Birmingham and Solihull Mental Health NHS Foundation Trust

MEDICINES CODE

Policy and Procedures for Managing Clinical Risks associated with Medicines

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Policy author *(if different from above)*	**Chief Pharmacist** **Deputy Director of Nursing**	
Exec Sign off Signature (electronic)	XXXX	
Disclosable under Freedom of Information Act 2000	**Yes**	

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Policy context

- This Medicines Code defines the policies and procedures to be followed within the Birmingham and Solihull Mental Health Foundation Trust (BSMHFT) for the prescribing, ordering, dispensing, carriage, and transport, storing, administering and disposal of medicines. HMP Birmingham has its own specific Medicines Code.
- This policy covers all staff working in the Trust, including agency and bank staff, permanent and temporary staff, who are involved in any way with the use of medicines.

Policy requirement (see Section 2)

All staff, involved at any stage with the management of medicines (prescribing, ordering, dispensing, carriage and transport, storage, or administration), will adhere to the practices and procedures outlined within this policy document and its associated appendices.

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Appendices

1. Introduction

1.1 Rationale

1.1.1 NHS Trusts are required to establish, document and maintain an effective system to ensure that medicines are handled in a safe and secure manner.

1.1.2 There have been a number of changes and developments in recent years: •

New professional practices concerning the use of medicines have developed and continue to develop.

- The formation of community based functional teams which have had to create new approaches to care provision for people who would have previously been in patients.
- New healthcare practitioners are dealing with medicines as a routine part of their day-to-day work.
- The use of new information technology to assist medicine use requires new policies and procedures.
- The concepts of service user focused care and service user empowerment require a fresh approach to some long-established practices.
- Good clinical governance and risk management systems are necessary to support the safe and high quality care of service users.
- The introduction of electronic prescribing and medicines administration systems to replace the paper based systems

1.1.3 This Medicines Code defines the policies and procedures to be followed within the Birmingham and Solihull Mental Health Foundation Trust (BSMHFT) for the prescribing, ordering, dispensing, carriage and transport, storing, administering and disposal of medicines. HMP Birmingham has its own specific Medicines Code.

1.2 Scope of the Policy

This policy covers all staff working in the Trust, including agency and bank staff, permanent and temporary staff, who are involved in any way with the use of medicines. All these staff must familiarise themselves with the correct procedures contained in this Code. Those staff in charge of wards/teams and departments are responsible for ensuring that their staff, especially new starters and locum staff, follow procedures in this Medicines Code, which may differ from procedures in other Trusts. Copies of the Medicines Code should be available in all wards/teams and departments and on the Trust Intranet.

Medical students are not permitted to prescribe medicines in BSMHFT.

This policy applies to all medicines and medicinal products used in BSMHFT. These include topical lotions, applications, intravenous infusions, medicated dressings and complementary medicines.

1.3 Principles (Beliefs)

The Trust positively supports individuals with learning disabilities and ensures that no-one is prevented from accessing the full range of mental health services available. Staff will work collaboratively with colleagues from learning disabilities services and other organisations, in order to ensure that service users and carers have a positive episode of care whilst in our services. Information is shared appropriately in order to support this.

2. Policy

All staff, involved at any stage with the management of medicines (prescribing, ordering, dispensing, carriage and transport, storage or administration), will adhere to the practices and procedures outlined within this policy document and its associated appendices.

3. Procedure

3.1 Pharmacy Services

The role of the pharmacy is to:

- Advise on and monitor the safe, effective, appropriate and economic use of medicines.
- Procure medicines.
- Supply stock medicines to wards and teams
- Dispense ready to administer medicines for self-administration, discharge medication or for community based service users,
- Support prescribers to review the medication history of service users,
- Advise service users, relatives, carers and staff, on the use of medicines,
- Audit medicines management within the Trust,
- Provide education and training to healthcare professionals and other staff relating to medicines management.
- Support the appropriate configuration of the electronic prescribing and medicines administration (EPMA) system

3.1.1 Medicines will be procured supplied and dispensed in accordance with the relevant legislation, professional standards and NHS recommended practice.

3.1.2 Pharmacists will monitor all new requests for medicines for service users in their care and place special emphasis on complex and potentially toxic medicines that require higher levels of monitoring. Continuing medicine treatment will be reviewed as necessary.

3.1.3 When a request for a new medicine has been made a pharmacist must check the prescription and other related service user records to ensure the safe, effective, appropriate and economic use of medicines. Attention must be given to each step of the medicine use process. This includes the need for the medicine, the medicine selected, the dose regimen including the duration of treatment, the

medicine formulation and the route of administration. In addition pharmacists must monitor for medicines interactions/adverse reactions (including side effects) and where possible whether the therapy is achieving the desired therapeutic end points. The pharmacist will confirm they have screened each prescription item through the clinical check icon within the EMIS EPMA system

3.1.4 In order to clarify a prescription, Authorised Pharmacy Staff may annotate a prescription. This may be clarified within the EPMA system through the use of an electronic post it note attached to the prescription by the pharmacist for prescribers or nursing staff to view. Where necessary, pharmacists may 'prescribe on behalf of a prescriber' where this is necessary to clarify a prescription, either following a conversation with the prescriber or where the prescriber's original intentions are clear.

3.1.5 Where a pharmacist wishes to make a recommendation to change or modify a service user's therapy, the pharmacist should record the recommendation in the service user's electronic patient record and the reasons for it. Records should be made of any verbal communication with the prescriber concerning a service user's treatment. When recommendations are made from a dispensary they must be included in the service user's electronic record. The pharmacist may also record pharmacy notes within the clinical pharmacy desktop within the EMIS Pharmacy system where this is useful to other pharmacists who may need to view the patient's prescription.

3.1.6 Where possible, service users should be given advice about their medicines by Authorised Pharmacy Staff. This should be a part of an agreed programme for each ward or unit.

The Nurse in Charge should agree with the pharmacist and consultant the arrangements for advising service users about their medicines.

Alternative arrangements for advising service users about their medicine may be provided if:

• The nature of the discussion is considered inappropriate by the consultant •

There is insufficient availability of suitably trained pharmacy staff

Such alternative arrangements must identify the person responsible for the provision of information and the nature of the information to be provided.

3.1.7 Routine supplies of newly prescribed medicines are made when the pharmacy department is open. Out of hours, medicines are available via a number of out of hour's medicines cupboards across the Trust. Details of the contents are available via the Pharmacy and Medicines Connect pages. Access is usually via the nurse in charge of the unit. In addition there is an on-call pharmacist who can be contacted for advice or to arrange supply of urgent medicines where this cannot wait until normal Pharmacy services are available. The on-call pharmacist will determine the clinical urgency of the items in conjunction with the nurse in charge of the ward and/or on-call doctor and arrange for the supply to be made if it is not appropriate to wait until the Pharmacy is next open.

3.1.8 Authorised Pharmacy Staff must be involved in advising on security and medicine storage conditions on the ward/unit or department.

3.1.9 The pharmacy will provide a medicine information service for other healthcare staff as well as service users, linking into the PALS service as required.

3.2 Prescribing of Medicines

3.2.1 Medicines may only be prescribed on the EMIS EPMA system or approved BSMHFT prescription stationery. Such stationery includes an outpatient prescription intended for Summerhill Pharmacy, an FP10 prescription form or a trust controlled drugs prescription form. When prescribing on a trust prescription stationery, the following service user details must be included:

- Service user's name, including aliases.
- Date of birth.
- Ward, Team or Clinic name, or agreed Trust code.
- Consultant.
- Service user's RiO number and/or NHS number

The EMIS EPMA system will automatically populate these. All prescribing should wherever possible be undertaken via the EMIS EPMA system. In addition,

- Known sensitivities to medicines. These should be added manually to the patient's EMIS EPMA record following the correct procedure.

3.2.2 Prescriptions for service users transferred from one BSMHFT ward/team to another will require a new EPMA episode. Prescribers should normally reconcile the medicines from the immediately previous episode into the current episode, taking account of any changes in medication at the end of the previous episode or EPMA discharge instructions.

<u>On admission</u>

When service users are transferred into BSMHFT care from other Trusts, within 24 hours the prescribed medicines must be added to the trust EPMA system, Administration of medicines must be undertaken against an EPMA prescription

3.2.5 When there is a transfer from one team to another, the patient must be transferred to the new team on EPMA and a new episode should be opened.

3.2.6 Initiation <u>of Treatment</u>

- Qualified doctors or suitably authorised non-medical independent and supplementary prescribers have the authority to prescribe medicines for service users under the care of BSMHFT.

- Practitioners must not administer medicines that have not been prescribed by an authorised prescriber unless they are covered by a patient group direction or are included in the list of homely remedies that can be administered via the patient group direction mechanism on the EMIS EPMA system.
- This authorisation must be in writing, in the form of a signed prescription, or added to the patient prescription record on the trust EPMA system in advance of the administration of the medicine.

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3.2.7 Range of medicines to be prescribed are:

- Medicines for psychiatric conditions approved for use by the BSMHFT Pharmacological Therapies Committee (PTC).
- General medicines included within the formulary published by the Birmingham, Sandwell, Solihull and environs Area Prescribing Committee (APC).
- Medicines newly introduced to the market place may only be prescribed in BSMHFT after due consideration and approval by the trust Pharmacological Therapies Committee (PTC) or APC. Physical health medicines that have been prescribed by the service users GP will be supplied by a Trust Pharmacy for service users during an inpatient stay or, if necessary, whilst the trust is supplying medicines for service users undergoing home treatment.
- Limited exception is given to service users' own medicines, medicines undergoing clinical trial and specialist therapy for individual service users that have been agreed with the Chief Pharmacist
- A defined procedure authorised by the PTC must be followed in order to request a new medicine for use within the Trust. Details of the procedure are available from the Chief Pharmacist or Chair of PTC. Where such medicines will be prescribed by GPs or where funding may be sought from commissioners, this will also need to be approved by the APC. • Unlicensed medicines should be prescribed in accordance with guidance included in Appendix 3: Use of unlicensed medicines.
- Guidance on the use of medicines within clinical trials in included in Appendix 4.

3.2.8 Function of the EPMA Prescription Record • To provide a permanent record of all medicines prescribed, supplied and administered to the service user whilst under the care of the Trust.

- To indicate a service users' sensitivity to medicines.
- To facilitate the supply of medicine from a pharmacy.

- To record the indications for each prescribed medicine.
- To direct the supply or administration of the medicine to the service user.
- To provide a record of any secondary dispensing done by staff for individual service users.

3.2.9 The EPMA prescription will include:

- Date the prescription was written**.**
- Name and Form of the Medicine

This is normally done by selecting an appropriate prescription template on the EMIS EPMA system. Prescription templates may be amended to reflect the prescribers precise instructions or to give additional instructions to staff administering or dispensing medicines against that prescription.

- Dose and Route of Administration

The prescription template on the EMIS EPMA system will automatically select the appropriate units and route of administration. All prescription templates will use the convention of the British National Formulary and write doses and routes of administration in full English terminology rather than Latin or English abbreviations.

Do not prescribe IM and oral in same prescription entry due to differences in bioavailability. The EMIS EPMA system has standardised order sets for medicines that may be prescribed by the IM or oral route.

- Times of Administration

Within the trust EPMA system, medicines will be generally prescribed via one of the available templates. Before saving the prescription, the specified administration times should be checked and confirmed or amended if necessary.

- Signature of Prescriber

In the EMIS EPMA system, each prescriber will have logged into the system using their trust username and password. The system will record permanently the prescriber for each prescribed medicine

- Cancellation of Treatment

The trust EPMA system will record which prescriber stops each prescription and the date of cessation. The prescription and all details of medicines administration will be available to view in the current medicines screen for 24hours after which it is archived to history.

- Length of Treatment

Medicines prescribed in the trust EPMA system are valid until a prescriber discontinues or amends the prescription. The system will not automatically cancel an expired prescription. Prescribers and nursing staff will need to ensure prescriptions remain appropriate and arrange for a review of prescribed medicines at regular intervals.

- Allergies/Sensitivities

The prescriber is responsible for entering any known drug allergies/sensitivities in the appropriate section of the EMIS EPMA system and service user's electronic patient record. The system will ask for confirmation of allergy status, enter allergy or none known. Only the extreme or high allergy status should be chosen. An extreme allergy would be a life threatening allergy, e.g. anaphylaxis. Non-life-threatening allergies that require medical intervention and are serious enough to record should be recorded as high. Non-significant allergies that do not affect therapeutic decisions do not need to be recorded on the system.

Within the EPMA system, if the allergy status is unknown and cannot be confirmed the allergy status will be given an amber status until it can be confirmed and entered. All healthcare professional staff should assist in identifying medicine allergies/sensitivities. Pharmacists, nurses or other professional staff may also enter allergies/sensitivities into the appropriate section of the prescription chart, or trust EPMA system where they are documented using good evidence, e.g. following a medicines reconciliation process.

3.2.10 Once Only Doses (Stat Doses)

Medicines that are intended to be given once only must be prescribed in the 'once only' section of the patients EPMA prescription record.

3.2.11 'When Required' Prescriptions (PRN)

- The 'when required' section of the EPMA prescription record must only be used for those medicines to be given at the nurse's discretion according to the needs of the service user.
- The prescriber must define the reasons for the prescription and qualify the directions
- An entry in the service user's electronic patient records must give reasons for administration and outcome. This will be subject to periodic audit.
- The minimum interval between doses and indication for administration must be clearly specified by the prescriber. The maximum dose to be given in a 24-hour period must also be stated.
- When signing to indicate that the medication has been given, in the case of a variable dosage (e.g. 1 or 2 or 5 -10mg) the actual dosage administered must be recorded by the professional administering the dose • A 'when required' prescription must be reviewed regularly by a prescriber to determine and confirm the clinical need. To prevent the accumulation of unnecessary 'when required' prescriptions the following guidelines should be observed:

- Any PRN medicine that has not been required or administered for one month should be cancelled. This should normally be done by a prescriber but can also be done by a pharmacist in liaison with

clinical staff or in line with other therapeutic guidance. Exceptions include those medicines administered in very occasional medical emergencies, e.g. GTN spray or a salbutamol inhaler.

- Not more than one medicine from any BNF therapeutic category should be prescribed as a PRN at any one time.
- Not more than two medicines should be prescribed as a PRN at a time for any one indication.

- Prescribing a medicine on an 'when required' basis provides a useful method of assessing the person's requirements of certain medicines such as anticholinergics, analgesics and hypnotics as well as those used in alcohol detoxification regimens.
- Medicines originally prescribed 'when required', but which are needed regularly as indicated by the administration record, must be reviewed and rewritten in the regular section of the patient's EPMA prescription record.
- Once a service user's medical condition has improved there may be fewer requirements for certain medicines. The 'when required' prescription can provide a useful tool to ensure that medicines that are no longer required are not continued. However, 'when required' medicines should be reviewed regularly to ensure they remain appropriate and required.
- Care must be taken not to duplicate "when required "medicines with those being taken regularly as this risks overdose. Homely remedies should not normally be given if prescribed on the 'when required' list of prescribed medicines. Combination analgesics frequently contain paracetamol, which may already be prescribed in the regular section of the prescription chart. Rapid dose escalation using combinations of PRN and regularly prescribed antipsychotic drugs is one of the most common causes of sudden death and neuroleptic malignant syndrome in schizophrenia and should be avoided.
- Where regular mediation is prescribed in addition to 'PRN' use, the electronic 'PRN' prescription must be include a note that regular medication has also been prescribed.

3.2.12 Verbal Prescriptions

Registered Nurses cannot accept verbal orders for medication for which there is no EPMA prescription.

