a defect in the medicinal product. The

prescriber and the Trust's responsibilities and potential liability are somewhat increased with unlicensed and/or off label medicines use.

9.1 Unlicensed and off label prescribing guidance from the General Medical Council

Prescribers should usually prescribe licensed medicines in accordance with the terms of their licence. However, unlicensed /off label medicines may be prescribed where, on the basis of an assessment of the individual patient it is concluded, for medical reasons, that it is necessary to do so to meet the specific needs of the patient. For example, unlicensed medicines/off label prescribing may be necessary where:

(a) There is no suitably licensed medicine that will meet the patient's need. Examples include (but are not limited to), where:

- there is no licensed medicine applicable to the particular patient. For example, if the patient is a child and a medicine licensed only for adult patients would meet the needs of the child; or
- a medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child patient, but a medicine licensed for the same condition or symptom in adults would do so; or
- the dosage specified for a licensed medicine would not meet the patient's need; or
- the patient needs a medicine in a formulation that is not specified in an applicable licence.

(b) Where a suitably licensed medicine that would meet the patient's need is not available for example, if there is a temporary shortage in supply

(c) The prescribing forms part of a properly approved research project.

The GMC advises that when prescribing an unlicensed medicine you must:

- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
- make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine

The GMC advises that patients are informed about the licensing status of medicines as follows:

- You must give patients (or their parents or carers) sufficient information about the medicines you propose to prescribe to allow them to make an informed decision
- Some medicines are routinely used outside the terms of their licence, for example in treating children. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population. You must

always answer questions from patients (or their parents or carers) about medicines fully and honestly

- If you intend to prescribe unlicensed medicines where that is not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and your reasons for doing so.

9.2 Off-label use of Medicines In children

This section must **not** be considered in isolation from the rest of the document. There are many drugs which are not licensed for the treatment of children but are widely used in this age group and are therefore used off-label, The Trust supports the stance taken by the Standing Committee on Medicines, a joint committee of the Royal College of Paediatrics & Child Health (RCPCH) and the Neonatal and Paediatric Pharmacists Group (NPPG). It has drawn up a guiding statement on prescribing for children which states:

- Those who prescribe for a child should choose the medicine which offers the best prospect for that child, with due regard to cost.
- The informed use of licensed medicines for unlicensed applications or unlicensed medicines is necessary in paediatric practice
- Health professionals should have ready access to sound information on any medicine they prescribe, dispense or administer, and its availability.
- In general, it is not necessary to obtain the explicit consent of parents, carers or child service users to prescribe or administer licensed medicines for unlicensed indications.
- NHS trust and health authorities should support therapeutic practices that are advocated by a respectable, responsible body of professional opinion.
- Peer approval for prescribing unlicensed or off-label medicines for children is enshrined in the BNF for Children 2005. The Trust will support the prescribing of unlicensed medicines and off label prescribing if it is in accordance with the guidance provided by this publication.
- Where UMPs or OLMPs are dispensed, the manufacturers statutorily supplied patient information leaflet (PIL) will not necessarily reflect paediatric usage. Parents and children may be confused to read that the medicine is not suitable for use in children. To avoid misunderstanding, it is suggested that a patient information leaflet produced by the RCPCH (Royal College of Paediatrics and Child Health and the NPPG (Neonatal and Paediatric Pharmacists Group) if available for that medicine and its intended use is issued alongside the PIL. There is additionally a generic unlicensed medicines use PIL available from the RCPCH and NPPG. The most up to date version of the leaflet can be accessed via the Royal College of Paediatrics and Child Health website (www.rcpch.ac.uk) or via this link.

9.3 Process for prescribing/requesting UMPs and OLMPs

The prescribing of unlicensed medicines within the Trust may only be initiated by a Consultant Psychiatrist. Off label prescribing can be conducted by all grades of medical staff but treatment should be discussed with the Consultant beforehand and documented in the EPR.

If a Consultant wishes to use an unlicensed medicine:

1. The request should in the first instance be discussed with the ward/unit Pharmacist. This discussion must be documented in the service users EPR.
2. Subsequent to the discussion, the unlicensed medicine request form in appendix 1 must be completed and sent to the Chief Pharmacist.
3. The Chief Pharmacist in conjunction with the chair of the Drugs And Therapeutic Committee will review the application and complete the risk assessment section of the form
4. The Chief Pharmacist will notify the requesting Consultant of the decision
5. A copy of the application form and decision must be kept by the Chief Pharmacist and a copy must be scanned into the service users EPR by the Consultant.

In a scenario where the Pharmacy department need to procure a unlicensed medicine for a commonly used stock medicine due to the unavailability of the licensed product (usually due to a manufacturer supply problem) the unlicensed medicine request form in appendix 1 will be completed by the Chief Pharmacist and DTC Chair. The form will be reviewed and approved by DTC. A memo will be sent to all prescribers and nursing staff regarding the use of unlicensed product.

In general the prescribing of unlicensed medicines will remain the responsibility of the Trust. General Practitioners are under no obligation to continue to prescribe UMPs or OLMPs. However, where such prescribing is custom and practice and has national guidance to support it, GPs may feel comfortable to accept clinical responsibility for ongoing prescribing. It is suggested that this is discussed with the GP individually, to obtain their agreement, and that written information is provided, including the risks and benefits of the treatment, and sources of supply if appropriate. The pharmacy department can supply the latter and are able to advise further on the information that may be required by the GP. GPs must not decline to accept prescribing responsibility on cost grounds alone.

For off label prescribing there is no form to be completed or approval process; however there must be a reasonable body of evidence for medicines to be prescribed off label. Off label prescribing should be discussed with service users/carers to ensure they are not confused when reading the patient information leaflet as the information contained will only relate to licensed applications.

10. Formulary and Non Formulary Medicines

The Trust's medicines formulary is a list of medicines that have been approved for use within the Trust. The aim of this formulary is to promote safe, rational and cost-effective prescribing within the Trust and wider health economy. This formulary comprises of a list of medicines and their respective formulations that have been approved for use by the HPFT Drugs and Therapeutics Committee (DTC), or have been routinely prescribed in psychiatry over many years. All drug treatments initiated for service users within HPFT should be selected from this prescribing list. Recommendations made to GPs for prescribing in primary care should also be from this list unless indicated not suitable for primary care prescribing. The trust formulary is available on the HPFT internet or via this this link. As a mental health and learning disabilities Trust, HPFT formulary will generally only consider and include applications for medication to treat psychiatric or related conditions, and will otherwise follow the recommendations of

Hertfordshire Medicines Management Committee (HMMC) where such treatments are initiated within the Trust.

The DTC will be responsible for the decisions around the drug choices that appear in the formulary. The Area Prescribing Committee (Hertfordshire Medicines Management Committee) will be asked to further ratify decisions on drugs that are considered appropriate for primary care prescribing. The Pharmacy team will horizon scan for all new medicines relevant to HPFT and proactively aim to review new medicines. It is the responsibility of the DTC to consider whether the medicines are added onto the trust formulary, however for prescribing to be able to transfer to primary careHMMC will also be required to review the application and authorise. Adherence to the Trust Formulary will be monitored and fed back to clinical teams and DTC.

If a prescriber wishes to initiate a medication that is not on the trust medicines formulary or has been designated non formulary an application must be made to the drugs and therapeutic committee using the form in appendix 2.

If the request is for permanent inclusion into the formulary the consultant with support from the Pharmacy team will need to produce a written evaluation. Evaluations produced by the product manufacturer/pharmaceutical company will not be acceptable. The committee's decision, together with the evaluation, will be referred to the Director of Finance for comment and approval if there is a significant budgetary implication**.** Shared Care Guidelines may be required by the Clinical Commissioning Groups. Where a psychiatric medication is recommended by a NICE technology appraisal, the medication will still be discussed at DTC and HMMC to confirm place in therapy before introduction into use within the Trust within the statutory time limits. The pharmacy team will lead this process and will discuss with key clinicians to inform place in therapy and likely volume of use.

11. Transcribing Prescriptions

Transcribing by registered nurses should only be done in exceptional circumstances. The Nursing and Midwifery Council (NMC) Standards for Medicines Management states "As a registrant you may transcribe medication from one direction to supply or administer"' to another form of "direction to supply or administer". The nurse is responsible for their actions and omissions and is accountable for what s/he has transcribed.

All prescriptions given by telephone, fax, text message or e-mail must be confirmed by the doctor who must provide a written prescription at the earliest opportunity, normally within 24 hours.

The transcribing of prescriptions must not include Controlled Drugs (including temazepam).

The procedure for the transcribing of prescriptions is set out below:

11.1 Verbal Orders

Verbal orders are given to a registered nurse by a doctor when they are in the same room but are unable to write up a prescription. They should only be given in extreme circumstances.

Verbal orders must be restricted to medicines commonly prescribed on the ward/unit and the prescription written up by the doctor following the administration, as soon as possible, but no later than within 24 hours.

11.2 Telephone Orders

Telephone orders are not normally permitted in the Trust unless in circumstances where the doctor is not immediately available to see a service user, and there is an immediate need to administer a drug. Telephone orders for controlled drugs (including temazepam) are **NOT** permitted under any circumstances. The following principles should be adhered to:

- Wherever possible an electronic transmission (fax, e-mail or text) should be provided by the prescriber as a follow up to the telephone order. The nurse must ensure that service user confidentiality is maintained. If the device used is not encrypted, patient identifiable information must not be used e.g. use the NHS number used rather than a full name. In the case of a text, the text is deleted from the receiving handset **after** documentation of the content has been made (that is the complete text message, details of sender, telephone number (it was sent from), the time sent, any response given, and the signature and date when received by the registrant and a second signature obtained that the documentation agrees with the text message.
- The fax or e-mail or transcription of the text must be attached to the prescription chart/medicine administration record and entered on the prescription chart by the nurse and administration recorded in the usual way. Where there is no prescription chart, the fax must be attached to the EPR and an entry made on the record.
- In an EXCEPTIONAL SITUATION when it is impossible to obtain a written prescription to prevent deterioration in a service user's condition, an instruction may be given over the telephone to a registered nurse to change a dose or give an additional dose of an existing prescription.
- The nurse retains the right to refuse to take a telephone message to administer a medicine.

All such orders must follow the procedure below:

- The prescribing doctor must either be employed by the Trust or be a General Practitioner that is working under a Service Level Agreement (SLA) for the trust.
- The instructions must only be taken by a registered nurse over the telephone from the prescribing doctor. If possible the conversation should occur over the speakerphone with an additional staff member (ideally a nurse) verifying the conversation. Telephone instructions must then be read back to the prescribing doctor for verification.
- The nurse must record the instructions in black ink in the appropriate place on the prescription chart with the date and time, noting the fact that it was a telephone order from a named doctor. The doctor's name must be recorded with the date and time of the message. Where there is no prescription chart, an entry must be made in the EPR.
- Whenever possible, a second registered nurse or another colleague should witness this procedure and countersign the entry.
- The nurse should request confirmation of the prescription in writing as soon as possible. This request should be recorded.
- Administration should be recorded in the usual way.

11.3 The transcribing of written medication prescriptions by a registered nurse onto a medicines administration record.

This situation only occurs when a service user is admitted as a **non-acute admission** e.g. into a rehabilitation unit, and there is a delay in the medical practitioner attending to write up the prescription card. The fax from the surgery or a copy of a repeat prescription must be available. It is responsibility of the transcribing nurse to ensure that transcribed medicines administration record matches with what the patient currently takes.

Within the Trust the transcribing of medication prescriptions by a registered nurse onto a medicines administration record in order to facilitate administration of medication is only carried out in exceptional circumstances**.** The fax from the surgery or a copy of a repeat prescription must be attached to the record. Due diligence is required to ensure such information is the most recent one and accurately matches with what service user currently takes.

The transcribing of prescriptions must not include Controlled Drugs (including temazepam).

The transcribing can only be carried out by **a registered nurse**. The nurse must record the instructions in black ink in the appropriate place on the medicines administration record with the date and time, noting the fact that it is a transcribed prescription. **A second registered nurse** should witness this procedure and countersign the entry.

Transfer/Discharge Notification Form should only be written by prescribers and not transcribed by any other staff.

12. Transfer of Service Users

12.1 Transfer of service users between wards

When a service user is transferred to another ward within the Trust, the current prescription chart should be used on the new ward until a new prescription chart is written; the ward identification should be amended; the name of the consultant changed and any individually dispensed medicines for the service user must be sent with them to the new placement as part of the transfer process. This may include the patient's own medicines (PODs) if these have been retained for use on the ward.

12.2 Transfer of service users between ward & community team

When a service user is transferred from the inpatient (I/P) setting to a community team, a Transfer/ Discharge Notification Form must be completed by the transferring doctor to enable a full medication history to be disseminated to the team acquiring responsibility for the service user's care after transfer. This will include physical and mental health medication.

12.3 Transfer of service user between one community team & another

On transfer of a service user between community teams, a Transfer/Discharge Notification Form must be completed by the transferring doctor to inform the receiving team of the service user's full medication history so that all previous medication continues to be prescribed until such times as a medication review has taken place by the team and/or the service user's GP.

12.4 Transfer of HPFT service user to acute trust hospital wards

When a service user is transferred from a HPFT service to a service in another hospital/NHS trust in particular acute hospital setting a full up to date medication history regarding mental health medicines should be provided. If possible the service users own medicines should be transferred to the receiving acute trust hospital along with them, if the service user is maintained on clozapine it is imperative that arrangements are made to ensure supply of medication.

12.5 Communication of medicines related information during transfers of care

There is a substantial body of evidence that shows when service users move between care settings the risk of miscommunication around their medicines are a significant problem. Within HPFT this too is an issue and miscommunication incidents have been reported.

Within HPFT, the Transfer/Discharge Notification Form is the key document that should contain the service user's medication regime when transferring care and this must be provided at the point of care transitions. An additional safety measure is to provide a photocopy of the current drug chart in use that supplements the information contained in the Transfer/Discharge Notification Form. This is particularly useful for service users maintained on long acting injections (LAI) as it allows the receiving team to observe the last LAI administration and next due date.

Particular care must be taken when communicating medication changes. Medicines that have been stopped, started or have had their doses changed during the inpatient stay must be clearly documented on the HPFT Transfer/Discharge Notification Form. The HPFT Transfer/Discharge Notification Form must be sent to the service user's GP in order for them to update their clinical systems such that they have the correct medication history.