In most circumstances, a prescriber can prescribe onto the EPMA system remotely from the ward and this should always be the preferred method. In exceptional circumstances, a prescriber may not have access to the EPMA system and will be remote from the trust. In this rare circumstance, the use of information technology (such as email) must confirm the prescription before it is administered. Any communications must be compliant with information governance policies. This must be followed up by updating of the EPMA prescription as soon as practicable.

3.2.13 Controlled drug prescriptions

Community prescriptions and discharge prescriptions for controlled drugs

should comply with the prescription requirements under the misuse of drugs regulations. Full details can be found in the BNF. Such prescriptions should include

- The signature of the prescriber
- the date
- written or printed indelibly
- the prescriber's address
- the name, form and strength of the preparation
- the dose and frequency
- the total quantity in word and figures. Where the medicine is available in dosage units, the total number of dosage units should be expressed in words and figures
- the name and address of the service user
- for instalment prescriptions, directions specifying the amount of instalments and the intervals

Controlled drug prescriptions are only valid for 28 days by law. It is good professional practice that they cover a maximum of 30 days supply unless there are exceptional reasons to extend this.

3.2.14 Verbal changes to prescriptions in pharmacy

Pharmacists may need to accept verbal orders from prescribers in order to clarify prescriptions. Where this is the case, the pharmacist may 'prescribe on behalf of' a prescriber. Where this occurs, it should be documented by the pharmacist and the prescription reviewed within 24 hours (at weekends/bank Holidays this period may be extended to a maximum of 72 hours).

3.2.15 Patient Group Directions (PGD)

A PGD is a written direction relating to the supply and administration, or administration only, of a prescription only medicine to service users of the Trust without a prescription.

It applies to the administration of medicines in an identified clinical situation in service users who may not be individually identified before presenting for treatment.

A range of healthcare professionals may administer medicines under a PGD. They must be registered (or equivalent) members of their profession and act within their code of conduct and be suitably trained. The PGD must include the following information

- The name of the business to which the direction applies
- The date the direction comes into force and the date it expires
- A description of the medicine to which it applies

- The clinical condition covered by the direction
- A description of the circumstances in which further advice should be sought from a doctor and arrangement for referral made
- Appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration and minimum or maximum period over which the medicine should be administered
- Relevant warnings including potential adverse reactions • Details of any follow up action and the circumstances

A statement of the records is to be kept for audit purposes

The range of medicines that can be administered via a PGD is restricted and cannot include an unlicensed medicine nor generally schedule 2 and 3 Controlled Drugs

PGDs will be developed by a multidisciplinary team under the guidance of the Pharmacological Therapies Committee and subsequently be signed by the Directors of Medicine, Nursing and Pharmacy and approved by the Trust Pharmacological Therapies Committee.

3.2.16 Guidance for use of Patient Group Directions

'The majority of clinical care should be provided on an individual patient specific basis. The supply and administration of medicines under a PGD should be reserved for those where this offers an advantage in service user care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability' An application for a PGD will include:

- Details of the clinical situation and the medicines to which the PGD will apply
- Benefits to the service user
- Risks to the service user and the Trust of not developing the PGD
- Qualification of staff who will be involved in the supply and administration of the medicine
- Outline of training that staff require to operate under the PGD

3.2.17 Responsibilities for working under Patient Group Directions • The PGD should be reviewed regularly and within the expiry date of the PGD

- The names of staff who are authorized to operate under a PGD must be kept in a register and the ward/team manager is responsible for ensuring that all relevant training has been completed.
- Staff who operate under a PGD should only agree to do so if they are confident that they can follow the directions within the PGD. Staff must not undertake any aspect of service user care for which they are not trained and which is beyond their competence.

- All staff working under a PGD should have their own copy of the PGD for which they have signed.
- The manager should be responsible for ensuring that staff are given updated copies. Conversely, staff should not operate under expired PGDs.
- Responsibility for supply and administration of any medicines covered by a PGD cannot be delegated to another member of staff not authorized to work under that PGD.

3.3 Ordering and Receipt of Medicines

Stock medicines are those commonly prescribed for in-patients, outpatients/community teams or items required in the event of an emergency. Stocks are retained on the ward/team regardless of whether they are currently prescribed for any service user.

Individual service user supplies are those medicines dispensed and labelled for a particular service user. Once the service user is discharged from the ward they should be returned to the pharmacy. Individually dispensed medicines for service users who regularly receive planned respite care may remain on the ward for future use.

Medicines to take out (TTOs) are individually dispensed medicines which are labelled with directions for administration for an individual service user, who has authorised leave from the ward or who is to be discharged.

3.3.1 Controlled Drugs

The responsibility for the ordering, receipt and storage of Controlled Drugs is that of the Nurse in Charge of the ward/department.

Controlled Drugs can only be ordered from the pharmacy by submitting a requisition from the official Controlled Drugs Requisition Book. Ordering is restricted to a nurse acting under the authority of the nurse in charge. All nurses who may order Controlled Drugs must provide the Pharmacy Department with specimen signatures.

The order for controlled drugs, benzodiazepines or hypnotics must include:

- Name of ward or team
- Drug name (approved name), form and strength
- Total quantity
- Signature and printed name of the nurse ordering the controlled drugs
- Date
- Signature of pharmacy staff issuing item from pharmacy

All Controlled Drugs issued as stock must be delivered to wards or departments in a tamper evident package. The porter, transport driver or

messenger must sign either a Pharmacy transport sheet or the controlled drugs order book in the appropriate place. Where portering staff or transport drivers collect Controlled Drugs in this way, Pharmacy staff will endorse the controlled drugs order book 'in box' to indicate that it has been placed in the Pharmacy box.

Upon receipt, a nurse must check the contents of the package containing Controlled Drugs against the requisition. Any discrepancy must be reported to the Pharmacy immediately. If correct, the nurse must sign the Receipt. The nurse must enter the new stock into the Controlled Drugs register on the appropriate page, witnessed by another nurse, nursing associate, an authorised member of the Pharmacy Staff or an Authorised Employee who must verify the stock level and sign the register. The Controlled Drug must then be immediately locked away in the Controlled Drug Cupboard.

Where sealed packs of Controlled Drugs are supplied with tamper evident seals, there is no requirement to open these packs for stock checking purposes. These can be assumed to contain the stated quantity. If packs are not sealed or have been opened then the contents must be checked at each stock balance check, including after administration of a controlled drug.

Controlled Drugs must be stored in a locked, suitable controlled drugs cupboard, that meets BS2881 and is approved by pharmacy and reserved for the sole storage of Controlled Drugs. Access is limited to nurses and Authorised members of the pharmacy staff

Stocks within ward controlled drug cupboards must be inspected at a minimum of six monthly intervals by an authorised member of the Pharmacy Staff.

Registers and Requisition Books for Controlled Drugs are controlled stationery and obtainable only from the pharmacy. Requisition books should be locked away. All issues of controlled stationary should be recorded in the Pharmacy.

Orders and records must be in permanent ink and must be retained for two years. Orders should have two copies the carbon copy in the order book to be retained on the ward/unit, the original copy to be retained in the pharmacy.

Where either requisition books for controlled drugs or registers for controlled drugs are lost then these must be reported to the Pharmacy Dept. as soon as possible. An eclipse incident form must also be completed. The Chief Pharmacist will assess the actions that have been taken and advise on any further actions necessary. The loss will be reported to the Accountable Officer for Controlled Drugs by the Chief Pharmacist.

3.3.2 <u>All other Stock Medicines</u>

3.3.3 <u>Ordering of Stock Medicines</u>

A nurse or authorised member of the Pharmacy staff shall be responsible for ordering medicines from the pharmacy for the purposes of maintaining stocks.

Stock medicines may be ordered by:

- Ordering via the Pharmacy Stores module in the EPMA system.
- By means of the pharmacy technician/ATO top-up service.

3.3.4 Delivery of Stock Medicines

All medicines must be delivered to wards/teams in a secure tamper evident container.

A porter or messenger will deliver medicines in a tamper evident package, tamper evident box or locked box. The porter or messenger must sign a Drugs Delivery Record Sheet before receiving them in Pharmacy. A nurse must receive the package or box and sign the Drugs Delivery Record Sheet. The nurse signs for the receipt of a tamper evident pharmacy container or locked box.

Medicines may be collected by a nurse, nursing associate or approved messenger and must be transported back to the ward in a tamper evident pharmacy package or locked box.

3.3.5 Receipts and Records The

nurse must:

- Check the medicine against the delivery note
- Sign the note and file it within the ward/team, where it must be kept (for 2 years) as a record that the supply was complete.
- Lock the medicines in the medicine cupboards or refrigerator immediately.
- Report any discrepancies to the Pharmacy immediately.

3.3.6 Individual Patient Supplies

Medicines for named service users may be ordered by:

- Through the trust EPMA system
- By means of the pharmacy technician supply service.

It may not always be possible to have individual medicine supplies available from the pharmacy for the next medicine administration round. If the medicines have been ordered and have not yet been supplied by the pharmacy the nurse or professional administering the medicine must record the reason in the patients EPMA record. Where this occurs, the administering nurse or professional administering the medicine is responsible for ensuring medicines have been ordered or to arrange ordering from Pharmacy, including out of hours procedures.

If the Pharmacy has not yet supplied or is unable to supply medicines required, the service users own medicines, if available, may be used with the service user's consent, providing they comply with the criteria set out in Appendix 16 until they run out or the Pharmacy Department can obtain further supplies. Antibiotics may be used until the end of the prescribed course.

For out of hours supply, the on-call pharmacist may be contacted who will make supplies of medication if it is deemed urgent and required before the trust pharmacy service is open and can make a supply. Supply of the majority of medicines will not be urgent and can normally be left until the Pharmacy Department is open. The on-call pharmacist may assist ward staff in determining what is clinically urgent.

For community teams, ordering via Summerhill Pharmacy, teams are

responsible for ensuring that individual health prescriptions are sent to Summerhill Pharmacy for each supply required for each service user. Individual health prescriptions should be printed from the EPMA system.

3.3.7 Delivery of Individual Patient Supplies

The process is the same as for stock medicines.

3.3.8 Receipt of Individual Patient Supplies

The nurse shall receive all individual service user supplies arriving on a ward/department and check against the pharmacy packing sheet. They should then be locked in the appropriate medicines cupboard, medicines refrigerator or medicines trolley. Any discrepancies should be reported to Pharmacy as soon as practicable.

3.3.9 Medicines 'To Take Out' (TTOS)

3.3.10 TTO's can be ordered by a doctor, nurse or when necessary, a pharmacist and can include benzodiazepines or hypnotics. Schedule 2 and 3 controlled drugs should be ordered via the trust CD prescription form available on the Pharmacy Forms page on Connect.

TTOs can be ordered by:

- Ordering via the trust EPMA system

- All prescriptions for schedule 2 and 3 controlled drugs must conform to the legal requirements and be written in full. To ensure that the prescription complies with the legal requirements of the Medicines Act and Misuse of Drugs Regulations, the Trust's CONTROLLED DRUGS prescription template should be used, which can be downloaded from the Pharmacy Forms page on Connect.

N.B. Controlled Drugs cannot be supplied to a service user until the original prescription has been received by the Pharmacy.

3.3.11 The delivery of TTOs is the same as for stock medicines or individually supplied medicines.

3.3.12 All TTO medicines coming into a ward, department or team shall be received by a nurse or nursing associate, who must

- Check them against the patient's EPMA record, to confirm that all details are correct i.e. name, medicine, dose,

- Lock them in the medicines cupboard immediately.

- Report any discrepancies to pharmacy immediately.

3.3.13 It is important that the service user receives adequate information about their medicines prior to discharge. The service user should know the purpose of each medicine, how to take each medicine correctly, for how long it is to be taken, key side effects and how to manage them and what to do if they are concerned about anything to do with their medicines or condition.
This is a shared responsibility between medical, nursing and pharmacy staff.

It is the responsibility of the nurse who discharges the service user from the ward to ensure that the service user has received adequate information about their medicines. Any information communicated verbally should be backed up and supported by an appropriate leaflet, e.g. Choice and Medication leaflet that are available via the 'ChoiceandMedication' website that can be accessed via Connect or www.choiceandmedication.org/bsmhft .

3.3.14 Controlled Drugs to Take Out

Schedule 2 (e.g. Morphine) and 3 (e.g.Temazepam) Controlled Drugs to take out should be ordered on the Controlled Drugs prescription form that has been written by a prescriber in accordance with current legal requirements. This prescription must be sent to pharmacy for dispensing. A supply can only be made against an original prescription. Photocopies or faxes are not acceptable.

Delivery and receipt of controlled drugs for TTO purposes should be as for other medicines, but storage on the ward/department should be in the controlled drug cupboard, with the exception of TTOs containing benzodiazepines or hypnotics (NB temazepam must be kept in the CONTROLLED DRUGS cupboard). TTOs containing Controlled Drugs should be segregated from other 'stock' controlled drugs.

N.B. It is not necessary to enter the TTO into the Controlled Drug Register.

3.3.15 Borrowing of Medicines

Medicines must not be borrowed from a ward or department during normal working hours, unless a supply cannot be obtained directly from the pharmacy in time. Only stock medicines may be borrowed. These medicines should be borrowed by keeping the medicine in the original container only. Transferring medicines into another container is forbidden.

The senior nurse of the supplying ward must be contacted and agree that an item can be borrowed. Where necessary, the Pharmacy Dept or the on-call pharmacist should be contacted for advice and/or to arrange a suitable supply as soon as practicable.

Controlled Drugs must not be borrowed except in an extreme emergency, following contact with the Pharmacy or on-call pharmacist. Normally, only 'one dose' of a controlled drug maybe borrowed on a single occasion, this must be administered to the service user and witnessed by a nurse from the borrowing ward and a nurse from the receiving ward. The nurse in charge is responsible for ensuring adequate stocks of controlled drugs are ordered

from Pharmacy during normal working hours. Out of hours, if necessary, emergency stocks should be ordered via the on-call pharmacist.

Records of a borrowed dose of a Controlled Drug must be made in the Controlled Drugs register of the ward or department who has provided the medicine; i.e. the dose must be booked out of the supplying ward's register directly to the service user in the receiving ward. The pharmacy must be informed as soon as practical after a borrowed supply of Controlled Drug has been made.

3.4 Patient's own Medicines

3.4.1 All medicines brought into an inpatient unit by service users remain their own property and should not therefore be destroyed or otherwise disposed of without their agreement or, if this is not possible, their relatives' agreement.

3.4.2 Medicines brought into hospital by service users should be reviewed by the admitting doctor who may or may not wish to prescribe them. This is an important component of medicines reconciliation which is covered by the Trust Medicines Reconciliation policy.

3.4.3 Where wards are using the traditional ward stock system it is usual for the ward to receive medicines for administration to service users solely from the hospital pharmacy. However, it acceptable to use service users own medicines providing they meet specific criteria set out in Appendix 16. Otherwise, all medicines brought into hospital by service users would, following their agreement or the agreement of relatives, be either taken home by the service user's relatives or sent to the pharmacy for destruction. If service users own medicines are to be destroyed the agreement of the service user must be gained. A service user medicines return form should be completed with one copy filed in the service user's integrated care record and one copy sent to Pharmacy with the medication for destruction.

3.4.4 Where medicines belonging to service users are to be used whilst that service user is within in-patient or care settings, they should only be used if assessed as suitable. Appendix 16 – Use of Patients Own Medication on an in-patient unit outlines a standard operating procedure for assessing service users own drugs.

Use of Patients Own Drugs (POD) may often be appropriate when service users are admitted to an inpatient unit to

- Reduce the delay in availability of medication especially out of hours
- Enable continuity of treatment where the pharmacy does not stock the item
- Minimise waste

Consent must be obtained from the service user as these medicines are their property. If service users do not agree to their use then they should be removed from the ward and returned to the service user's home by their representative

The assessment of the suitability of using PODs should ideally be that of a pharmacist or a technician. However the senior nurse on duty or a doctor can assess if appropriate

The assessment involves a clinical review of treatment, agreeing with the service user what medicines they are willing to take and examining the physical state of the products.