When receiving referrals from external hospitals/placements, a version of the referring organisation's Transfer/Discharge Notification Form and a copy of the service user's current drug chart must be requested. This will enable/support HPFT clinicians to reconcile the service user's current medicines in a more reliable and timely manner.

13. Administration of Medicines

13.1 Who Can Administer Medicines

Registered practitioners may administer medication within their scope of practice, own competencies and in keeping with their professional guidance. All practitioners are accountable for their actions and omissions.

Registered Nurses

Nursing staff registered with the Nursing & Midwifery Council are the main professional group within the trust responsible for administering medication. Nursing staff should be familiar with the NMC standards for Medicines Management 2010. Nursing staff must:

- Complete and pass the HPFT Medicines Optimisation eLearning 3 yearly

- Undertake a medicines administration competency framework assessment 3 yearly

Agency registered nurses are registered practitioners accountable for their actions, the senior nursing staff employing the agency staff must assure themselves that the agency have the necessary knowledge and skills to administer medication.

Registered nurses may administer medicines to adults without a second checker with the **exception** of intravenous medication, medicines administered by syringe drivers and controlled drugs.

Student Nurses

The administration of medicines is an important part of professional practice and it is essential that student nurses are provided with relevant experience of this activity in order to achieve the outcomes and standards required for registration.

Student nurses must never administer/supply medicinal products without direct supervision.

Student nurses need to be assessed by a registered nurse when administering medicines in a way which provides them with an understanding of the administration and management of medication.

The registered nurse is accountable for identifying the competency levels of the student to consider if the student is ready to undertake administration in whatever form. Equally a student may decline to undertake a task if they do not feel confident enough to do so. The relationship between the registered nurse and the student is a partnership and the registered nurse should support the student in gaining competence in order to prepare for registration.

Student nurses must not administer vaccinations, intravenous or cytotoxic drugs. The student nurse's participation in the administration of controlled drugs is confined to observation and to witness the second check for receipt, administration, stock balances of CDs.

In all cases where a student nurse is involved with the administration of medicines, the registered nurse must remain with the student throughout the process. The student and the registered nurse must sign the service user's prescription chart. Accountability for the safety of the service user and adherence to Trust and standard operating procedures remains with the registered nurse at all times.

Medical Staff

Medical staff can administer medication; however within the trust, medical staff are rarely involved in the administration of medicines unless in emergency situations or for anaesthesia during ECT. Ideally, there should be separation of prescribing and administering duties.

Unregistered Practitioners and Health Professionals registered under the Health Professions Council and Social Workers

The role of the unregistered practitioner (support worker, drug worker, health care assistant as well as social workers and occupational therapists) is diverse within the Trust and they may be required to assist in supporting the administration of medicines. The trust has a specific policy

that supports the medicines management activities of unregistered staff, for further information refer to the Trust Policy on “Role of the unregistered members of staff in the administration of medication”.

Carers

In the community setting, with the agreement of the service user, a carer, having been given information with clear and concise instructions, may support in the administration of medicines to a named individual as deemed appropriate.

13.2 Principles for the Administration of Medicines

The NMC standards for Medicines Management 2010 states that as a nursing registrant you must:

- be certain of the identity of the patient to whom the medicine is to be administered
- check that the patient is not allergic to the medicine before administering it
- know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications
- be aware of the patient’s plan of care (care plan or pathway)
- check that the prescription or the label on medicine dispensed is clearly written and unambiguous
- check the expiry date (where it exists) of the medicine to be administered
- have considered the dosage, weight where appropriate, method of administration, route and timing
- ensure that the medicines to be administer match the prescription
- administer or withhold in the context of the patient’s condition (for example, digoxin not usually to be given if pulse below 60) and co-existing therapies, for example, physiotherapy
- contact the prescriber or another authorised prescriber without delay where contra-indications to the prescribed medicine are discovered, where the patient develops a reaction to the medicine, or where assessment of the patient indicates that the medicine is no longer suitable
- make a clear, accurate and immediate record of all medicine administered, intentionally withheld or refused by the patient, ensuring the signature is clear and legible. It is also your responsibility to ensure that a record is made when delegating the task of administering medicine.

A useful aide memoir to support safe medicines administration is the “10 Rights of Medicines Administration” – see below. A poster version of the “10 Rights of Medicines Administration” for can be downloaded from the Pharmacy Web Page.

RIGHT SERVICE USER CHECK NAME ON PRESCRIPTION CHART, NAME ON DISPENSING LABEL (if present), ASK SERVICE USER TO IDENTIFY THEMSELVES WHERE POSSIBLE (BY OPEN QUESTIONS); CHECK MENTAL HEALTH ACT STATUS (IF T2, T3, S62 OR CTO IS APPLICABLE); MENTAL CAPACITY
RIGHT MEDICATION CHECK ALLERGY STATUS, PRESCRIPTION CHART & VALID DATE; MEDICINE NAME ON LABEL OR CONTAINER (INCLUDING PHARMACY WARNING LABEL & EXPIRY DATE)
RIGHT DOSE CHECK MEDICATION LABEL & PRESCRIPTION CHART; CONFIRM APPROPRIATENESS OF DOSE USING A CURRENT DRUG REFERENCE (E.G BNF OR PIL); CALCULATE DOSE (IF NECESSARY) WITH ANOTHER NURSE (PHARMACIST OR DOCTOR IF 2ND NURSE UNAVAILABLE)
RIGHT ROUTE CHECK PRESCRIPTION CHART & MEDICATION LABEL; CONFIRM SERVICE USER CAN TAKE OR RECEIVE MEDICATION BY PRESCRIBED ROUTE
RIGHT STRENGTH CHECK STRENGTH OF MEDICATION IS APPROPRIATE FOR PRESCRIBED DOSE
RIGHT FORMULATION CHECK PRESCRIBED FORMULATION IS APPROPRIATE FOR SERVICE USER'S NEED
RIGHT TIME CHECK FREQUENCY OF PRESCRIBED MEDICATION; DOUBLE CHECK GIVING PRESCRIBED DOSE AT CORRECT TIME; CONFIRM WHEN LAST DOSE WAS GIVEN (BE AWARE OF ANY PRN DOSE(S) GIVEN CONTAINING THE SAME MEDICATION)
RIGHT REASON CONFIRM RATIONALE FOR PRESCRIBED MEDICATION (SERVICE USER'S HISTORY? WHY TAKING THE MEDICATION?) CHECK IF ANY RECENT CHANGES; REVISIT REASONS FOR LONG TERM MEDICATION; CHECK WRITTEN INDICATION ON PRN PRESCRIPTION
RIGHT RESPONSE ENSURE PRE & POST DOSE MONITOIRNG (INCLUDING SIDE-EFFECTS) ARE CARRIED OUT & CORRECTLY DOCUMENTED, INCLUDING ANY NURSING INTERVENTIONS
RIGHT DOCUMENTATION RECORD ADMINISTRATION IMMEDIATELY AFTER GIVING PRESCRIBED MEDICATION; RECORD TIME, ROUTE & ANY OTHER SPECIFIC INFORMATION AS NECESSARY; IF DOSE RANGE IS PRESCRIBED, RECORD ACTUAL DOSE ADMINISTERED. REMEMBER TO COUNTERSIGN ADMINSITRATION BOX IF STUDENT NURSE INVOLVED.