Assessment is a professional matter and medicines must not be used if there are concerns about the identity, appearance, or physical and chemical stability of the medicine

The medicine must be clearly labelled with:

- The service user's name
- The name and strength of the medicine
- Date dispensed (do not use if dispensed more than 6 months ago or the expiry date has passed)
- Name and address of the supplier

If the medicine has no dispensing label, it must not be used

Medicines such as Glyceryl Trinitrate tablets and eye drops which have a short shelf-life once opened must not be used unless the date that the medicine container was opened is clear, the item is within the accepted expiry date and is in otherwise good condition.

There must be confirmation that the medicines have been stored appropriately. e.g. items that require refrigeration such as insulin have been stored in a refrigerator, or are within the manufacturers designated time period for in-use storage at normal temperatures.

The overall appearance of the bottle, label and medicine must be acceptable e.g. the container must be intact and clean. The medicine must be without visible sign of deterioration.

The medicine in the container must be all of the same type. If the appearance of the dosage units is not uniform they must not be used.

The medicine in the container must be as described on the label. If there is any doubt it should not be used.

After the assessment medicines should be either

a) Stored on the ward for use by the service user

b) Stored securely in the hospital during the service user's stay

c) Sent home with a service user's representative

d) Removed for destruction (with the service user's permission)

3.4.5 Controlled drugs must be stored in the CONTROLLED DRUGS cupboard and recorded as detailed in the procedure for making entries into the Register.

3.4.6 Unidentified Substances See appendix 11.

3.4.7 In the event of a death of a service user while on the ward:

3.4.8 PODs must never be returned to a relative or carer and must be kept on the ward in quarantine for two weeks in case they are requested by the coroner.

3.4.9 The PODs, including any Controlled Drugs, must be placed in a sealable bag with the service user's name on it. A list of these medicines, along with their quantities, must be made in the ward diary and the entry dated, witnessed and signed by two nurses or a nurse and a pharmacist or doctor. The bag should then be sealed and the two people involved in witnessing the sealing should sign across the seal along with the date. The bag should then be stored in the drug cupboard or if it contains Controlled Drugs, in the Controlled Drugs cupboard. (However, as any Controlled Drugs will have been booked out of the Controlled Drugs register they do not need checking when the weekly Controlled Drugs check is done).

3.4.10 If any of the service user's own medicines are Controlled Drugs, these must be booked out of the Controlled Drugs register and an entry made stating 'Patient deceased and their medication has been put into quarantine'. This should be witnessed and dated by either two nurses or a nurse and an authorised pharmacist.

3.4.11 If the Coroner asks for the medicines, they can be released to his or her approved representative. The wording 'Handed over to the Coroner' along with the date handed over should be written against original entry in the ward diary and this should be signed by the coroner's representative removing them and by a nurse who must witness the removal.

3.4.12 If after two weeks the Coroner has not asked for the medicines they can be returned to pharmacy in the sealed bag. The wording 'Returned to pharmacy' along with the date returned, should be written against original entry in the ward diary and this should be signed by the member of the pharmacy team removing them and by a nurse who must witness the removal.

3.5 Transportation of Medicines

3.5.1 <u>Transport within hospitals</u>

- Medicines must be transported within hospitals by members of Trust or contracted transport services staff.
- A record of the transport of medicines including signatures from the persons issuing the medicine, transporting the medicine and receiving the medicine is required.
- Medicines must not be left unattended at any time during transport. • When medicines are received at their final destination they must not be left unattended or unsecured. They should be handed to a nurse and locked away in a medicine cupboard at the earliest opportunity and items for refrigeration placed in a refrigerator immediately.

Where the medicines are delivered to a central point, the containers must be securely stored while waiting to be transported to the wards/teams/clinics. The responsibility for the security rests with those transporting the medicines until the delivery is completed and the necessary signatures obtained. Where the responsibility for containers containing medicines is transferred from one team to another, the consignment note must clearly identify the containers transferred and the new transport/portering team accepting responsibility.

3.5.2 Transport of medicines between health services premises.

Medicines accompanying a service user being transferred from one hospital to another may be transported between hospitals with the service user in an ambulance or by authorised hospital transport, or taxi. It is important that medicines are packaged securely and where necessary are labelled with the final destination.

3.5.3 Transport of medicines from the pharmacy department by authorised transport.

- All medicines must be transported in sealed, tamper evident containers.
- Containers must be kept securely or under surveillance whilst awaiting collection from or on receipt at the designated areas.
- On arrival on the ward/team/clinic, containers should be handed to a nurse. Once delivered to the ward/team/clinic the responsibility for the security of the medicines rests with the nurse in Charge, who will arrange for the contents to be unpacked, checked and put away securely as soon as possible.
- Delivery vans carrying medicines should not be externally distinguishable from other trust vans. • Delivery vans should not carry any unauthorised passengers whilst carrying medicines.
- Delivery vans should be locked when unoccupied.
- The driver shall carry a consignment note stating the number of containers. The authorised person accepting the delivery must sign the note on receipt. The consignment note must be returned to the pharmacy.

3.5.4 Transportation by Taxis

- All items must be transported in tamper-evident sealed containers. Controlled Drugs must not be uniquely identified.
- Transport must be obtained from the Trust's contracted service and the car number and drivers name must be recorded.
- Only hospital contract taxis with drivers able to produce identification bearing a photograph shall be used.
- Items must be collected from the pharmacy or an agreed designated area and delivered to the addressee or pre-arranged point.
- If items are not delivered directly to the addressee the responsibility for security rests with those receiving the container until delivery is completed and documentation countersigned.

3.5.5 Transport of medicines to individual service users at home.

- Medicines may be transported home by service users or their carers following a hospital attendance or on discharge.
- Service users or carers who have left the hospital before all their medicines have been dispensed should be instructed to return to the hospital at a later date to collect them unless arrangements have been made e.g. through home treatment/assertive outreach.
- The transport of medicines to a service user's home at other times must be by a member of the team caring for that service user (e.g. home treatment or assertive outreach team). See section 10.7 for further details of carriage of medicines to patients in the community. • In exceptional circumstances contracted transport service staff may deliver medicines to service users at home. In these circumstances a member of the Pharmacy or the team caring for the service user must confirm the medicines have been received.

3.5.6 Carriage of Medicines in the Community

3.5.7 Medicines issued to, or accepted by, an employee are the responsibility of the person to whom they are issued.

3.5.8 All staff required to carry prescribed medication must have a valid identification card issued by the Trust. This should be shown if requested by a service user or any other person having reason to check the identity of the employee.

3.5.9 Medication carried by staff must be prescribed as a specified dose for a named service user by a prescriber (except as described in (c) below. Additional medicines may be carried to allow for breakages or emergencies. These will be for:

a) Direct administration by a nurse to an identified service user, or

b) Delivery to an identified service user for self-administration over a specified period, or

c) As a limited stock supply of medication required by nursing and medical members of Home Treatment or Assertive Outreach teams when called to an initial assessment of a new service user, or an existing service user whose medication requires urgent review and pharmacy services are not immediately available.

d) Use under PGD. Where a supply of medication is to be left with a service user the pharmacy will supply medicines in pre-pack format

All medicines carried by qualified nursing staff must be prescribed by an appropriate prescriber and be accompanied by an EPMA print out or access to the EPMA medicines administration record, except as described in c and d above.

3.5.10 Home Treatment and Assertive Outreach Teams are sometimes required to carry a limited stock of medication to an initial assessment, where the service user may require the immediate prescription, administration and dispensing of medication. This may avoid undue delay in commencing a

course of essential and urgent pharmacological treatment. The team will have the stock requirements ("Emergency Stock Box") agreed with, and closely monitored by, the Pharmacy Department. Medication from this stock must only be administered against a valid written prescription or EPMA record.

3.5.11 Teams will normally receive prescribed medication from the Pharmacy Department. On occasions it may be appropriate for a Trust employee to collect prescribed medication from a community pharmacist issued through a prescription from the service user's General Practitioner(Form FP10) or from their hospital prescriber (FP/HP10) when the hospital pharmacy is

unable to supply.. Any such actions will be clearly detailed in the service user's clinical records.

3.5.12 Staff who are not registered nurses may deliver medication for self-administration by the service user. However where medication is to be administered, via any route, the person supervising the administration of the medication must be a nurse whose registration is recorded on the NMC professional register.

Staff who are not registered nurses may witness, and subsequently report back to the clinical team that a service user has self-administered medication as prescribed. The clinical team should be satisfied that it is appropriate for the service user to self-medicate, having regard to both the medication prescribed by the team, the GP and any other prescribers caring for the individual as well as the service users clinical state.

Registered and non-registered staff must enquire about all stocks medication the service user has access to prior to administering or supervising self-administration of medication.

If indicated, staff can offer to remove unused and excessive medication in the interests of safety (working with family and carers where possible.)

If the service user is unwilling to cooperate with this (or we are unsure that it is safe to supply medication) the MDT will need to consider whether it is safe to continue providing medication.

Should a decision be made to withhold medication then an explanation must be provided to the service user and documented on their record. The risk assessment will also be updated

A registered professional should always oversee the initial self-administered dose(s).This enables the healthcare professional to explain the purpose, potential side effects and anticipated benefits of the new medication in addition to further routine checks on what other medication the service user may have access to (and encouraging/assisting to dispose of any medicines no longer used.)

3.5.13 When carrying medication, the following requirements must be adhered to

(a) When medicines are transported personally by a member of staff they must be transported in a robust container and kept out of view of the general public. For reasons of personal safety and security for individual employees medicines must be carried in a fashion that

does not draw attention either to the individual or to the medicines being transported. The Trust will provide suitable carriage containers that meet both of these needs in consultation with local managers and the Pharmacy Department.

(b) When transporting medication by car, the employee will ensure that the medication is contained within a secure locked container and is out of sight, locked in the car boot or equivalent, depending upon the make and model of vehicle. Staff members using their own vehicle and who carry medication must ensure they have adequate insurance for this purpose. Medicines must be transported in such a way that prevents damage.

(c) Medication for self-administration must be directly handed to the service user for whom they have been prescribed, or to a responsible adult nominated to receive the medicines by the service user. On a one off basis and only in exceptional circumstances, medication may be delivered through a letterbox. This should be agreed in advance with the service user or carer and documented in the care plan. In all cases there should be a clear risk assessment that enables the team, and individual members of staff who will be accountable, to demonstrate that the benefits of such action far outweigh any risks. Additionally, the minimum quantity should be supplied wherever possible where medication is delivered through a letterbox. Medication should never be delivered in this way if it is known, or suspected, that children live on the premises, or into communal letterboxes. Should medication have to be delivered in this way this should be recorded on the medicines chart and a clear account should be made in the service users clinical record, identifying the staff involved, and who authorised such action. Safe delivery should be confirmed with the service user or carer as soon as is practicably possible, and at most within 24 hours of delivery.

Such deliveries should normally be authorized by team managers or staff working on their behalf who should report such occurrences through the incident reporting system.

(d) Staff will normally return to their base at the end of the working day and will ensure that any medication not delivered or administered as planned will be returned to the medicine cupboard before they leave the workplace.

(e) In exceptional circumstances, it may be appropriate for the employee not to return to their base prior to finishing their span of duty; this will normally be agreed with the team manager beforehand. In these circumstances the employee will ensure that the secure container and any medication or equipment contained therein is taken into their home overnight and not left in a vehicle. The case or container should be stored out of sight, preferably in a locked cupboard, and returned to the base on the next working day. These circumstances may also include the carriage of the agreed Emergency Stock Box by On-Call Home Treatment or Assertive Outreach Staff.

(f) Medicines can only be carried where they are prescribed for a named individual, accompanied by a written prescription, EPMA print out or where there is access to the EPMA medicines administration record, in a specific dosage, and contained in appropriate packing that meets all minimum legal requirements regarding displayed information. The only exceptions to this are as described for PGDs and home treatment teams as above.

3.5.14 Controlled Drugs

Controlled drugs will be transported from Pharmacy via the trust transport and taxi service as above.

All controlled drugs ordered as a stock medicine must only be transported

with the controlled drugs requisition book. The Pharmacy Dept. will indicate that the controlled drugs for transport have been placed in the Pharmacy box and sealed. The Pharmacy box will be signed for in the normal manner as for all Pharmacy boxes by transport staff.

On receipt of the Pharmacy box by the ward/team, the box should be unpacked as soon as possible and controlled drugs placed in the controlled drug cabinet and the controlled drugs register completed.

TTO and outpatient medication that includes controlled drugs will be transported in the normal manner. The Pharmacy controlled drugs register will be annotated to indicate that the person collecting the Pharmacy box is known to Pharmacy staff and that identification has been checked. The Pharmacy packing sheet should be annotated to indicate that a person's TTO includes controlled drugs and that they should be stored appropriately on receipt. The Pharmacy box will not contain any reference to controlled drugs.

3.6 Storage of Medicines

The Nurse in Charge is responsible at all times for the safekeeping of all medicines on their ward or department or team.

The design and location of all ward or department medicine storage cupboards must be approved by Authorised Pharmacy Staff, and regularly monitored.

All internal and external medicines, disinfectants, and reagents must be stored in locked cupboards, trolleys or other secure cabinets - all reserved solely for the purpose. The only exceptions to this requirement are medicines for clinical emergencies, intravenous fluids, sterile topical fluids and nutritional products and some bulky medicated dressings that, because of their bulk, are stored in a clean area (as agreed between the Ward Manager and an Authorised member of the Pharmacy Staff).

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

Controlled drugs including benzodiazepines and hypnotics must be stored in a separate designated controlled drugs cupboard that is compliant with the Misuse of Drugs Regulations. Each ward and team will keep an up to date Register of Controlled drugs including benzodiazepines and hypnotics. This must include controlled drugs received, controlled drugs administered, a running balance and details of any controlled drugs returned to pharmacy for re-use or destruction.

Records of the maximum and minimum temperatures of clinic rooms where medicines are stored must be made on a daily basis, resetting the thermometer daily.

Where cold storage of medicines is necessary, a lockable, temperature controlled/monitored medicines fridge must be made available which must be reserved solely for the purpose. Records of the refrigerator temperatures are recorded on the trust 'Checkit' system, which gives a real time record of the refrigerator temperature.

Where there are temperature excursions, advice should be sought from Pharmacy on the appropriate continued use or replacement of medicines.

For each community team base where medicines are stored, a suitable nurse must be designated as the Nurse in Charge. This Nurse in Charge is ultimately accountable for the stock of all medicines held, ensuring that the Medicine Code is followed and that the security of medicines is maintained.

All medicines will be supplied by the Pharmacy and must be kept in a separate locked medicine cupboard to which the Community Nurses have access.

3.6.1 Siting of Cupboards and Trolleys**.**

The siting of medicines storage cupboards and the cupboards themselves must conform to the requirements of the British Standard 2881. Cupboards and trolleys must be sited where most convenient for staff, allowing adequate space and permitting surveillance to afford maximum security against unauthorised access. Medicine cupboards must generally be sited in a clean utility room to which the general public does not have access. Cupboards must not be sited where they may be subjected to higher than recommended humidity or temperature. Reagent cabinets must be sited in areas where testing is carried out.

For community teams, each team manager will be responsible for identifying a suitable lockable cupboard for storing medication. The Trust's Pharmacy Department must approve the location and specification of the cupboard. Normally, the medicine cupboard will be affixed to an internal wall, situated in a discrete location within the team base and only accessible by qualified nursing or pharmacy staff.