13.3 Procedure for Nurses to Administer Discretionary Medicines in Inpatient Units

Before administering prescribed PRN (when required) medicines the nurse must ensure that a prescription has been written, dated and signed by the doctor, and includes:

- The medication name
- The dosage
- The route
- The reason for use

- The repeat frequency if any and maximum daily dose

The nurse must be aware of situations when they should liaise with the prescriber

Nursing staff (**Inpatient Units Only**) may administer the three medicines below without a prescription as a "one off"

<table>
<tr><td>Paracetamol</td><td>
Adults and Children over 16 years of age:
TWO 500mg tablets every 4 to 6 hours up to maximum of FOUR doses in 24 hours.

Infants on Thumbswood Ward

<table>
<tr><th colspan="3">Pain; pyrexia (fever) with discomfort</th></tr>
<tr><th>Age</th><th>Volume</th><th>Frequency</th></tr>
<tr><td>3 – 6 months</td><td>2.5ml of the 120mg in 5mls suspension</td><td>4 doses in 24 hours</td></tr>
<tr><td>6 – 24 months</td><td>5ml of the 120mg in 5mls suspension</td><td>4 doses in 24 hours</td></tr>
</table>

<table>
<tr><th colspan="3">Prophylaxis of post-immunisation pyrexia (fever)</th></tr>
<tr><th>Age</th><th>Volume</th><th>Frequency</th></tr>
<tr><td>2 – 3 months</td><td>2.5ml of the 120mg in 5mls suspension</td><td>Single dose then 2.5ml 4 – 6 hours if needed. Further doses must be prescribed.</td></tr>
<tr><td>4 months</td><td>2.5ml of the 120mg in 5mls suspension</td><td>Single dose then 2.5ml 4 – 6 hours if needed. Further doses must be prescribed.</td></tr>
</table>

The Nurse must be aware of situations regarding concomitant medication or any contra-indications and should liaise with the doctor if necessary.
</td></tr>
<tr><td>Nicotine Replacement Therapy</td><td>See Nicotine Replacement Therapy Policy</td></tr>
<tr><td>Lactulose</td><td>15 mL twice daily.

The Nurse must be aware of situations regarding concomitant medication or any contra-indications and must inform the doctor of the administered dose as constipation maybe a side effect of other drug treatments particularly clozapine and opiods.</td></tr>
</table>

13.4 Covert Administration of Medicines

Covert administration of medicine is described as a process where medicine is disguised in food and drink and the service user is not aware that it is being done. For further information please refer to the trust policy for covert administration of medicines.

13.5 Administration of medicines to patients detained under the Mental Health Act (MHA)

Medication for mental health disorders can be prescribed for, and administered to, certain categories of patients detained under the Mental Health Act without their consent, for a period of three months from the day on which such medication was first commenced (the 'three month rule').

Once the three month period has expired, such medication can only be administered to detained patients provided the safeguards referred to in Section 58 of the Mental Health Act have been observed. These require that a Form T2 (patient consents to treatment) or Form T3 (patient does not or cannot consent to treatment) must be completed. These forms document what medications can be administered and need to be used in conjunction with the patient's prescription chart. A patient's T2 or T3 and prescription chart must be kept together at all times. It is the responsibility of the medical, nursing and pharmacy staff to ensure that a valid T2 or T3 form is available for patients detained under the MHA if appropriate. Within community teams, for service users who are under a community treatment order, similar forms to T2 and T3 (CTO11 and CTO12) forms are used.

Further guidance from the pharmacy team and/or Trust Mental Health Act office can be sought. Further information is also contained in the Trusts Mental Health Act policies and procedures which are available on the trust intranet.

14. Dispensing

14.1 Dispensing Prescriptions

Dispensing is a process of labelling and supply of a medicine in accordance with the directions of the prescriber. The dispensing process generally follows the procedure below:

1. A pharmacist checks that the prescription is unambiguous, legible, safe, and appropriate for the service user and has clear directions for administration. The prescriber is alerted if changes to the prescription are required.
2. The pharmacist checks that any newly-prescribed medicines will not dangerously interact with or nullify each other, or result in a serious adverse effect.
3. Additions and amendments to prescriptions by a pharmacist will be made if necessary usually by contacting the prescriber
4. The correct medicine is then selected against the prescription and decanted into an appropriate container or provided in the original packaging and a pharmacy label attached.
5. The final check, on dispensing for accuracy, will be carried out by a pharmacist or by an accuracy checking technician (ACT) who has been formally accredited as competent.
6. Dispensed medicines must be in appropriate containers and must be labelled in accordance with the requirements of the Medicines Act 1968.
7. Dispensed medicines must not be decanted into other containers except in exceptional circumstances e.g medicine compliance aids

All supplying pharmacies will have local standard operating procedures for the dispensing process.

All inpatient areas must utilise the designated hospital Pharmacy for dispensing inpatient, discharge and short term leave medication. In exceptional circumstances or for medications that need to be provided in a compliance aid a FP10 prescription can be used.

14.2 Nurse Dispensing

Nurses in HPFT are not normally authorised to dispense medicines.

The NMC "Standards for Medicines Management" states: Registrants may in exceptional circumstances label from stock and supply a clinically appropriate medicine to a patient, against a written prescription (not PGD), for self-administration or administration by another professional.

If a registered nurse is engaged in dispensing, this represents an extension to their professional practice. The service user has the legal right to expect that the dispensing will be carried out with the same reasonable skill and care that would be expected from a pharmacist.

If in EXCEPTIONAL CIRCUMSTANCES a nurse is required to repackage drugs, a standard operating procedure should be written for the service in conjunction with the Chief Pharmacist, the necessary equipment made available along with a level of assurance on the competence of the nursing staff undertaking the dispensing activity. A visible audit trail must be kept.

The exceptional circumstances are to be agreed by the Deputy Director of Nursing and Quality or the appropriate Head of Nursing and the Chief Pharmacist.

15. Ordering and Supply of Medicines

15.1 Stock Medicines

Each inpatient and community area has a list of stock medicines with agreed stock levels. This should be routinely reviewed every 12 months in conjunction with the ward/unit Pharmacist. For the majority of inpatient wards, the pharmacy staff will re-order stock up to the agreed level for the ward on the designated 'top up' day. Inpatient wards that do not receive a 'top up' service from pharmacy must designate an authorised member of the nursing staff to reorder stock items that need replacing as per the process set out in the ward Pharmacy information folder.

All community clinics must designate an authorised member of the nursing staff to reorder stock items that need replacing as per the process set out in the ward Pharmacy information folder.

All stock medicines received must be checked against the delivery note and confirmation of this check recorded. The delivery note for stock medicines should be kept for two years. Any discrepancies must be reported to the supplying pharmacy.

15.2 Non-Stock Medicines

Medicines not kept as stock on a ward are ordered and supplied by the visiting member of pharmacy staff or on presentation of the medicine chart for an individual patient to the pharmacy dispensary. In patient areas that do not have a Pharmacy on site will need to fax a copy or email a scanned copy of the full medicine chart that includes all the pages and any additional medicines charts , to their supplying pharmacy dispensary.

Pharmacy staff will endorse the supply given on the prescription (e.g. medicine chart) as a record of supply and to provide any necessary additional information as required in the clinical pharmacy standards.