3.6.2 Review of Storage of Medicines

The quantities, range and storage of medicines stocked will be reviewed regularly by the Authorised Pharmacy Staff together with the Nurse in Charge.

3.6.3 Controlled Drugs (schedule 2 and 3)

No ward, clinic or team must store Controlled Drugs unless there is an appointed Nurse in Charge responsible for their storage and administration.

3.6.4 Samples of Medicines

No samples (of medicines or dressings) may be left on wards, clinics or teams. Representatives of pharmaceutical companies wishing to leave samples must be referred to the Pharmacy.

Representatives from the pharmaceutical industry should not normally have access to clinical areas without the necessary authorisation from a consultant or the Chief Pharmacist

3.6.5 Closure of a Ward or Department

If a ward, clinic or team is to close, the controlled drugs must be handed

over by the Nurse in Charge to an Authorised member of Pharmacy Staff who will sign the appropriate section of the register and return the Controlled Drugs to the Pharmacy.

If a ward, clinic or team is to close for more than a week, all other medicines must also be returned to the pharmacy. However, if a ward is to close for only a few days, the medicines (other than Controlled Drugs) may, with the agreement of an authorised member of the Pharmacy staff and the Nurse in Charge, stay on the ward provided there is adequate security to prevent unauthorised access to the cupboards.

3.6.6 Breach of Security

Any incident must be reported immediately and investigated as soon as practical by the Nurse in Charge together with an Authorised member of the Pharmacy staff. An Eclipse form should also be completed.

3.6.7 Storage Accommodation

Clinical areas may have some or all of the following medicine storage units.

- Controlled Drug Cupboards - reserved solely for the storage of Controlled Drugs and secured to the wall. These cupboards may be separate from others or be inside other locked medicines cupboards used to store internal medicines. The lock must not be the same as any other lock in the hospital.
- Internal Medicine Cupboard(s) - for the storage of tablets, liquid medicines, injections etc. Medicines should not be stored at temperatures above 25oC unless stated otherwise on the label. They should be stored in alphabetical order according to approved name or another suitable system understood by all staff.
- External Medicine Cupboard(s) - for the storage of creams, lotions etc.
- Medicine Refrigerator - medicines must not be stored together with food or pathological specimens, but in a separate small locked fridge. Medicines requiring storage below room temperature will be marked

"Store between 2ºC and 8ºC, in a refrigerator." The temperature of medicine fridges must be continuously monitored and recorded, using the Checkit system. In the case of high or low temperatures outside the acceptable range then Pharmacy must be contacted for advice and next steps. Until it is advised that refrigerated medicines are safe to use, affected medicines must be removed to another refrigerator that is in good working order and the affected medicines quarantined and not used. The Estates and Facilities Dept. Must be contacted to correct the problem. Once the problem is rectified then the refrigerator can be restocked from Pharmacy and/or the original medicines removed from quarantine and placed back in the original refrigerator (or replacement)

- Reagent Cupboard(s) - situated in the area where urine testing is carried out. Some wards/units may not require a separate cupboard if urine testing is only very rarely carried out but in such circumstances there should be an agreement about where such testing is to take place. They must not be stored with internal medicines
- A Clean Storage Room - for intravenous fluids and sterile topical fluids, if no suitable cupboard is available.
- Medicine Trolley - Where used for storage of medicines in current use on the medicine administration round. When not being used the medicine trolley must be locked and secured to the wall. The trolley must not be left unattended during the medicine round. If the nurse of healthcare professional undertaking the medicines round leaves the trolley, it must be locked immediately.
- Medicines for Clinical Emergency - must be readily accessible and in a position to afford supervision to prevent unauthorised access. For further details refer to the Clinical Emergency Policy for your locality.

Clinic Room temperatures must be monitored and recorded on a daily basis. If the temperature exceeds 25^0C on a regular basis then the Pharmacy must be contacted for advice and if necessary to quarantine medication until its safety/efficacy for use can be assessed. The Estates Department must be informed to see if the problem can be rectified and if necessary, a business case for climate control may need to be developed and agreed through the Trust.

3.6.8 Flammable Liquids, Gases, Aerosols - advice is obtainable from the Trust Fire, Health and Safety Advisor.

3.7 Checking of Stock Balances

3.7.1 Controlled drug registers are available from the Trust Pharmacy service as bound books. A separate page should be used for each supply of controlled drugs. For each preparation, entries should be in chronological order, in indelible ink and with a running balance. If the end of the page is reached then the balance should be transferred clearly to a new page. This transfer should be witnessed.

If a mistake is made then it should be bracketed in such a way that the original entry is still legible and the correction made as close to it as possible

with the brackets and correction signed and dated. Alternatively, a single straight line through the entry may be made as long as the original entry is clear and legible. Under no circumstances should entries in controlled drug registers be erased or obliterated.

Controlled drug registers must be kept for a minimum of two years by the ward or department after the last entry has been made. After two years, they should be destroyed as confidential waste. If there is record of any controlled drug destruction in the Controlled Drug register, it must be kept for a minimum of seven years. After seven years they should be destroyed as confidential waste.

3.7.2 Controlled Drugs including benzodiazepines and 'Z' hypnotics

3.7.2.1 It is good practice to check stock balances of all schedule 2 and 3 Controlled Drugs, benzodiazepines and 'Z' hypnotics with every shift change involving a change of Assigned Nurse in Charge. The audit minimum standard is that the stock balance of all Controlled Drugs entered in the Register must be checked once a week against the actual stock held in the ward/department. Between these limits the frequency of stock checks carried out on each ward/department is at the discretion of the Nurse in Charge. There is no

need to open packs with intact tamper evident seals for stock checking purposes. However, when such packs are opened for the first time, this should be done in the presence of a suitable witness. Where possible there should also be verification of entries in the register against entries made on individual inpatient prescriptions. This also applies to those medicines deemed controlled drugs by local agreement.

3.7.2.2 Two Practitioners, one of whom must be the Nurse in charge, must perform the check.

3.7.2.3 A record indicating this check has been carried out must be kept in the Controlled Drug Register and must confirm the stock is correct. The record must be dated and signed by both Practitioners. The Nurse in Charge must ensure that these checks are carried out.

3.7.2.4 The Nurse in Charge must undertake a random check of all Controlled Drugs cupboards at least once a month and record it in the ward register.

3.7.2.5 It is recommended that stock balances of individual preparations be checked after every administration. Both individuals must initial the entry to confirm the stock balance has been checked and is correct. If there any discrepancies then the procedure outlined in section 16 should be followed.

Liquid medicines will only be accurately checked against full and empty bottles. In between, balance checks can only be estimated. Where overage/under ages are identified then this should be checked by the nurse and the Nurse in Charge. Where overage/underage quantities are confirmed, this should be recorded in the Controlled Drug Register, clearly marked as an overage/underage and signed by both practitioners and dated. It is therefore good practice to check controlled drug register balances for liquid controlled drugs when an in-use bottle is empty and before the next new bottle is opened.

3.7.2.6 Any need for more frequent checks will be decided by the Nurse in Charge in liaison with the Chief Pharmacist or Deputy Chief Pharmacist.

3.7.2.7 Authorised pharmacy staff should check the Controlled Drugs balance at a minimum of every three months and when asked to do so, for example when overall responsibility for the medicines change e.g. change of appointment of the Nurse in Charge. Where necessary there should also be verification of entries in the register against entries made on individual inpatient prescriptions. Pharmacy staff will also carry out audits of the safe and secure handling of controlled drugs every six months.

3.7.2.8 Other Medicines

Any need for checking stock balances of other medicines must be left to the discretion of the Nurse in Charge. If, however, there is suspicion of abuse of medicines this must be reported to the department manager and the Chief Pharmacist. In such cases it is advised that a stock balance must be recorded and regular checking introduced. If this shows discrepancies the medicine must be made subject to similar procedures required for Controlled Drugs and register entries must be made whenever the medicine is administered.

3.8 Custody and Safe-keeping of Medicine Keys

3.8.1 The Controlled Drug Cupboard Key

On wards, the key must be kept on the person of the Nurse in Charge or Designated Nurse nominated by them. The key must be kept on a separate key ring that can be readily identified. Responsibility remains with the Nurse in Charge.

On community teams, the key will be kept in the teams safe. Only qualified nursing staff will have access to this safe.

No practitioner can have access to the Controlled Drug cupboard except with the agreement of the Nurse in Charge, officially holding the key. The key must not be handed over to medical staff.

Authorised Pharmacy Staff may have access to the controlled drug cupboard key for the purpose of performing statutory checks.

In the event of the person in charge being inappropriately qualified, the key must be handed to the Nurse in Charge of a ward or department in the near vicinity. This information must be made known to the staff in either the ward or department and to the manager in charge of that section.

Where Controlled Drugs keys go missing, every effort must be made to find or retrieve them. The service manager should be informed as soon as possible and a senior pharmacist also informed who will advise on any actions including emergency access to additional controlled drugs where necessary. If keys cannot be found then the Chief Pharmacist should be informed who will agree any additional actions with the Trust Accountable Officer for controlled drugs.

3.8.2 Keys for Medicine Cupboards, Medicine Trolleys and Refrigerators

The keys for the external medicine cupboard, internal medicine cupboard, medicine trolley, medicine refrigerator and pharmacy transport box (if applicable) must be kept together on one key ring reserved solely for these keys. This may be included on the main bunch of keys. The keys must be clearly identified.

The keys must be kept on the person of a qualified nurse. In the event of no suitable nurse being on duty in a ward or department, the keys shall be handed to the Nurse in Charge on a ward or department in the near vicinity. This information must be made known to the staff on the ward or department manager in charge of that section.

Medicine cupboard keys may be handed over to Authorised Pharmacy Staff who are undertaking audit or operating a topping up service.

For community teams, drug cupboard keys must be kept securely in code protected cupboard which can only be accessed by qualified nurses, nursing associates or pharmacy staff.

At Community Team bases where a number of nurses may require access to the medicine cupboards at different times of the day. A secure system must be agreed between the Nurse in Charge and the Chief Pharmacist.

Only registered nurses, registered nursing associates or pharmacy staff are to be issued with access to this repository. The manager is responsible for retrieving the key (if issued on an individual basis) when a member of staff leaves their team. Team managers are also required to ensure that there is a record maintained of the dates of issue and return of keys. Keys should be individually identifiable and easily related to the member of staff to whom they are allocated. Where a safe with an electronic code is used then the team manager is responsible for managing access and for changing the access code on a regular basis.

3.8.3 Keys to individual service user's medicine cupboards, where they exist

The master key for individual service users' medicine cupboards opens all such cupboards on the ward. The master key must be kept on the ward medicine cupboard key ring at all times and must never be issued to a service user.

Keys that open individual service user medicine cupboards must be individually numbered and stored in a locked cupboard on the ward when not in use.

If a service user is to self-medicate and have responsibility for the storage and safe-keeping of their medicines, the appropriate numbered key may be issued to the service user who signs for receipt of this key. The key that is issued to an individual service user only opens one medicine cupboard and must be kept securely by the service user. The service user must return the key to the Nurse in Charge on discharge or when they are no longer selfadministering their own medicines.

3.8.4 Reagent Cupboard

The key to the reagent cupboard may be kept separately and in a place designated by the Nurse in Charge.

3.8.5 Loss of a Medicine Cupboard Key

Every effort must be made to find the key or retrieve it from off duty staff. Should access to the medicine cupboard be required before the keys are retrieved the duty manager must be informed and a duplicate key may be obtained. A second set of keys must be kept with the appropriate manager or in a secure place where 24-hour access is available. The keys must be clearly identified and easily accessible to the duty manager/pharmacist. Where the cupboard keys are not found a new lock must be fitted to the cupboard. If there is no duplicate key, the duty manager will arrange for the cupboard to be broken open and a new lock fitted. The pharmacy department must also be notified when it is next open.

3.9 Dispensing, Preparation and Administration of Medicines

It is the role of the Pharmacy Department to dispense medication, but recognising the 24-hour nature of many of the Trust's services, the Pharmacy Department is not always able to provide such an extended service. In such circumstances, secondary dispensing may be required. Secondary dispensing involves re-packaging medicines that have been dispensed for an individual service user into another container bearing another copied (from the original) label carried out by suitably trained staff. Further information on secondary dispensing can be found in Appendix 8.

There may be occasions where medication may have to be prepared for delivery to a service user, when the Pharmacy Department is unable to provide this service. Out of hours, there is an on-call pharmacy service available which should normally be contacted in such circumstances. The on-call pharmacist will advise on the most appropriate action to be taken including supply of medication if it is deemed that this cannot wait until Pharmacy services are next open.

Only medicines that have been supplied on behalf of BSMHFT, approved service users own medicines, or medicines approved for use by BSMHFT PTC, or APC may be administered to service users. This also applies to complementary medicinal products, e.g. aromatherapy oils, homeopathic medicines.

Medicines must only be prepared, checked or administered to a service user by the following categories of healthcare staff:

- Nurses or Nursing Associates
- A Medical Practitioner
- Authorised Pharmacy Staff
- A student nurse, but only under the direct supervision of a registered nurse. The registered nurse remains responsible for ensuring that the correct procedure takes place
- Other Authorised Employees

3.9.1 Preparation of Medicines

Errors can occur during the preparation of medicines for administration, particularly where some form of dose calculation is involved. Whenever possible medicines are presented to ward areas from the Pharmacy in a ready-to-use form where no further dilution or minimal dose calculation is required.

Where the preparation of medicines is performed outside the Pharmacy, the following procedure must be observed:

- Read the patients EPMA prescription record carefully. Determine the name, dose, diluent, route for administration and expiry date of the medicine.
- The nurse or authorised professional administering the dose must clearly know and understand the actual amount of the medicine to be administered. If a dose calculation is required, it is recommended that the nurse or authorised professional checks all calculations with a second practitioner or a pharmacist before administration.
- Where a calculation is involved and where the medicine is intended for intravenous administration, a second practitioner must check all aspects of the preparation of the medicines and sign and date the entry.
- If the nurse or authorised professional is unclear as to the correct diluent for a medicine or precise method for medicine preparation, he/she must obtain this information from the Pharmacy or the on-call pharmacist before proceeding further.
- An appropriate area for the preparation of intravenous infusions must be identified. This area should be separated from the direct service user areas and enclosed (all doors and windows should be closed). These precautions reduce the risk of microbial contamination and interruptions, which can lead to errors.

3.9.2 Administration of Medicines

The Nurse in Charge is responsible for ensuring that prescribed medicines are administered within a reasonable time of the prescribed time. Doses may be given earlier or later than the prescribed time where this is appropriate and in the patient's interest. The acceptable time difference will depend on the daily frequency of administration of the drug, the time difference between the prescribed time of administration and the intended time of administration, when the next dose is due and any specific risks that may be identified should doses be given relatively close together. Where there is doubt then the administering nurse should contact a doctor or take advice from Pharmacy.

For long acting injections, where the timing of administration is less critical, administration can be up to two days either side of the intended date of administration or longer if the product summary of characteristics (SPC)

defines a longer time period. The PTC has prepared guidance on the early/late administration of long acting injections which should be followed.

Before administration of a medicine, a nurse or professional administering the medicine must:

- Read the electronic prescription record carefully.
- Check authorisation of administration (Forms T2, T3, section 62 and CT11/12) if the service user is detained under the Mental Health Act 2007. Further information on consent to treatment is included in Appendix 6.
- **Ascertain from the record of the administration of medicines that the prescribed dose has not already been given.**
- Select the medicine required and check the label against the prescription.
- Practitioners administering medicines must assure themselves that the service user has capacity to understand and consent to the administration of the medication, unless they are detained under the MHA and subject to a T3 or section 62.
- Practitioners administering medicines must then check and confirm the identity of the service user and administer the medicine. Extreme care is required to ensure that the service user's identity is confirmed by visual recognition and verbal questioning before proceeding to administer the dose.