15.3 Resuscitation/Emergency Medicines

The nurse in charge of the ward/clinic is responsible for ensuring that emergency resuscitation medicines are checked each day. If stocks are expired or have been used the ward staff must replace stocks by ordering from their supplying pharmacy. For further information please refer to the Trust resuscitation policy.

15.3 Discharge and Leave Medication (TTAs – To Take Away)

Discharge TTAs should be written on the Discharge TTA prescription form. Short term leave prescriptions must be written using the appropriate section on the drug chart. Both discharge TTAs and short term leave prescriptions must be ordered from the designated hospital Pharmacy. TTAs and short term leave prescriptions should be written 24 hours or more in advance of discharge to ensure the medicines can be dispensed and delivered in a timely manner. Short term leave prescriptions should not exceed a period of 2 weeks. If a service user is discharged whilst on short term leave, a discharge TTA must still be written and medication supplied to complete the discharge process.

15.4 Borrowing Medicines

Medicines should not be borrowed from another location, other than on an exceptional occasion, when a supply is needed urgently and cannot be obtained directly from pharmacy or out of hours. The location lending the medicine should replenish their stocks from Pharmacy the next day.

15.5 Out of Hours

The key details of the hospital Pharmacy including out of hours service provision can be found in the ward pharmacy information folder.

15.6 Procedure for emailing scanned medication orders

Off – site wards/clinics that require medicines outside of pharmacy scheduled visits and receive their medicines from the Kingsley Green Pharmacy should order by scanning the relevant orders and emailing to Harperbury.Pharmacy@hpft.nhs.uk. The request should be followed up with a telephone call to the pharmacy dispensary to ensure that the transmission has been received successfully..

For wards/units receiving a service form the local acute trust pharmacy department please see supply arrangements in the pharmacy information folder.

16. Transport and Receipt of Medicines

Medicines will generally be transported by the hospital portering or transport services, in exceptional circumstances a private courier firm may be utilised. Registered healthcare staff may also transport medication if required; they must have their identification badge on their person at all times. All medicines are delivered in sealed/locked transport boxes or bags.

All medication should be accepted for delivery by the ward or clinic staff and signed for. The medication should be either unpacked or stored in the medication cupboards immediately or temporarily stored in a secure room that has only authorised entry. Medication should be must not be left unattended at any time.

16.1 Transport of medicines from community clinics to patient's residence

When medicines are being transported from community clinic bases to patient's homes/residence for the purposes of administration these medicines become the responsibility of the member of trust staff carrying them. The medicines must be transported in a tamper-evident and secure receptacle that is inconspicuous. Staffs are responsible for the security of medicines in their possession and must act with due care and diligence, if transporting medicines in a car the medicines should be locked in the boot of the car and not be visible from the outside of a car. Due regard must be given to the temperature within the vehicle and medicines must not be stored within vehicles for extended periods.

17. Storage and Security of Medicines

17.1 Storage Arrangements

All pharmaceutical products must be stored in locked cupboards / drug refrigerators with the exception of medicines incorporated into emergency kits e.g. emergency bags/boxes, intravenous infusion fluids, sterile topical fluids, medical gases.

The medication drug cupboards to be used for internal and external medicines should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29). The medication cupboards should be located in a designated, locked clinic room, but if unavailable, in a locked clean utility room, to which patients and the general public do not have access. They must be fixed securely to the wall.

All medicines must be stored in their containers as supplied by pharmacy. They should not be transferred from one container to another or left loose. Additionally:

- Storage conditions should ensure security, and prevent deterioration by humidity, light, extremes of temperature, or exposure to other substances.
- Where required the cold chain must be maintained
- Label details may indicate storage needs
- Cupboard / refrigerator for medicines and pharmaceuticals must not be used for other items, such as money, valuables, food or specimens

- The Pharmacy Team should be consulted prior to the purchase and fixing of medicines cupboards, including refrigerators
- Flammable products - seek advice from Fire Officer and Pharmacy Team
- Where community nurses retain supplies of a service user's medication when it is not advisable to leave them in the home, the medication should be kept in a suitable lockable cupboard at the clinic site.
- Emergency bags/boxes must be kept where they are secure but accessible. The emergency crash bags must be sealed with "tamper evident" seals

The following table provides information on where drugs should be stored.

Type	**Storage**
Medicines Trolley	For storage of drugs in current use on wards/units. The trolley must be locked and secured to the wall when not in use. Drugs should not be stored on the bottom shelf of the trolley if this is not locked.
Medicines Cupboard	For tablets, liquids, injections etc for internal use which are not in current use (e.g. stock).
External Medicines Cupboard	For medicines for external use, disinfectants and antiseptics, medicated and interactive dressings.
Controlled Drug Cupboard	For storage of Controlled Drugs only. No other items e.g. valuables may be stored in this cupboard. The cupboard is normally within a cupboard for internal medicines with a red light to identify when the door is open and comply with the Standards of Misuse of Drugs Act (Safe Custody) Regulations. Temazepam must be stored in the Controlled Drugs cupboard.
Drugs Refrigerator	Drugs requiring storage in a refrigerator will be marked "store in a refrigerator" or state the exact temperature range. (Normally 2- 8^0C). The Ward/Department/Team Leader must ensure that the refrigerator is kept locked. The temperature should be taken using a maximum/minimum thermometer and the maximum/minimum, as well as the actual temperature must be recorded daily, to ensure operation in the correct temperature range. A record of action taken if the temperature is outside these limits should be made. The reset button must be pressed after the daily reading of the temperature. The date of refrigerator defrosting/cleaning and maintenance should be recorded. Refrigerators work best when they are approximately 50% full, so if necessary, cool packs or bulking bags should be used. Items which do not require refrigeration and non-drug items must not be stored in the drugs refrigerator.
Reagent/ Diagnostic agents Cupboard	Reagent/Diagnostic agents for urine testing, blood testing etc.
Individual Service	Some wards have individual locked cupboards for storage of each

User Cupboards	service user's medication.

17.2 Expiry Dates and Shelf Life

All stock must be checked for expiry dates on a regular basis at least every 3 months. In ward areas where a pharmacy technician service is in operation, this will be conducted by the pharmacy technician. In ward areas and clinics where there is no pharmacy technician service available, expiry date checking will need to be conducted by a member of the nursing team. An expiry date is not always present on dispensed containers, since it is understood that medicines are supplied for immediate use. In case of uncertainty, nursing staff are advised to seek advice from supplying pharmacist or from the Pharmacy and Medicines Optimisation Team regarding expiry date guidelines.

When using a medicine which is in the manufacturer's original container, record the date of opening on the label, e.g. for liquid preparations the expiry is 3 months from date of opening or shorter expiry date if specified on the container. Expiry date for antibiotic liquids should be as indicated on the bottle once reconstituted.

Original packs have a stated expiry date which must never be exceeded. Once opened, shelf life may be greatly reduced e.g. eye drops, insulin.

For further information on expiry date checking please see SOP in ward/clinic pharmacy information folder.

17.3 Medicines requiring Cold Chain - recommended for items stored between 2-8^{o}C.

For medicines that require to be stored between 2°C and 8°C it is important to ensure that the cold chain is not broken. The Pharmacy will deliver such medicines in validated cool boxes. The medication should immediately be stored away in the drugs fridge.