Medicines dispensed and labelled for an individual service user must be administered only to that service user (supplies labelled for individual service users must not be shared).

Practitioners who administer or supervise the administration of the medicine must, at the time of administration, record the administration on the trust EPMA system.

Multiple medicines must not be dispensed into multiple tots in preparation for administration to more than one service user

Service users must be observed to have taken their medicines by the practitioner administering the medicine. Prepared medicines must not be left unsupervised unless the Trust self-administration policy (Appendix 13) is being followed.

If a medicine is omitted the following codes must be entered on the medicines administration record on the trust EPMA system:

- 1 – Medicine not available
- 2 – Service user refused
- 3 – Patient on leave
- 4 – Patient not on ward
- 5 – Medicine not required

- 6 – Patient unable to take e.g. If the service user is nil by mouth and the practitioner has been given clear instructions to omit the oral doses. It must be noted that some medicines are essential even if the service user is “nil by mouth” – if there is doubt advice should be sought from medical or pharmacy staff.
- 7 – Patient asleep and it is not necessary to wake them
- 8 – The service user is self-administering
- 9 – Prescription is illegible / incorrect / invalid
- 10 – Administered by mother to baby
- Other - if any of the above do not apply

If necessary, an explanation must be recorded in the patient’s electronic patient record, the only exception to this being when a service user is on leave.

Failure to record the administration of a medicine or use an omission code constitutes a medication incident and must be reported via the trust untoward incident reporting system. Such records will be the subject of regular audit.

If the service user is absent from the ward, or has missed a dose for some other reason, the delayed dose can be administered at a later time provided a medical practitioner or pharmacist has confirmed that it is appropriate to do so or that it is according to an agreed protocol. The actual time of administration must be clearly recorded in the administration record by the nurse or professional administering the medicine .

Service users classified ‘Nil by Mouth’, prior to a diagnostic procedure or receiving an anaesthetic (e.g. ECT), must have all their prescribed oral medicines administered to them at the prescribed time unless specifically advised otherwise by medical or pharmacy staff. The medicines should be taken with sufficient water to enable them to be swallowed. Only medicines that have been clearly marked as such on the patient’s electronic prescription may be omitted. It is the responsibility of the prescriber to provide clear written instructions to the nursing staff concerning the intended omission of prescribed doses.

3.9.3 Checking of Administration

It is good practice that, wherever possible, all medicines be prepared and administered in the presence of another practitioner. However, this is not required under this policy. Where practitioners decide to undertake medicines administration with a second practitioner, they should undertake all administration tasks together rather than the two practitioners separately sharing the tasks involved in administration. E.g. there should *not* be one practitioner reading from EPMA while the second practitioner retrieves and prepares the medication for administration.

Except in extreme emergency, the following must be checked by TWO qualified practitioners

- All medicines given by continuous administration, e.g. IV infusion, syringe drivers. There should be a record of the individual practitioner setting up and replenishing each intravenous infusion.
- All bolus injections, IV additives and injections via drip tubing.
- All injections taken from multi-dose vials. When a service user has proven competent to self-administer the medicine (e.g. insulin) the checking of administration need only involve one practitioner.
- All medicines administered to a child under 12 years of age.

Health Care Workers may be authorised by the Trust to check and witness the self- administration of medicines following patient specific assessment and training and assessment of the Health Care Worker by a nurse. The necessary training and assessment process will be provided by the Trust.

3.9.4 Schedule 2 and 3. Controlled Drugs, benzodiazepines and hypnotics

The preparation and administration of all Controlled Drugs including benzodiazepines and hypnotics must be witnessed by a second practitioner.

An entry must also be made in the ward or department Controlled Drugs register and include:

- date and time of administration
- name of service user
- dose administered
- full signature of both practitioners

The remaining stock balance must be checked and confirmed. Any medicine prepared and not used, or only partly used, must be destroyed in the presence of a second practitioner. An entry must be made in the Controlled Drugs register and signed by both practitioners. Any discrepancies must be brought to the notice of the Nurse in Charge and the pharmacy, when next open.

It may be assumed that all sealed and unopened containers contain the stated quantity. These containers should be opened in the presence of a second witness and any discrepancies reported to Pharmacy immediately.

3.9.5 Administration in police custody

This excludes medication listed under the misuse of drugs regulation 2001, schedule 2 or 3, for example methadone, temazepam and buprenorphine.

A detainee may only self-administer such medication under the personal supervision of registered medical practitioner authorising such use.

- It may be necessary to administer medication to service users who are in police custody. This could be regular or ‘as required’ oral medication (for example, lorazepam or procyclidine)
- In instances where there is already a valid prescription in existence, a registered nurse (mental health) or doctor can administer the medication

as per that prescription after discussion and agreement with the custody officer who may liaise with the Forensic Physician. This intervention must be appropriately recorded both in the trust clinical records and in the police custody record.

- For those service user users who are without a valid prescription, a prescription may be written and medication administered as above.

OR

- Medication may be administered under a relevant patient group direction (see appropriate section of the BSMHFT medicines code) after discussion and agreement with the custody officer who may liaise with the Forensic Physician. This intervention must be appropriately recorded both in the trust clinical records and in the police custody record.

Please note:

If a person in custody has been arrested for an offence, they will usually have to be interviewed and then if charged, appear in court to answer the charge/s.

In this case the registered nurse (mental health) or doctor should not administer any medication, which may impair the person's mental capacity in any way.

If any medication is to be administered, discussion and agreement must take place with the custody officer, who may liaise with the Forensic Physician. The Forensic Physician (Under Police and Criminal Evidence Act 1984) has the final say in what medication is given to a person in custody.

Once medication has been administered to the person in custody, a registered nurse (mental health) or doctor should be available to the custody staff for advise/guidance/support.

3.9.6 Homely Remedies (for use in inpatient areas only)

3.9.6.1 Homely remedies are medicines that can normally be purchased over the counter. A small range of medicines can be administered to service users by appropriately trained nursing staff, when certain conditions and criteria are met. This policy allows:

- The service user to receive rapid treatment for relatively minor, self-limiting symptoms
- Unnecessary calls to prescribers are avoided
- Medicines wastage is minimised.

Senna 7.5mg tablets	One or two tablets at night
Throat lozenge	1
Simple Linctus	5mls
Paracetamol 500mg tablets	1 or 2
Antacid	10 mls

3.9.6.2 The homely remedies above may be administered by nursing staff on the Trust EPMA system using the patient group direction desktop.

3.9.7 Principles of administration

A registered nurse or nursing associate must administer the medicine

Each medicine may be given a maximum of three times only for each episode of a minor ailment. If a medicine is required for longer, a doctor must review the service user and if appropriate, prescribe the medicine on an 'as required' basis or regularly. Care must be taken to ensure that no more than three doses are given without medical review, particularly for Senna tablets or throat lozenges in patients taking clozapine.

3.9.8 Procedure

Following a request from a service user for 'homely remedy' the nurse will:

- Confirm the reason for the request and the nature of the discomfort
- Ensure that the medication requested is required and appropriate to the needs of the service user
- Check that the medication requested has not been administered previously; or if it has been given before that sufficient time has elapsed

  for a second dose to be administered safely.
- Check that the requested medicine has not been prescribed and administered on another section of the trust EPMA prescription record
- A record of the administration is made on the trust EPMA system using the PGD function.

3.9.9 Administration without a prescription for the purpose of life saving in an emergency

Under Section 19 of The Human Medicines Regulations, 18 drugs are listed that can be given in an emergency without the need for a prescription. These exceptions cited in Section 19, enable lifesaving drugs to be given quickly. . Any other medications not listed in Section 19 can only be administered against a prescription or under a PGD or homely remedy.

There is no legal problem in any person administering one of these drugs listed, which is either prescribed for a specific person or needs to be administered to an unknown person in such a lifesaving situation. However the health care provider involved must work within their professional standards, and must therefore be competent in being able to recognise the problem and act safely.

As an example, the health care provider must be competent in recognising an anaphylactic reaction and be able to administer adrenaline safely.

Those medicines included in Schedule 19 applicable within the trust include

- Chlorpheniramine injection
- Glucagon injection
- Glucose (10%) injection
- Hydrocortisone injection
- Naloxone hydrochloride injection
- Adrenaline 1:1000 up to 1mg for intramuscular use in anaphylaxis

Administration of medicines outside of those listed in Schedule 19 can be enabled by the Trust's Pharmacological Therapies Committee, e.g. via a PGD (e.g. GTN/Aspirin) but the same professional obligations apply regarding competency.

Anaphylaxis

- Adrenaline IM injection 1 in 1000 (dose of 500 micrograms) or Epipen (dose of 300 micrograms) may be administered by medical staff or registered nursing staff trained in enhanced life support (ELS) or immediate life support (ILS) and repeated after 5 minutes if necessary in line with Resuscitation Council Guidelines
- Oxygen 15 litres per minute (via high concentration non-rebreathe mask) may be administered by all staff trained in ILS/ELS

Cardiac Arrest

- Atropine Sulphate 3mg IV may be administered by medical staff or registered nursing staff trained in immediate life support (ILS) when an IV cannula is in situ in line with Resuscitation Council Guidelines
- Adrenaline injection 1 in 10,000 – an IV injection of up to 1mg may be administered by medical staff or registered nursing staff trained in immediate life support (ILS) in line with Resuscitation Council Guidelines

Oxygen 15 litres per minute may be administered by all staff, trained in ILS, for service users who are acutely unwell and deemed to require oxygen.

Further information on administration of other medicines required in the emergency treatment of chest pain, hypoglycaemic attacks, chest pain, seizures or status epilepticus and asthma attacks is approved via the Resuscitation Committee.

3.9.10 Administration of medicines contained in patch formulations A number of medicines are available in patch formulations including some controlled drugs. The following procedure should be followed when applying patches containing medicines.

Remove the old patch before applying a new one. The new patch should be dated and a patch chart (Appendix 17) used to indicate the date and position of the patch on the service user so that sites can be rotated. It should also be clear on the administration record when a service user's patch should be changed

Ensure all patches are removed prior to the application of a new patch - it is important to remember that some drug remains in the patch after the duration period specified e.g. 72 hours has elapsed. Overdose may occur if patches are not removed appropriately before the new patch is applied.

When a new patch is to be applied, it should **not** be applied immediately after a bath or a shower or immediately after using creams, talc or soap on the skin. The skin should be completely dry before application of the patch. The patch should be applied to a clean, dry area of skin which is non–hairy; if necessary, the hair may be clipped with scissors but not shaved. Do not apply the patch to irritated, recently irradiated or shaven skin, or on lymphoedematous areas.

Press in place firmly with the palm of the hand for 30 seconds. Some patients may need a semi-permeable dressing to ensure adherence. If more than one patch is applied they should be applied at the same time and placed far enough apart so they do not overlap. The patient information leaflet (PIL) for information as to where the patch may be applied.

Ideally the underlying skin should be allowed to rest for 3-6 days before applying another patch to the same area. The site of application should be rotated in accordance with the manufacturer's guidance.

The patch should be checked each day to ensure that it is still in place.

Used patches still contain significant quantities of active drug. It is important to ensure used patches are disposed of correctly as described below:

- After removal, fold the patch in half and stick together with the adhesive sides inwards

- Discard in a sharps bin or return to the Pharmacy for destruction. Patches containing controlled drugs should be disposed of following the procedure in Appendix 17.
- Any unused patches should also be returned to Pharmacy following appropriate procedures.

Application of patches containing medicines should be recorded using the form in Appendix 17. Care should be taken to record the place of application so it can be checked when in situ and can be checked that it has been removed before applying a new patch.

3.9.11 Covert Administration, Self-Administration and Medication Concordance.

These are dealt with in the Covert Medicines Administration policy and

appendices 13 and 14 respectively.

3.9.12 Adverse Reactions and medicine defect reports.

3.9.13 The nurse or professional administering the medicine must observe and note any adverse side effects of medicines and inform the responsible medical staff. Any adverse side effects must be documented in the service user's electronic patient record.

3.9.14 Serious suspected adverse reactions to medicines are notifiable by doctors, nurses, pharmacists or service users/carers through the Medicines and Healthcare Regulatory Agency (MHRA) Yellow Card system. For new drugs or those annotated with a black triangle in the BNF or other medicines literature then all suspected adverse reactions should be reported to the Committee on Human Medicines (CHM), part of the MHRA. Advice and Yellow Cards are included in the British National Formulary and are also available from:

https://yellowcard.mhra.gov.uk/

Medicines and Healthcare products Regulatory Agency

CHM Freepost, SW2991

London SW8 5BR

Telephone: 0800 731 6789

The trust EPMA system also contains a link to the electronic yellow card reporting system.

3.9.15 Medicine defect reporting

The following procedure applies when a defect is found or is suspected in any medicine.

1. Inform the Pharmacy who will advise on all reporting, recording and investigating on the defect.

2. Retain any remaining product and any associated products or equipment (e.g. administration sets, infusion devices etc).
3. Record the details of the product and defect in the patient's electronic care record.
4. If the product has been administered to a service user inform the doctor responsible for the service user and record the defects in the service users' notes.
5. Report the incident to the Nurse in Charge of the ward or department.

If a drug defect is suspected outside normal opening hours of Pharmacy, contact the on-call Pharmacist.

Suspected defective medicinal products are notifiable by doctors, pharmacists, nursing staff or patients to:

dmrc@mhra.gsi.gov.uk or online at

https://www.gov.uk/report-problem-medicine-medical-device

Any clinician considering making a report of an adverse drug reaction or defective medicine, or requiring advice, should contact a clinical pharmacist and also complete an Eclipse incident Report Form. Such reports will then be considered as part of the medicines management incidents by the Pharmacological Therapies Committee.

3.10 Losses or Discrepancies

3.10.1 Controlled Drugs, Schedule 2 and 3, benzodiazepines and 'Z' hypnotics

In the event of a discrepancy between the stock balance and register for Controlled Drugs, the Nurse in Charge must immediately and thoroughly investigate the loss, checking the CONTROLLED DRUGS register against prescription administration records and brief interviews with staff.

If the initial investigation is unsuccessful, the discrepancy must be reported immediately to the senior manager responsible for the ward or department and the Chief Pharmacist, at the earliest opportunity who will then consider appropriate further actions and reporting to the Trust Controlled Drugs Accountable Officer and Local Intelligence Network for Controlled Drugs. An Eclipse form should also be completed. This also applies to all medicines similarly assigned as controlled drugs by local agreement.

Where the discrepancy or concern is serious then this will be reviewed by the Chief Pharmacist and the Controlled Drugs Accountable Officer. If necessary then an investigation will be commissioned into the discrepancy/concern with terms of reference and an investigation team appointed. Where the concern is of a very serious nature and there is a suspicion of criminal activity then the matter will be reported to the Police for investigation.

3.10.2 Other Medicines

Any loss of other medicines must be reported to the senior manager responsible for the ward or department (via the Nurse in Charge) and the Chief Pharmacist who can then decide on a further course of action. **3.11 Disposal of Medicines no Longer Required**

3.11.1 Controlled Drugs.

Controlled Drugs must not be returned from the wards or departments in the pharmacy box without the approval of Pharmacy staff. Controlled drugs no longer required by a ward or department can be destroyed on the ward by the Nurse in charge only in the presence of a pharmacist. This should be done using controlled drugs destruction kit provided by Pharmacy and in line with the instructions for using this product. An outline standard operating procedure is included in Appendix 16. Alternatively, controlled drugs may be removed by Authorised Pharmacy Staff or sent via Pharmacy box only after authorization by Pharmacy staff.