The minimum, maximum and current temperature of the drug fridge must be recorded on a refrigerator monitoring form (which can be found in the ward Pharmacy information folder) and be retained for at least two years.

18. Storage and Security of FP10 Prescriptions and controlled stationary

All stationery used to order pharmaceuticals must be kept in a secure, locked place. FP10 prescription forms are intended to be dispensed by community pharmacies, FP10 prescription forms have known to be stolen to obtain medicines particularly those that are liable to abuse. FP10 prescription security is covered in a SOP that can found in the ward/clinic pharmacy information folder.

18.1 Posting of FP10 Prescriptions

It is generally advised that FP10 prescription forms are not posted as they are controlled stationary and will potentially provide access to prescription only medicines for unintended recipients if lost. If for exceptional reasons a prescription needs to be posted it must be done so by signed for delivery postage service that allows a full audit trail and details of the recipient

signing for the package. A safer signed for delivery address would be the Pharmacy that the service user intends to use rather than the service user's home address.

Posting of prescriptions for controlled drugs is NOT allowed under any circumstances.

19. Safe custody of keys that access medicine cupboards and safe storage areas

In in-patient areas the keys for the controlled drug cupboard, medicines cupboard, drug trolley and refrigerator are the responsibility of the nurse-in-charge. These keys should be kept on his/her person at all times or in a digital key safe with limited named staff access.

Keys to the external medicines and reagent cupboards must be held securely, but it is not obligatory for these keys to be on the medicines key ring.

In clinics and community units the keys must be kept securely at all times.

Keys for the controlled drugs cupboard must be kept separately from other keys – see CD policy for further details.

19.1 Lost Keys

Every effort must be made to find the keys or retrieve them from off duty staff as a matter of urgency. If unsuccessful, the Manager must be informed, who will obtain duplicate keys. Arrangements must be made for preserving the security of the medicines until the key is found or new locks fitted. The date and time of issue of duplicate keys must be recorded together with the names of the persons handing over and receiving them. When the original keys are found, the duplicates must be returned to the ward manager and a record of the date and time of return made.

If the lost keys are not found the manager must arrange for new locks to be fitted and make appropriate interim arrangements for drug storage as a matter of urgency. An incident report must be completed and the Pharmacy Department informed.

20. Service User's Own Medicines

Service users should be asked to bring all the medication they are taking into hospital with them when they are admitted. This is to enable the practitioner to gather details of the patient's medication history in order to conduct medicines reconciliation.

20.1 Procedure on Admission

Medication brought into the unit by the service user is the personal property of the service user. A service user's own medicines must not be administered to him/her until a Trust prescription chart has been written by a doctor. The service user/relative/carer should be informed that, if suitable, the drugs may be used during the inpatient stay and/or will be returned on discharge unless therapy is changed. On the ward/unit service users' own drugs must be stored securely in the medicine trolley/ locked medicines cupboard or individual drug locker.

20.2 Use of a Service User's own drugs within inpatient units

A service users own medicines may be used whilst the patient is in hospital if they agree (as they are the patient's own property) however the service users own medication must be examined, preferably by a member of the Pharmacy team to ensure it is suitable for use.

The service users own medication can be used without a member of the Pharmacy team checking their suitability in exceptional circumstances e.g where the Pharmacy is closed and by using the service users own medication it prevents missed doses. In such cases the ward staff must:

- Confirm the identity of the medicine
- Confirm medicine(s) belongs to that service user, for example, by dispensed label.
- Confirm the medicine has been recently dispensed and the expiry date not exceeded.
- Check label states name and strength (if there is one) of the medicine.
- "Loose" drugs should not be used unless they are in a container labelled by a pharmacy
- Check and record quantity of medicine(s) received from the service user.

20.3 Return of Service Users own drugs

If service user's medicines are not used they should be returned to the service user at discharge depending on the final discharge prescription and in particular any medication changes. The risk of giving back medication should be considered before return to the service user with particular note to the quantities being returned.

20.4 Disposal of service users own medication

Medicines may be sent to pharmacy for destruction if they are no longer required or not suitable for use, with the prior agreement of the service user or their representative. Details of patients' own medicines sent to pharmacy for destruction should be noted in the patient's records.

20.5 Removal of service user's medication in the Community

Where the community nurse, e.g. CATT worker, feels that it would be advisable to hold or dispose of a service user's medication, normally for reasons of the safety of the service user, this must be negotiated with the service user and they must give verbal agreement and if possible, provide written consent. An entry must be made in the EPR and the prescriber notified if possible.

Such medication must not be destroyed without the consent of the service user.

20.6 Service User's OTC/Herbal/Complementary Medication

Service users should be asked whether complementary or self-prescribed medications are being taken as these may affect their treatment, for example, by interacting with drugs or reacting with diagnostic markers used in therapeutic drug monitoring. Prescribers should be notified if any such medications are being taken.

If a service user wishes to take complementary medication the prescriber should discuss the issues involved and come to an agreement on its use. If a service user insists on using a medication which would interact with their proposed treatment, alternative treatment should be sought.

If prescribers are uncertain about the suitability of complementary medicines, they should seek advice from the pharmacy team.

The prescriber once satisfied that he/she has sufficient information may then be prepared to prescribe the medication on the prescription chart and the product is stored in a locked trolley or cupboard along with the service user's medication.

Service users should not have any OTC/Herbal/Complementary medication in their possession whilst in an inpatient unit. For safety reasons, any such medication must be locked in the drug trolley and discussion take place with the service user regarding disposal.

Complementary medication is not normally supplied by the Hospital Pharmacy.

21. Self-Administration of Medicines

If a service user requires their medication to be in their possession, e.g. a salbutamol inhaler, arrangements must be made for the safe and secure storage of the medication which prevents access by other service users.

The items for self-administration must be prescribed by the doctor on the drug chart as normal. The named nurse must check that the medication is authorised for self-administration and that the service user has taken the drug and endorse each item "SELF ADMINISTRATION." The administration boxes should be completed with the code for self-administration.

21.1 Self-Administration of Medicines Scheme

A ward/unit may introduce a scheme whereby selected service users administer their own medication e.g rehabilitation units. A self-administration standard operating procedure which meets the specific requirements of the unit must be written. A member of the HPFT pharmacy team must be involved in drawing up the procedure. The procedure is required to be formally agreed by the MDT team e.g Dr, nurse, pharmacist, occupational therapist.

The nurse jointly with other health care professionals is responsible for the initial and continued assessment of service users who are self-administering and have continuing responsibility for recognising and acting upon changes in a service user's condition with regard to safety of the service user or others. This may include assessment under the Mental Capacity Act 2005.

21.2 Aids to Support Compliance

Self-administration from dispensed containers may not always be possible for some service users. Compliance aids e.g. a monitored dose container or a daily/weekly dosing aid, should only be used when all other methods have been considered e.g. reminder charts, large print labels, and when it is thought only to increase the chances of the correct taking of medication.

If a compliance aid is considered necessary, the service user must be risk assessed for their suitability for the compliance aid and their understanding of how to use it safely by the ward/unit pharmacist/technician. All service users should be regularly assessed for continued appropriateness of the compliance aid. Generally the use of a compliance aid within an

inpatient setting should only occur a few weeks preceding the discharge date; this allows the MDT team to support and train the service user in using the compliance aid.