Upon removal of the controlled drug, the Nurse in Charge or authorised nurse will make an entry into the controlled drugs register, including the new stock balance and sign the controlled drugs register. The transaction will be witnessed by the Pharmacist or Nurse in Charge who will also sign the register. See also Appendices 11 (Protocol for the return of unidentified substances) and 12 (Return of Controlled Drugs to Pharmacy).

3.11.2 Any Controlled Drug removed from the ward or department by Authorised Pharmacy Staff must be returned to the pharmacy department where an appropriate entry will be made in the pharmacy Controlled Drug Register. Any dose of a Controlled Drug that is prepared but not administered, including partly used syringes used in syringe driver pumps shall be destroyed on the ward or department in accordance with the Trust Waste Management Policy. The destruction of the Controlled Drug must be in the presence of a second nurse and an appropriate entry should be made in the Controlled Drug Register, which includes the signatures of the two practitioners involved in the destruction.

3.11.3 Controlled Drugs brought in to the hospital by the service user may be: • Used by the ward staff for administration to the service user (see Patient's Own Medicines section)

• Stored for subsequent destruction with the permission of the service user or their carer

In both of the above the Controlled Drug in question must be stored in the Controlled Drug cupboard. An entry must be made in the Controlled Drug Register either on a new page specifically allocated for that service user's own medicine or on a page specifically identified for the recording of "Patients Own Medication for destruction".

3.11.4 All unwanted Controlled Drugs returned to the pharmacy must be recorded as having been received before being stored in an approved secure place until an Authorised Person can witness their destruction.

3.11.5 The Trust Pharmacy service will assess returned controlled drugs for reuse or destruction. Where controlled drugs are destroyed, this will be done in accordance with current Home Office guidance on destruction of controlled

drugs, the Trust Waste Management policy and waste management regulations.

3.11.6 Disposal of small quantities that have been prepared for administration

Any Schedule 2 or Schedule 3 Controlled Drug (which is subject to CD register record keeping requirements) that has been prepared and not used, or only partly used, must be destroyed in the presence of an appropriate witness and an entry made in the Controlled Drugs register. The remaining stock of the Controlled Drug must be checked and recorded by both parties.

Only small amounts of CDs (i.e. individual doses), can be destroyed on wards by registered nurses, in the presence of an appropriate witness, in the following situations:

- Any surplus when the dose is smaller than the total quantity in the ampoule or when only part of a tablet is required
- When a dose is prepared/drawn up but not used
- When a patient refuses a dose or partial dose

The unused or partially used remaining dose of tablet CDs and unused or partially used doses of liquid CDs, must be firstly denatured by crushing/grinding any solid dose formulation then placing either the liquid or crushed solid dose into a small amount of hot, soapy water (hot tap water and washing up liquid is sufficient) ensuring that the drug has been dissolved or dispersed. The resultant mixture should then be placed into the appropriate waste medicines bin.

3.11.7 Other Medicines

All out of date medicines as well as those no longer required by the ward/team must be returned to the pharmacy in a Pharmacy box.

In the community, service user specific unwanted medicines are the responsibility of the service user. When it is in the service user's best interests, community staff may take unwanted medicines in the patient's home to a local community pharmacy for safe disposal.

3.11.8 Disposal of Sharps

The Trust provides sharps disposal boxes which must be carried (discretely) and used whenever medication requiring the use of needles and syringes is being administered.

Used Sharps boxes must be disposed of according to local arrangements.

3.12 Training

3.12.1 All newly appointed clinical staff will receive training with respect to the Medicines Code during their Trust induction.

3.12.2 Training will be provided to update and develop existing staff, as outlined in Fundamental Training Prospectus.

3.12.3 Specific medicines management training is a component of Rapid Tranquillisation Training.

3.12.4 Staff participating in secondary dispensing within wards/teams must also receive training in secondary dispensing before commencing such dispensing. Wards/teams and Pharmacy will keep records of staff who have received secondary dispensing training. Initial secondary dispensing training provided by the pharmacy team will be valid for three years. Following this, training will need to be renewed online every year.

4. Roles and Responsibilities

4.1.1 The Executive Medical Director is the identified Trust lead for Safe Medicines Practice. The Executive Medical Director is also the Trust's accountable officer for controlled drugs. Both of these roles are supported by the functions of the PTC, the Chief Pharmacist and the Assistant Medical Director (Pharmacological Therapies).

4.1.2 The responsibilities of the various practitioners associated with the prescribing, ordering, dispensing, carriage and transport, storing, administering and disposal of medicines are as follows:

- The Chief Pharmacist will be responsible for the organisation, monitoring and reporting of a system for assuring the safe and secure handling of medicines
- Medical staff and non-medical prescribers are responsible for prescribing medicines for service users. They must comply with the legal framework for medicines and the Medicines Code when performing these duties. • A record showing appointments and signatures of all prescribers (including locum appointments) must be kept in the pharmacy and updated, upon any change, by the appropriate manager.
- The Nurse in Charge of a ward or department is ultimately accountable for the stock of all medicines held and is responsible for ensuring that the Medicines Code is followed correctly and that the security of medicines is maintained.
- A record showing appointments and signatures of all nurses must be kept in pharmacy and updated upon any change by the appropriate manager.
- The Nurse in Charge of the ward or department is responsible for the stock of medicines held in the ward or department and for ensuring that stocks of Controlled Drugs, if held, correspond with the details shown in the register. The Nurse in Charge is responsible for ensuring that this is carried out. Any discrepancy must be reported according to the procedure laid down in 3.10.
- Pharmacists are responsible for the stocks of medicines held in the pharmacy, their manipulation and preparation into user ready presentations and for their supply to wards, teams and units. They are also responsible for advising on the safe, effective and economic use of medicines. These responsibilities include advising practitioners on the storage of medicines in clinical areas. Authorised Pharmacy Staff will inspect the stocks of medicines held on the ward or department at any

time to ensure the medicines are in date and stored under the proper legal and environmental conditions. This will occur at least annually.

- The administration of medicines is the responsibility of the Nurse in Charge of the ward or department who may delegate these duties to a nurse or another suitable professional but who must exercise supervision as is necessary
- Student nurses must be given every opportunity to become proficient in medicines related activities under appropriate supervision. The supervising nurse has responsibility for medicine procedures at such times.

4.2 Definitions

4.2.1 Only staff with contracts (or honorary contracts) of employment to work in Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT) are recognised as having any involvement with medicines. The term "Practitioner" is used in parts of this Medicines Code. This is a general term used to describe a medical practitioner, nurse, pharmacist or other authorised healthcare employee. In may part of this Medicines Code, specific reference to medical nursing or Pharmacy professionals is specified where necessary and appropriate.

Designated Complementary Therapist

Any practitioner of a complementary therapy (see Appendix 2) who has obtained the appropriate qualification from a recognised organisation and is approved by the Trust. Authorised Pharmacy Staff

Any pharmacist, or pharmacy technician or pharmacy assistant technical officer (ATO) authorised by the Chief Pharmacist as competent and appropriate to perform a specific function.

Authorised Employee

A member of staff who has, following training, been authorised by BSMHFT to undertake specific duties in relation to medicines, e.g. support workers.

4.2.2 Medicines

Whether for internal or external use, will be regarded, for the purpose of this Code, as comprising the following categories:

- Controlled Drugs controlled under the provisions of the Misuse of Drugs Act 1971, with stringent requirements for supply, storage and administration.
- All other medicines and medicinal products prepared for administration to service users and which are controlled by the Medicines Act, 1968. This also includes many diagnostic agents, X-ray contrast agents and medical gases.
- All complementary medicines e.g. aromatherapy, herbal or homeopathic remedies. These products are used for therapeutic purposes and require the same safeguards as other medicines.

4.2.3 Electronic Prescription and Medicines Administration System (EPMA)

An electronic system that enables electronic prescriptions to be generated and recorded and then the recording of medicines administration to be completed electronically.

5. Development & Consultation Process

Consultation summary	
Date policy issued for consultation	August 2020
Number of versions produced for consultation	One
Committees / meetings where policy formally discussed	**Date(s)**
Pharmacological Therapies Committee	August 2020
Heads of Pharmacy, nursing and Allied Health Professionals	
Issued to local governance fora Chairs	

Where received	Summary of feedback	Actions / Response

6. References

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Police and Criminal Evidence Act 1984 (PACE) – Code of Practice Guide

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Mental Health Act 1983.

http://www.legislation.gov.uk/ukpga/1983/20/contents

BSMHFT – 'Consent to Treatment Policy 2017

http://connect/corporate/governance/Policies/Consent%20to%20Treatment%20Policy.pdf

BSMHFT – 'Mental Capacity Act (2005)
http://connect/corporate/governance/Policies/Mental%20Capacity%20Act%20Policy.pdf

BSMHFT – 'Advance Statements and Advanced Decisions 2019

http://connect/corporate/governance/Policies/Advance%20Statements%20and%20Advance%20Decisions.pdf

BSMHFT – Medicines Reconciliation Policy 2018

http://connect/corporate/governance/Policies/Medicines%20Reconciliation%20Policy.pdf

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http://www.legislation.gov.uk/ukpga/1968/67

NICE Guideline NG46: Controlled Drugs: Safe Use and Management

https://www.nice.org.uk/guidance/NG46/chapter/Context

Misuse of Drugs Act (1971) & Misuse of Drugs Regulations (1985) and subsequent legislation.

https://www.legislation.gov.uk/ukpga/1971/38/section/18 NICE

Guidance MPG 2: Patient Group Directions

https://www.nice.org.uk/guidance/mpg2/resources/patient-group-directions-pdf-1779401941189 DH:

Reference Guide to Consent for Examination or Treatment (2nd Edition)

https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatmentsecond-edition

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8. Glossary of Terms

Medicine

Any substance or combination of substances presented for treating or preventing disease. Any substance or combination of substances which may be administered with a view to making a medical diagnosis or restoring, correcting or modifying physiological or psychological functions.

Prescribe

To authorise, by full signature, the supply and administration of a medicine.

Primary Dispensing

To prepare a clinically appropriate medicine for a service user either for self-administration or administration by another. The act of dispensing includes supply and also encompasses a number of other cognitive functions (e.g. checking the validity of the prescription, the appropriateness of the medicine for an individual service user, assembly of the product). These functions are performed under the supervision of a pharmacist or in exceptional circumstances a medical practitioner

Secondary Dispensing

This involves re-packaging medicines that have been dispensed for an individual service user into another container bearing another label. Only nurses who have undertaken Trust approved training are able to undertake secondary dispensing **Supply**

To supply a medicine to a service user or carer for administration.

Administer

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

Adverse Drug Reaction

Any untoward and unintended response in a service user to whom a medicinal product has been administered or taken including occurrences that are not necessarily caused by or related to that product.

Defective Medicine

A medicine that proves to be harmful under normal conditions of use, lacking in therapeutic efficacy or the qualitative and quantitative composition of the product is not as declared or the controls on the medicinal product and/or the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled.

9. Review and Audit

This policy will be formally reviewed by the Pharmacological Therapies Committee in 2021. The Committee will, however, continuously monitor its implementation and practice through an agreed annual programme of medicines management audits covering inpatient wards and community teams and carried out by Pharmacy, medical and nursing staff.

Element to be monitored	Lead	Tool	Frequency	Reporting Arrangements
Six monthly submissions to PTC of audits of the management of controlled drugs across BSMHFT	**Chief Pharmacist**	**Audit Report**	**Six monthly**	**Audit submitted to PTC for discussion and acceptance**
Six monthly submission to PTC of audits into the safe and secure handling of medicines for inpatient units and community teams	**Chief Pharmacist**	**Audit reports**	**Each one annually**	**Audit submitted to PTC for discussion and acceptance**
Audit of PRN prescribing carried out by Pharmacy or medical staff submitted to PTC	**Chief Pharmacist**	**Audit reports**	**Annually**	**Audit submitted to PTC for discussion and acceptance**
Missed dose audits carried out by Pharmacy or nursing staff submitted to PTC	**Chief Pharmacist**	**Audit reports** **Nursing Metrics**	**Six monthly**	**Audit submitted to PTC for discussion and acceptance**
Reports of allergy recording on prescription charts included in Medicines Management Dashboard and reported to PTC and Trust CGC	**Chief Pharmacist**	**Medicines Management Dashboard**	**Quarterly**	**Dashboard submitted to Trust CGC for acceptance**
PTC receives a report on medication incidents and any recommendations for action	**Chief Pharmacist**	**Incident summary report**	**Six monthly**	**Report received**

Appendix 1

Equality Analysis Screening Form

Title of Proposal	**Medicines Code**		
Person Completing this proposal	**XXXX**	**Role or title**	**Chief Pharmacist**
Division	**Corporate**	**Service Area**	**Trust wide**
Date Started	**28th January 2020**	**Date completed**	**31st January 2020**
Main purpose and aims of the proposal and how it fits in with the wider strategic aims and objectives of the organisation.			
This policy outlines the policy and procedures to be followed within Birmingham & Solihull Mental Health Foundation Trust for the prescribing, ordering, dispensing, transport, storage and administration of medicines.			
Who will benefit from the proposal?			
Service users and all clinical staff handling medicines in the course of their duties.			
Impacts on different Personal Protected Characteristics – *Helpful Questions:*			
Does this proposal promote equality of opportunity? **No impact** *Eliminate discrimination?* ***No impact*** *Eliminate harassment?* ***No impact*** *Eliminate victimisation?* ***No impact***		*Promote good community relations?* ***No impact*** *Promote positive attitudes towards disabled people?* ***No impact*** *Consider more favourable treatment of disabled people?* ***No impact*** *Promote involvement and consultation?* ***No impact*** *Protect and promote human rights?* ***No impact***	
Please click in the relevant impact box or leave blank if you feel there is no particular impact.			

Personal Protected Characteristic	**No/Minimum Impact**	**Negative Impact**	**Positive Impact**	**Please list details or evidence of why there might be a positive, negative or no impact on protected characteristics.**
Age	**X**			
Including children and people over 65 Is it easy for someone of any age to find out about your service or access your proposal? Are you able to justify the legal or lawful reasons when your service excludes certain age groups				

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Disability	**X**			

Including those with physical or sensory impairments, those with learning disabilities and those with mental health issues Do you currently monitor who has a disability so that you know how well your service is being used by people with a disability? Are you making reasonable adjustment to meet the needs of the staff, service users, carers and families?				
Gender	**X**			
This can include male and female or someone who has completed the gender reassignment process from one sex to another Do you have flexible working arrangements for either sex? Is it easier for either men or women to access your proposal?				
Marriage or Civil Partnerships	**X**			
People who are in a Civil Partnerships must be treated equally to married couples on a wide range of legal matters Are the documents and information provided for your service reflecting the appropriate terminology for marriage and civil partnerships?				
Pregnancy or Maternity	**X**			
This includes women having a baby and women just after they have had a baby Does your service accommodate the needs of expectant and post natal mothers both as staff and service users? Can your service treat staff and patients with dignity and respect relation in to pregnancy and maternity?				
Race or Ethnicity	**X**			
Including Gypsy or Roma people, Irish people, those of mixed heritage, asylum seekers and refugees What training does staff have to respond to the cultural needs of different ethnic groups? What arrangements are in place to communicate with people who do not have English as a first language?				
Religion or Belief	**X**			
Including humanists and non-believers Is there easy access to a prayer or quiet room to your service delivery area? When organising events – Do you take necessary steps to make sure that spiritual requirements are met?				
Sexual Orientation	**X**			
Including gay men, lesbians and bisexual people Does your service use visual images that could be people from any background or are the images mainly heterosexual couples?				

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Does staff in your workplace feel comfortable about being 'out' or would office culture make them feel this might not be a good idea?				
Transgender or Gender Reassignment	**X**			
This will include people who are in the process of or in a care pathway changing from one gender to another Have you considered the possible needs of transgender staff and service users in the development of your proposal or service?				
Human Rights	**X**			
Affecting someone's right to Life, Dignity and Respect? Caring for other people or protecting them from danger? The detention of an individual inadvertently or placing someone in a humiliating situation or position?				