Compliance aids are not usually provided by the trust or SLA pharmacies. Where a compliance aid is required a FP10 prescription should be utilised to order the medications and the community pharmacist should be asked to prepare the medicines in a compliance aid.

In scenarios where the patient requires compliance aids to support short term leave requests an FP10 prescription should be utilised as above. In exceptional circumstances where a pharmacy/pharmacist cannot be utilised to provide a compliance aid a member of the nursing staff can carry out this role as per NMC Medicines Management Standards 2010 however the service user has a right to expect the same standard of skill and care as would be expected from a pharmacist. This includes the same standard of labelling and record keeping, therefore it is recommended that the drug chart is photocopied and provided with the compliance aid.

22. Disposal of unwanted or expired medicines

Unwanted or expired medicines and pharmaceuticals should normally be returned directly to the trust pharmacy following the pharmaceutical waste disposal SOP which is located in the ward/clinic pharmacy information folder. Returns should be packed and transported under conditions which prevent leakage or theft – many of our ward/units now have a blue medication waste disposal bin on site. For return or destruction of Controlled Drugs please see CD policy.

The Environmental Protection Act prohibits the discharge of medicines into public or private sewerage systems. Service users should be advised to return unwanted medicines to their community pharmacist. For vaccines - special procedures apply to the disposal of part used and 'empty' vaccine containers. This is set out in the Trust Policy “Immunisation Guidance and Procedure (Service Users)”.

For disposal of illicit substances please see Controlled Drugs policy.

23. Medication Errors

The potential for error at all stages of the medicines process should **not be under-estimated.** Such incidents may be related to any step in the medicines use process, including prescribing, dispensing, preparation and administration, storage and record keeping. Examples include:

- administration of a medicine to the wrong patient
- administration of the wrong medicine
- administration of the wrong dose
- the wrong route of administration used
- failure to administer a medicine without due reason (i.e. no ‘missed dose’ code recorded on the chart)
- failure to record administration on the chart
- a medicine incorrectly prescribed
- failure to sign and/or date the prescription
- a medicine incorrectly dispensed
- a medicine incorrectly stored

All medication related errors must be recorded in line with the Trust Incident and Serious Incidents Requiring Investigation Reporting. In the event of an incident occurring, the well-being of the patient is of prime importance.

24. Drug Recalls

Drug recalls are initiated by the Medicines and Healthcare Products Regulatory Agency (MHRA) and passed down a communication chain via the CAS alert process. This chain originates from the Department of Health. The recall will state the urgency class (refer below) and the pharmacy department will initiate the necessary action according to the class of the recall. During pharmacy hours local pharmacy staff will liaise directly with the affected clinical areas. Out of hours the on-call pharmacist will co-ordinate drug recalls and may enlist the help of ward staff on duty to remove recalled stock from clinical areas.

Class	Urgency of Action Required
1	Action immediately, including out of hours
2	Action within 48 hours
3	Action within 5 days
4	For information: caution in use

25. Medical Representatives

Medical Representatives must follow the Association of the British Pharmaceutical Industry (ABPI) Code of Practice, 2016 and the trust Standards of Business Conduct policy. Adherence to the ABPI Code by companies and their representatives should ensure that medicines and associated products are promoted in a **responsible and ethical manner**. The ABPI has a **complaints procedure** which may be invoked in the event of a representative or promotional literature breaching standards laid down in the Code.

New representatives should contact the Chief Pharmacist to acquaint themselves with the HPFT processes for the introduction of new medicines and pharmaceutical products, prior to meeting other professionals. Representatives must not promote a new product until the Chief Pharmacist (or delegated representative) has been contacted. The sponsorship by pharmaceutical companies of events e.g. educational meetings must follow HPFT Standards of Business Conduct policy.

25.1 Gifts and Benefits

The advertising and promotion of medicines is strictly regulated under the Medicines (Advertising) Regulations 1994, and it is important that nurse and non-medical prescribers, and

indeed all health professionals, make their choice of medicinal product for their service users on the basis of clinical suitability and value for money alone.

As part of the promotion of a medicine or medicines, suppliers may provide inexpensive gifts and benefits, for example, pens, diaries or mouse mats. Personal gifts are prohibited, and it is an offence to solicit or accept a prohibited gift or inducement.

Companies may also offer hospitality at a professional or scientific meeting, or at meetings held to promote medicines, but such hospitality should be reasonable in level and subordinate to the main purpose of the meeting.

26. Medical Gases

All medical gases used within the trust are licensed medicines and, as such, are subject to the Medicines Act (1968); they must be treated in the same way as any other medicines.
Within in-patient locations medical gases must be prescribed on the medicine chart, including:

- Name of medical gas
- Concentration to be administered (where appropriate)
- Method of administration
- Flow rate

Oxygen may be administered without a prescription by a nurse, in an emergency situation if there is no prescriber on site. The nurse is accountable for their decision and action taken, which must be fully documented in the patient's notes. Medical staff/emergency services must be contacted immediately.

For further information regarding please see trust policy on Oxygen – Storage & Administration

27. Management of Cytotoxic Therapies

All cytotoxic drugs are potentially dangerous to both those who administer them and those who receive them, if not handled correctly. The ward Pharmacist will endorse the drug chart if a cytotoxic medication has been prescribed. If a service user is receiving cytotoxic medication, staff must follow the instructions from the specialist service that has initiated them and/or the ward Pharmacist.

27.1 Health and Safety Issues

Great care should be taken when handling cytotoxic medication as they are hazardous substances within the Control of Substances Hazardous to Health (COSHH) regulations 2002. For further details on this refer to the Trust policy on **"Control of Substances Hazardous to Health Policy (COSHH)".**

Pregnant women are advised to avoid contact with cytotoxic medication. Refer to the Trust policy "Pregnant Workers and Nursing Mothers".

27.2 Disposal of Cytotoxic Medicines

Cytotoxic medicines are deemed to be hazardous and require segregation from other waste medicines. A purple lidded container for disposal of cytotoxic and cytostatic medicines must be used. For further information please see the SOP for pharmaceutical waste disposal in your pharmacy information folder.

28. Training

28.1 Prescribers (Drs and NMPS)

All junior prescribers (Drs) must complete the Prescribing and Medicines Optimisation eLearning at induction. A rolling monthly education and training session organised by the Pharmacy and Medicines Optimisation team is available for all staff to attend on a first come first serve basis.

28.2 Nursing staff

All nursing staff must complete the Nursing Medicines Optimisation eLearning once every 3 years. In addition all nursing staff must successfully complete the medicines administration competency framework once every 3 years.

A rolling monthly education and training session organised by the Pharmacy and Medicines Optimisation team is available for all staff to attend on a first come first serve basis.

28.3 Unregistered staff involved in the administration of medicines

All Unregistered staff involved in the administration of medicines must complete the HSC 3047 module “Support use of medication in social care”. For further information please see The Role of Unregistered Staff in the Administration of Medication Policy.

29. Process for Monitoring Compliance with the Medicines Policy

A series of clinical audits will be utilised to monitor compliance with the medicines policy namely:

- Quarterly medication safety KPI audit
- Annual safe and secure handling of medicines audits
- Appropriate POMH-UK audits

Part 3 – Document Control & Standards Information

30. Version Control

Version	Date of Issue	Author	Status	Comment
7	10.03.14	Head of Medicines Management	Superseded	
7.1	13.04.15	Head of Medicines Management	Superseded	
8	01.11.2017	Chief Pharmacist	Superseded	
8.1	17.04.2018	Chief Pharmacist	Current	Minor amendments: - Section 12.5 added - Section 13.3 extended to cover Thumbswood ward - Section 16.1 A sentence added to confirm that tamper-evident and secure receptacle must be used when transporting medicines

31. Relevant Standards

- The Medicines Act 1968 - Regulates the manufacture, distribution, import, export sale and supply of medicinal products
- Royal Pharmaceutical Society of Great Britain, “The Safe and Secure Handling of Medicines A Team Approach” (The Duthie Report) March 2005
- Standards for Medicines Management, The Nursing and Midwifery Council Reprinted 2010 www.nmc-uk.org
- British National Formulary (current edition)
- British National Formulary for Children (current edition)
- Health Care Professionals and students should also follow the standards and guidance of their regulatory and professional bodies body such as:

- Nursing and Midwifery Council - www.nmc-uk.org
- General Medical Council www.gmc-uk.org
- Royal College of Psychiatrists - www.rcpsych.ac.uk
- Royal College of Paediatrics and Child Health - www.rcpch.ac.uk
- Royal Pharmaceutical Society of Great Britain www.rpsgb.org.uk
- General Pharmaceutical Council www.pharmacyregulation.org

32. Associated Documents

- Controlled Drugs Policy
- Medicines Reconciliation Policy
- Covert Administration of Medicines Policy
- Mental Health Act and Mental Capacity Act policies
- Role of the unregistered members of staff in the administration of medication.
- NMP policy
- Patient Group Directions Policy
- Consent to Examination, Care and Treatment Including Electro-Convulsive Therapy (ECT), Guidance and Procedure
- Nicotine Replacement Therapy policy.
- Resuscitation Policy
- Standards of Business conduct Policy
- Oxygen storage and administration policy
- Pregnant workers and Nursing Mothers policy

33. Consultation

Job Title of person consulted
Deputy Director of Nursing and Quality
Several medical staff membership of DTC

Appendix 1

Hertfordshire Partnership NHS
University NHS Foundation Trust

Request and Risk Assessment for the use of Unlicensed Medicines

This form should be completed by the Consultant with assistance from the ward/unit pharmacist each time a new unlicensed medicine is required. The completed form is to be submitted to the Drugs and therapeutic Committee for approval. In the case of urgent clinical need, the Chief Pharmacist and Chair of DTC may authorise the single use of a new unlicensed medicine outside of the DTC.

Before completing this form you must have read and understood the unlicensed medicines section of the medicines policy. **NB: Parts 1, 2, 3, 4 & 6 to be completed by Consultant, Part 5 to be completed by Pharmacy.**

Part 1: Unlicensed Medicine Details

Approved (Drug) name:

Proprietary (Brand) name if known:

Dose form: Strength:

Manufacturer (if known):

Part 2: Patient Details

Is this to be used for a single patient only?

Single Patient Only

Patient name: Ward/Unit:

NHS number: Site:

Multiple Patients

Approximate number of patients per year:

Part 3: Clinical Details

Indication: Frequency:

Dose Range: Expected duration:

Route:

Why is an unlicensed medicine use being considered?

1.	Pharmaceutically equivalent licensed product temporarily unavailable **Yes / No**
2.	Equivalent UK licensed product unsuitable (explain)
3.	Other (give details)

Part 4: Clinical Evidence for Unlicensed Medicine

Is there any evidence to support its use for the proposed indication? Yes / No

If not, is there any evidence to support its use for other indications? Yes / No

Is there any evidence to support its proposed administration schedule? Yes / No

Is the product licensed for the specific indication in a different country Yes / No / Not Known

Are other centres in the UK using this medicine? Yes / No / Not Known
If yes, name:

Please summarise below any published evidence to support the use of the unlicensed medicine use and any previous clinical experience with medicine:

What are the risks to the patient of NOT using this medicine?

List any side-effects or toxic effects that have been reported?

Describe any monitoring required:

List any significant interactions:

List any contraindications and any other risks to the patient:

List any precautions, including precautions in use and pharmaceuticals precautions:

Is there a Patient Information Leaflet appropriate for intended use?
Yes* / No / Not Known (*Please attach) and any special instructions

How will the patient obtain further supplies?

Part 5: Procurement Details to be completed by Pharmacy

Where is the medicine to be obtained from?

Describe any expected problems associated with continuity of supply:

What is the cost of the product?

List any additional / indirect costs involved in obtaining this medicine:

Part 6: Details of person(s) completing form

Consultant name:

SBU:

Contact number:

Email address:

Consultant signature:……..…. Date:

Clinical pharmacist name:

Pharmacist signature:……..…… Date:

Part 7: Outcome of Risk Assessment

DTC approval Yes / No

Reasons if not approved:

Any restrictions on prescribing:

Name:

Signed by DTC Chair:…….. Date:

Appendix 2:

Hertfordshire Partnership NHS
University NHS Foundation Trust

NON FORMULARY / NEW DRUG REQUEST FORM

Patient name:		Ward/Unit:	
NHS number:		Site:	

1 Consultant ……

2 Drug:
Approved Name/Strength/Form ……

Brand Name/Manufacturer ……

Class of Drug/BNF Group ……

3 Licensed indications and dosage (state NONE if not yet licensed)

……

……
Any use outside licence or unlicensed dose intended

……

4 Previous relevant medication (doses, duration, effectiveness, tolerability, reasons for stopping)
……

……

……

……

……

……

5 Advantages:
Please state your reasons for wishing to use this product, any previous experience you have with it, and the advantage over present therapy. Include details of relevant clinical studies and supply copies of at least two of these studies with your application.

……..……

……..……

……..……

……..……

……..……

……..……

6 Place in therapy/guidelines on patient selection (1st line, 2nd line, adjunctive)

……..……

7 Please indicate if this is a substitution for an existing drug on the formulary

……..……

8 Please indicate whether this request is likely to be for this patient only or if it is likely to be required for other patients

……..……

……..……

9 GP Involvement

Will the GP be expected to prescribe	☐ Yes	☐ No
Does this raise shared care/funding issues	☐ Yes	☐ No
Have draft guidelines/protocols been produced (If yes, please supply a copy)	☐ Yes	☐ No

If the request is for the addition of the drug onto the HPFT formulary as the intention is to use the medicine routinely as part of the treatment options, the requesting Consultant in conjunction with the Pharmacy team will be need to prepare a full evaluation of the drug requested based upon published literature. If you have any papers that may be pertinent to this evaluation, please send them with the application.

The Chief Pharmacist may circulate requests to other consultants in the Trust who may have an interest in the outcome of this request.

The Drugs and Therapeutics Committee meet 2 monthly you should allow eight weeks before a meeting date for preparation and distribution of an evaluation.

It is essential for the Consultant requesting the medicine to attend the meeting to support the application and answer questions.

Consultant signature …… Date ……..
Declaration of interest in drug company …….

Please return completed form to the Chief Pharmacist

Date form requested ……
Date form sent ……
Date form returned ……
Date application submitted to DTC ……

Decision made by DTC **Approved / Not approved / Deferred**

Guidelines prepared ……

Funding available ……