If a negative or disproportionate impact has been identified in any of the key areas would this difference be illegal / unlawful? I.e. Would it be discriminatory under anti-discrimination legislation. (The Equality Act 2010, Human Rights Act 1998)

	Yes	**No**	**N/A**	
What do you consider the level of negative impact to be?	**High Impact**	**Medium Impact**	**Low Impact**	**No Impact**

If the impact could be discriminatory in law, please contact the Equality and Diversity Lead immediately to determine the next course of action. If the negative impact is high a Full Equality Analysis will be required.

If you are unsure how to answer the above questions, or if you have assessed the impact as medium, please seek further guidance from the **Equality and Diversity Lead** before proceeding.

If the proposal does not have a negative impact or the impact is considered low, reasonable or justifiable, then please complete the rest of the form below with any required redial actions, and forward to the **Equality and Diversity Lead.**

Action Planning:

How could you minimise or remove any negative impact identified even if this is of low significance?

N/A

o

How will any impact or planned actions be monitored and reviewed?
N/A
How will you promote equal opportunity and advance equality by sharing good practice to have a positive impact other people as a result of their personal protected characteristic.
N/A
Please save and keep one copy and then send a copy with a copy of the proposal to the Senior Equality and Diversity Lead at hr.support@bsmhft.nhs.uk. The results will then be published on the Trust's website. Please ensure that any resulting actions are incorporated into Divisional or Service planning and monitored on a regular basis.

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Appendix 2

USE OF ESSENTIAL OILS AND COMPLEMENTARY MEDICINES

Complementary therapies are therapies that may be used in conjunction with orthodox medical, nursing and paramedical treatments to enhance patient well-being, quality of life and symptomatic relief.

Before any new therapy can be recognised by the Trust it must be approved by the Pharmacological Therapies Committee. Once agreed the therapy must be used within the guidance of this code and according to a recognized protocol or procedure

Qualifications

A Designated Complementary Therapist must have obtained an appropriate qualification. Having obtained the qualification they must then ensure that the practice of the complementary therapy is in line with the scope of professional practice and code of conduct of the accreditation body for the therapy.

Before any complementary therapy is practiced the following must be viewed by the Nurse in Charge of the ward or department.

- The therapist's certificate or a copy of the syllabus studied, if still available
- Details of the organisation providing the training
- Examination results
- Membership of a recognised national body/professional body

NB Qualifications that have been gained wholly by correspondence or over short courses will not normally be accepted.

Insurance

Members of Trust staff practicing complementary therapies as part of their duties will be indemnified by the Trust. Private therapists contracted to provide a service must have personal indemnity insurance.

Competence

The interests and welfare of the service user are paramount and the Designated Complimentary Therapist has a duty of care to ensure that their skills and knowledge are updated and that they remain competent to practice the therapy.

The therapist has responsibility for the whole course of treatment and any delegation of tasks to others must be according to agreed written protocols approved by the Nurse in Charge.

Responsibility of the Nurse in Charge

The Nurse in Charge is accountable for ensuring:

- The use of the therapy has been approved by the Pharmacological Therapies Committee.
- The Designated Complementary Therapist has accepted personal accountability in accordance with their scope of practice and the code of conduct of the appropriate accreditation body.
- The Therapist has an appropriate qualification.
- A regular review of the practice.
- A system of monitoring clinical practice is in place.

In the circumstances of the Nurse in Charge also being the Designated Complementary Therapist the responsibilities lie with the next in line manager.

Consent

The service user or advocate for the service user must give informed consent for the practice of a specific complementary therapy. The multidisciplinary team members involved in the service user's care must be consulted by the therapist before any treatment is carried out.

Documentation

The Designated Complementary Therapist must document within the service user's care plan the therapy practiced, and maintain within the care plan, notes of treatments given, dates and evaluations of the treatment outcome. All documentation should be in line with the standards of the Trust on note keeping and the relevant accreditation body of the Complementary Therapist.

It is not appropriate for a service user (even if they are suitably qualified) to practice a complementary therapy on health services premises or to solicit other service users as prospective customers.

Appendix 3

USE OF UNLICENSED MEDICINES

In the UK no medicine can be marketed for human use without a Product Licence (PL) granted by the Licensing Authority (Ministry of Health). The PL specifies the indications for which a product may be used and also the dose, route of administration etc. Licensing arrangements are

determined by the Medicines Act 1968 and implemented through the Medicines and Healthcare Products Regulatory Agency (MHRA).

Professional guidance on the use of unlicensed medicines is available from the General Medical Council and General Pharmaceutical Council. The Royal College of Psychiatrists College Report CR142 ‘Use of licensed medicines for unlicensed applications in psychiatric practice’ 2007 also offers useful advice to prescribers.

Unlicensed medicines fall into 6 broad categories

1. Products derived from licensed medicines and prepared by the NHS or commercial unit with a "specials" manufacturing licence or prepared in a hospital pharmacy under a Medicines Act exemption. e.g. liquids for service users with swallowing difficulties.

2. Low dose formulations for children

3. Products whose licence has been abandoned, suspended, revoked or not renewed

4. Products for which a licence has not or is yet to be given, but available and licensed outside the UK.

5. Some clinical trial medicines.

6. Medicines used outside the terms of the Product Licence e.g. unlicensed indication, dose, route, age.

Negligence Liability

Prescribers have a duty in common law to take reasonable care and to act in a way consistent with the practice of a responsible body of their peers of similar professional standing. In using an unlicensed medicine the prescriber must act responsibly and with reasonable care and skill. Not to meet these standards lays the prescriber open to claims of negligence liability.

Strict Product Liability (or liability without fault)

The Product Liability Directive (EEC/85/374) and the Consumer Protection Act 1987, makes the producer or supplier liable for damage caused by a

defect in the product. The product can be considered defective on the basis of what the service user is entitled to expect. This may be affected by the verbal and written information and warnings given to the service user.

Practical Implications

The responsibility for use of unlicensed medicines lies with the prescriber. Mechanisms must be in place to ensure that a prescriber knows when a

medicine prescribed/supplied is unlicensed and that he/she is aware of his/her responsibilities.

Unlicensed medicines should only be used to fulfil the special needs of an individual service user where a suitable licensed medicine is not available. Use of an unlicensed medicine on a wider scale e.g. for routine stock use, must be approved by the Pharmacological Therapies Committee.

Trust Procedure

- The Pharmacy will advise prescribers of the unlicensed nature of the medicine at the time of dispensing.
- Prescribers should consider carefully the use of unlicensed medicines and only use unlicensed medicines when after assessing the patient, the benefits outweigh the risks and where there is no licensed alternative available that will meet the needs of the patient.
- Prescribers must obtain consent to treatment and inform the service user of the medicines' licence status. The service user must also be informed that the effects of an unlicensed product are likely to be less well understood than those of a licensed product.
- Prescribers should inform their medical colleagues (especially General Practitioners) of the medicine's licence status when advising them to continue use of unlicensed medicines or use of medicines outside their product licence.
- Any unlicensed use of a drug must be recorded in the service users electronic care record and care plan including confirmation that the service user has been informed. The service user should then receive a copy of the care plan.
- Unlicensed medicines can be included in a treatment plan when a service user lacks capacity and is sectioned under the mental health act. Form T3 must be completed in the normal way.

Appendix 4

CLINICAL TRIALS INVOLVING PHARMACEUTICAL PRODUCTS

All commercial and non-commercial research involving medicines conducted in the Trust will need to be reviewed and approved by the Research & Innovation Department before its commencement (‘R&D approval’). Approval procedures are described in the BSMHFT policy:
The approval of research projects in BSMHFT

Following approval, the study documentation will be reviewed by the R&I Department and will include:

- *investigators’ curriculum vitae and Good Clinical Practice (GCP) certificate*

- *the curriculum vitae and Good Clinical Practice (GCP) certificate of any supporting research staff*
- *a EudraCT number*
- *Medicines & Healthcare products Regulatory Agency (MHRA) approval letter*
- *NHS ethical approval letter*
- *an agreed template of all trial costings*
- *an agreed and signed (model) clinical trial agreement (mCTA)*
- *an up to date indemnity and insurance certificates from the trial sponsors*
- *other checks of **all** the study documentation (e.g. content forms, information sheets etc)*

All medicines supplied as part of clinical trials must be stored in the Trust Pharmacy department. The Chief Pharmacist will ensure that all medicines supplied as part of a clinical trial have appropriate research approvals and there are approved procedures in place for each trial governing the supply of clinical trial medicines. Until all requirements are in place, initial supplies of clinical trial medicines will not commence.

At the end of each trial, the Chief Pharmacist will arrange for all outstanding clinical trial supplies to be returned to the sponsor company or appropriate arrangements made for disposal. Compassionate use programmes for medicines prescribed after the end of a clinical trial will require approval by the Pharmacological Therapies Committee.

Appendix 5

MEDICATION ERRORS

A medication error is a preventable incident associated with the use of a medicine that may put a service user at risk. Such incidents may be related to any of the steps of the medicine use process. This includes the storage, carriage, prescribing, dispensing and administration of medicine, or the transfer of information.

Medical Review of the Service user

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

Monitoring and Reporting System

One of the responsibilities of the Pharmacological Therapies Committee is to oversee a monitoring and reporting system with the objective of preventing

medication errors. At the current time medication errors will be reported via the Trust Incident Reporting System.

- The objective of a reporting system is improvement in care and not the disciplining of staff. The Pharmacological Therapies Committee advises professional managers of the need to focus on systems rather than on individuals.
- In addition to serious incidents involving medicines, it is anticipated that a much larger number of less serious and near miss reports will also be reported to the Pharmacological Therapies Committee.
- An incident report form must be completed by the Nurse in Charge or by the individual concerned. Details of the incident and of the immediate action taken should be given.

Review of Medication Errors and External Reporting

The Pharmacological Therapies Committee should review reports of medication errors at least six monthly, to establish trends and to take action intended to prevent such errors. Action may involve system redesign and improvement and/or education, training and competency assessment of employees on any aspect of medicine use.

The Pharmacological Therapies Committee will report regularly to the Clinical Governance Committee on medication errors.

Advice on reporting medicines defects and adverse drugs reactions to MHRA is available from the Trust Pharmacy service.

Appendix 6

CONSENT TO TREATMENT

The medicines proposed to treat a service user should be discussed with the service user. The discussion should be carried out in such a way that the service user is able to contribute and express agreement or disagreement with the proposed treatment. The clinical record should document such discussions; including if they are considered unsuccessful or inappropriate because of the service user's behaviour or mental state. In such circumstances further attempts should be made if and when the service user is considered capable of participating in the discussion.

"Consent" is the voluntary and continuing permission of the service user to receive a particular treatment, based on an adequate knowledge of the purpose, nature, likely effects and risks of the treatment including the likelihood of its success and any alternative to it. Permission given under any unfair or undue pressure, or without adequate knowledge or explanation, is not consent (Mental Health Act 1983 Code of Practice).

For those under 16, we will utilise the concept of “Gillick Competence” to assess young people’s competence to consent to treatment. This concept reflects a child’s increasing development to maturity and increasing ability to make decisions for themselves. It is however good practice to consult with those with parental responsibility, in the decision making process.

All Capacity to Consent to Treatment Assessments should be completed on the Capacity Assessment Form 3

Section 62: Urgent treatment

The requirements of Section 57 and Section 58 do not have to be followed when urgent treatment is required:

- To save the service user's life.
- To prevent a serious deterioration in the service user's condition, so long as the treatment is not irreversible.
- To alleviate serious suffering so long as the treatment is neither irreversible nor hazardous.
- To prevent the service user from behaving violently or being a danger to self or others as long as the treatment is neither irreversible nor hazardous, and represents the minimum interference necessary.

It is the duty of everyone proposing to give treatment to exercise reasonable care and skill, not only in giving information prior to seeking a service user's consent, but also in meeting the continuing obligation to provide the service user with adequate information about the proposed treatment and alternatives to it.

Discussions about the drug treatment and consent to treatment should ideally be when treatment is initiated. It should be documented in the electronic care including the nature and outcome of the discussion together with an assessment of the capacity of the service user to consent. If the service user is too ill at the time of the initiation of prescribing, the prescriber should seek further consent when the service user is well.

Information given by pharmacists or other practitioners about the treatment should be provided in addition to that undertaken by the prescriber rather than as an alternative.

Treatment of those without capacity to consent.

When a service user who is informal is incapable of consenting to treatment, medicines can be prescribed for them in their best interests under the MCA. The same applies to a detained incapacitated patient for the treatment of unconnected physical disorders. Medical treatment for mental disorders for detained patients are covered by the s63 of the MHA.

For those who are under 16, informal and not “Gillick Competent”, it will usually be possible for the person with parental responsibility to consent on

their behalf. Before relying on parental consent, for such young people, an assessment should made as to whether the matter is within the “zone of parental control”.

The child/young person’s views should be taken into account even if not “Gillick competent”. If the decision is not within the “zone of parental control” or the consent of the person with parental responsibility is not given, the child/young person cannot be treated. An application under the MHA, should be considered, or if latter criteria are not met, it may be necessary to seek authorisation from the High Court.

The term zone of parental control is used in the MHA Code of Practice to describe the types of decisions that people with parental responsibility can make in relation to a child or young person’s care and treatment.(There are no clear rules on what decisions may fall within the zone of parental control and each decision will need to be considered in the light of the particular circumstances of the case. The parameters of the zone of parental control will vary from case to case and are determined not just by social norms but also by the circumstances and dynamics of a specific parent and child/young person.)

There are three main areas that need to be considered when assessing whether a decision fall within the zone of parental control. These are:

(i) Whether the nature of the decision is one that falls within usual parenting decisions
(ii) Whether there are any indicators that the parent might not be acting in the best interests of the child/young person; and
(iii) Whether the parent has the capacity to make the decision in question

For those aged 16-17 who lack capacity and are informal, a person with parental responsibility may give consent but only if decision falls within “zone of parental control”. Otherwise the MCA may be applied as it would be for those over 18yrs or consideration as to whether they meet the criteria for detention under the MHA. If the MHA is not applicable, it may be necessary to seek authorisation from the High Court.

Treatment of those detained under the Mental Health Act 1983.

The Mental Health Act 1983 provides the prescriber with a 3 month period to develop a treatment programme to meet a detained service user’s needs. Even though the Act allows treatment without consent the prescriber should observe the same principles of seeking consent described above. The 3 month period starts on the occasion when medicines for mental disorder were first administered.

Medicines after 3 months

A system should be in place to remind the Responsible Clinician (RC) at least 4 weeks before the expiry of the 3 month period. The RC should:

- Seek the service user's consent to continuing medication.
- Record the discussion in the medical notes including an assessment of the service user's ability to consent.
- If the service user consents to continued treatment complete a Form T2.
- If the service user refuses consent or is deemed unable to provide a reliable consent the RC must request a second opinion appointed doctor (SOAD) visit from the Care Quality Commission.

The SOAD must speak to the service user, a nurse and another professional involved in their care. They must see a copy of the treatment plan drawn up by the clinical team and they will complete a T3 form as appropriate if they agree with the treatment plan.

Practitioners must not administer medicines to service users detained under the Mental Health Act 1983 after the 3 month period without first ensuring that a valid Form T2, Form T3 or Section 62 form has indicated that the treatment can be given.

Forms T2 and T3 must be attached to prescription card whilst service users are under a section of the MHA and copies of the forms sent to Pharmacy along with prescription charts when requests for supply are made. Where a service users medicines are prescribed and administered using the electronic prescribing and medicine administration system, all forms T2 and T3 should be kept in a folder available to prescribers and nurses at the point of prescribing or administration so that they can be referred to or checked. There should be a signal within the EPMA system alerting prescribers and/or nurses administering medicines that the service user has a valid form T2 or T3.

Appendix 7

THE SAFE AND SECURE USE OF FP10 PRESCRIPTION FORMS

FP10 prescription forms are purchased by the Trust for prescribing medication to be dispensed by community pharmacies. FP10 prescription forms are controlled stationery and must be ordered, received and issued against strict procedures. Prescription form theft and misuse is an area of serious concern as these forms can be used to obtain drugs illegally, including controlled drugs for misuse or expensive drugs.

In addition to the potentially serious medical problems that can result from stolen prescription forms being used to obtain drugs illegally, the theft of prescription forms can also have a significant financial impact for the trust.

Procedures for the Issue of FP10 Prescription Forms

The pharmacy department is responsible for the ordering of FP10 prescription forms within the trust for the majority of teams. FP10 prescription pads are received with a pre-printed stamp. These will normally bear the name of the consultant to whom they will be issued. For a small number of teams, the stamp bears the name of the team, e.g. Addictions teams.

The pharmacy will maintain a record of all FP10 prescription pads/boxes ordered and supplied to prescriber in community teams including the serial numbers of FP10s.

FP10 prescription forms are stored securely within Pharmacy and issued to teams on receipt of an FP10 order form. Records are kept including:

- Date received
- The quantity and serial numbers of FP10s received
- Date of issue to authorised personnel
- Quantity and serial number of FP10s issued

FP10 prescription forms are issued either via a pharmacy box, or by collection in person. Only as a last resort are pads of FP10s distributed via internal post.

Storage and Security of FP10s on Community Units

FP10 prescription forms must be stored in a locked drawer/cupboard with strict limited access when not in use. Access to keys should also be controlled in the same way as drug cupboard keys. Service users, temporary staff and visitors should never be left alone with access to FP10s or be allowed into secure areas where forms are stored.

A record of all FP10 pads received by the team should be kept including:

- Date received
- The quantity and serial numbers received
- The date of first use of an FP10 prescription pad
- The prescriber to whom the pad is issued

Prescribers should ensure that FP10 prescription forms are not left unattended within consulting rooms or on desks. When they are not in use they should be kept in a closed and locked drawer / cupboard or locked medical bag.

A very small number of prescription forms should be kept at any one time within medical bags. During home visits, prescription pads should be kept in the medical bag which should be kept in boot of the car whilst travelling.

To reduce the risk of misuse, FP10 prescriptions must only be signed once they have been written, checked and the prescriber is happy with the contents.

FP10s should only be used for registered BSMHFT service users following a consultation and must not be used to prescribe for private service users. Neither should they be used for prescribing for trust staff or their families. Where any prescriber leaves the trust, any unused FP10s must be returned to the team base and an entry made in the record book.

Destruction of FP10s by Pharmacy Staff

Forms which are no longer in use should be returned to Pharmacy for secure destruction (e.g. by shredding) before being put into confidential waste. Destruction of FP10 prescription forms should also be recorded in the pharmacy record.

Missing / Lost / Stolen Prescription Forms

Any missing or lost prescription forms or any suspected theft must be reported immediately. The prescriber or staff member should notify both the pharmacy department and risk department immediately and should complete an Eclipse form. The trust counter fraud specialists should also be informed.

Pharmacy or the risk department will notify the local area team at NHS England, the NHS Business Services Authority Prescription Pricing Division and if necessary the police. The local counter fraud and security management officer will also be informed. Where it is suspected that stolen FP10 prescription forms will be used to obtain controlled drugs then the trusts controlled drugs accountable officer will also be informed and the controlled drugs local intelligent network will be informed.

The following details will be required for lost or stolen prescriptions:

- Prescriber / Team Name
- Prescriber / Team Code
- Type of prescription form
- Approximate number of prescriptions
- A reasonable estimate of the serial numbers
- Where and when they were lost / stolen including any details of persons involved.

Following the reported loss of prescriptions, prescribers may be asked to write and sign prescriptions in a specific colour for an agreed time period.

Appendix 8

SECONDARY DISPENSING

Introduction

Within BSMHFT dispensing will normally be carried out by the pharmacy service. Occasionally, qualified nurses may be required to secondary dispense medicines. Within the trust, the following definitions will be helpful:

Dispensing: *labelling from stock and the supply of a clinically appropriate medicine to a service user/carer, usually against a written prescription, for self-administration or administration by another healthcare professional, and to advise on safe and effective use.*

Primary Dispensing: *when the supply of a medicine to a service user is the result of labelling medication that has been taken from stock or from a named in-patient supply (which does not have dose instructions included on the label).*
Within BSMHFT medicines can only be primary dispensed by the pharmacy service.

Secondary dispensing: *the process of re-packaging medicines, which have been dispensed and labelled with instructions by trust pharmacy services for an individual service user, into another container bearing another label for use by the same service user.*

Registered doctors or nurses may carry out secondary dispensing provided they have received training from the Trust Pharmacy services and have been signed off as competent to secondary dispense by their team manager in conjunction with Pharmacy. To enable team managers to do this, they will be trained by Pharmacy and signed off as competent by a member of the pharmacy team once they have completed the secondary dispensing training package.

Only fully labelled individual patient medicines dispensed by one of the trust pharmacies may be secondary dispensed by BSMHFT doctors or nurses. Medicines supplied by any other pharmacy must not be secondary dispensed.

Guidance from Professional Bodies

The Royal Pharmaceutical Society (RPS) guidelines on the safe and secure handling of medicines, state that individuals handling medicines must be competent, legally entitled, appropriately trained and authorised to do the job. There are four governance principles that apply to secondary dispensing:

(i) Establish assurance arrangements – 'say what we do and why we do it'

(ii) Ensure capacity and capability – 'train people and ensure they have necessary competencies and resources'

(iii) Seek assurance – 'safe and secure handling reinforced by proactive audit and review, and by reporting, sharing, learning and taking action on patient safety incidents'

(iv) Continually improve – 'culture of evaluation (both qualitative and quantitative) and learning and improvement is embedded throughout the healthcare setting; it is seen as everybody's responsibility'

The Royal College of Nursing (RCN) in collaboration with RPS also states:
'Wherever possible, the actions of prescribing, dispensing/supply and administration are performed by separate healthcare professionals. Exceptionally, where clinical circumstances make it necessary and in the interests of the patient, the same healthcare professional can be responsible for the prescribing and supply/administration of medicines. Where this occurs, an audit trail, documents and processes are in place to limit errors. The organisations administration procedure is followed and includes:

(i) Checking the prescription or other direction to administer: meets legal requirements, is unambiguous and includes where appropriate the name, form (or route of administration), strength, and dose, frequency and where necessary, times of the medicine to be administered
(ii) A check of any allergies or previous adverse drug reactions
(iii) Ensuring any ambiguities or concerns regarding the direction for administration of the medicine are raised with the prescriber or a pharmacy professional without delay
(iv) Any calculations needed are double checked where practicable by a second person and uncertainties raised with the prescriber or a pharmacy professional
(v) Check the identity of the medicine and its expiry date (where available)

The Nursing and Midwifery Council Standards of Proficiency for nurse and midwife prescribers goes further by adding the following:

'It is important that practice-based learning is integral to the programme so that the student is provided with the opportunity to observe prescribing-in-action. This should include all aspects of medicines management, and time should be spent with a range of non-medical prescribers, dispensing pharmacists, pharmacy technicians, as well as medical prescribers where possible.'
Practice standard 10 guidance states 'dispensing medication is defined as the 'labelling' of medication from a stock supply that is then administered to an individual patient/client. Where a stock supply of medication has been labelled and dispensed by a pharmacist and is then supplied by a nurse/midwife in an 'out of hours' or family planning situation, this is not dispensing, but supplying.'

‘Nurses and midwifes are advised to ensure they have indemnity insurance to cover their dispensing practice, and if they are unable to get indemnity cover they must inform the patient/client of this and its implications.’

Additional guidance states: ‘Whilst there is no legal bar to a nurse or midwife dispensing, there must be a local policy in place, agreed by clinical governance directorates to endorse the registrant’s actions. The recipient of the medication will expect the same level of practice from a nurse or midwife as they would from a pharmacist. As a registrant you are accountable for your actions and should understand the medication that you are dispensing, its therapeutic effect, correct dosage, side effects and contra-indications. You should be able to inform the patient/client about what they should expect when taking the medication, and to whom any adverse reaction should be reported.
You should only dispense medication if you feel competent to do so, and in the knowledge that you are accountable for your actions. A record should be kept of your dispensing practice. Following clinical governance policy should ensure that an audit trail is present and visible.’

‘The same principles apply for all drugs, whether they are Prescription Only Medicines or pharmacy-level medicines. The NMC recommends that nurses ensure they are covered for vicarious liability and seek appropriate indemnity insurance for this practice.’

Training

All Registered nurses who need to carry out secondary dispensing must undertake a training course provided by the trust pharmacy and further demonstrate that they are competent to carry out the process accurately. The qualification process will require the following:

(i) Online e-learning including introductory presentation and questions to work through followed by multiple choice questions assessment at the end
(ii) Compulsory attendance to face-to-face secondary dispensing training and practice provided by the Trust’s pharmacy department (once online assessment passed)
(iii) Supervised secondary dispensing practice by the team manager or other staff authorised to secondary dispense within their team
(iv) Successful completion of secondary dispensing practical assessment undertaken with the team manager or delegated individual, trained in secondary dispensing at the Team’s base
(v) Be approved to undertake secondary dispensing by their team manager. In the case of the lead nurse or nurse team manager, approval will be done by Pharmacy staff

Principles of Secondary Dispensing

Before carrying out secondary dispensing, check when your supplying trust pharmacy is open, the lead times for dispensing and the times the transport run will reach your base. Prescribers are able to use FP10 prescriptions for community dispensing if necessary.

Secondary dispensing of medicines can only take place using medicines prescribed for the service user within the trust EPMA system. The decision to undertake secondary dispensing may be taken for patient safety when it is not suitable to leave a larger quantity of medication with a service user after a risk assessment is carried out, or pharmacy are unable to facilitate a compliance aid at short notice.
In a ward setting, items that are correctly labelled may be given to the service user without re-dispensing, unless there is a valid reason for limiting the quantity of supply such as an identified suicide risk.

In the community, the prescriber must complete the trust EPMA prescription record showing ALL the medicines the service user is currently taking (so that interactions, contra-indications and additive adverse effects can be avoided) including those medicines being supplied by the GP. The GP should be requested to prescribe nonpsychotropic medication. If a service user has run out of a regularly prescribed medicine, the community pharmacy may be able to make an emergency supply until a prescription is available.

Schedule 2 and 3 controlled drugs (including temazepam) must be dispensed by pharmacy.

A number of medicines including some benzodiazepines and 'Z-drugs' may be supplied as a pre-pack This should be considered before secondary dispensing where necessary.

Equipment for Secondary Dispensing

The pharmacy service will supply the ward/team base, where secondary dispensing is carried out, with the following:

(i) A variety of pre-printed dispensing labels of various types to be completed by the secondary dispensing nurse, which include the name of the ward/base and the phone number.
(ii) Supplies of cautionary labels
(iii) Empty small bottles with child-resistant closures
(iv) Empty cardboard boxes/ cartons
(v) Dispensing bags
(vi) Empty compliance aid packs – these should only be issued to community based service users that have been assessed using the Trust's compliance aid assessment tool and found to meet the criteria for needing a compliance aid. Please note - not all medicines are suitable for inclusion in compliance aids and secondary dispensers must refer to the compliance aid compatibility guidelines or contact the pharmacy for advice

All of the above items can be ordered via the team's stock list on EPMA

The supply and the stock levels of the above must be agreed between the person in charge of the ward/team and their pharmacist or the pharmacy department. Patient information leaflets should be supplied with the medicines, if there is not a leaflet in the original pack then a Choice and Medication service user information leaflet should be supplied (these can be accessed through the Pharmacy and Medicines page on Connect).

Medicine containers and labels must be stored in a locked cupboard or drawer.

Secondary Dispensing Procedures

Secondary dispensing must be carried out using medicines dispensed and labelled for the individual service user by BSMHFT pharmacy and should only be done if it is not appropriate for the whole labelled container and quantity to be given to the service user. Secondary dispensing must not be carried out using stock medication. The quantity supplied should be determined by a risk assessment. All medication should be checked by a second registered person e.g. a registered nurse, pharmacist or pharmacy technician. In a community setting where there may not be a second registered person, a second member of staff should check and sign, but the responsibility for the procedure will lie with the registered person who is dispensing. Where there is no second person then the secondary dispenser must self-check and sign and endorse the relevant section of the prescription or register 'lone working'.

The medicines should be dispensed into the appropriate container provided by the trust pharmacy and labelled according to the following procedures.

The healthcare professional dispensing must follow the appropriate secondary dispensing Standard Operating procedures (SOPs) when assembling, recording, labelling and dispensing a prescription. An accuracy checking person must be identified and they must follow the accuracy checking process (consult SOP). Each team that has qualified secondary dispensing staff must keep a copy of the SOPs in an appropriate folder and these SOPs must be referred to each time secondary dispensing takes place.

All secondary dispensing details must be recorded in the secondary dispensing section of the electronic prescribing and administration system, under patient observations and monitoring tab. Notes must be made to document that secondary dispensing has taken place and by whom, as well as documenting when the secondary dispensed medicines were supplied including date, time and quantity supplied.

If a compliance aid is used in the community, the dispenser must also make a record in the patient's RiO record, including which medicines have been put into the box and how many days have been supplied. This is particularly important if the GP is also supplying medicines. The GP must be contacted to ensure that medicines are not being supplied twice and that boxes are not duplicated, cross-filled or changed after the original dispensing.

Labels must be completed legibly in indelible ink by the secondary dispenser. BNF cautionary and advisory labels should be included, for example 'with food' or 'swallow whole' (see appendix 3 and the last page of the BNF).

The new label must be checked against the label of the original container for identity, before attaching the label to the new container. The required amount of medication should be dispensed into the new container. Both containers should be closed and the dispensing area cleared before starting to dispense the next medicine.

The checking person should make a final check of the completed dispensing before the original medicine containers are put away and sign in the relevant section of the prescription card.
If the person is to be discharged from a ward or from the service, the secondary dispenser must ensure that the GP or the service that the service user is to be discharged to has a clear record of the medicines currently prescribed and supplied.

If any dispensing or checking errors are found (even if this is before the medicines reach the service user) these must be recorded via the Trust's Eclipse system.

Appendix 9

DAY UNITS AND RESPITE CARE

A variety of arrangements may be in place to prescribe and provide medicines for service users who attend Day Hospitals or who receive respite care. This will normally be via the general practitioner

Good liaison is vital to ensure that at all times both primary care and hospital based practitioners are aware of all the medicines to be received by the service user and, who is responsible for the prescription, the supply and the administration of each medicine.

The prescribing of medicines for service users who attend day care is usually the responsibility of the General Practitioner. In some situations a hospital prescriber may wish to take responsibility for part or all of the prescribing.

These situations include:

- If the hospital prescriber wishes to start a new medicine and stabilise the service user on that medicine before requesting the General Practitioner to take over the responsibility.
- If arrangements to continue supervision of the prescribing of medicines still remains with the hospital prescriber.
- If the prescription is subject to continual change.
- If there is no other reliable method of ensuring that the service user receives the medicine.

In such situations the prescriber will prescribe the medicines on the EPMA system and if the medicine is to be administered at the day hospital this will be recorded on the EPMA system.

Service users who attend day care will be encouraged to self-administer their own medicines received from their community pharmacy and prescribed by their General Practitioner. In some situations it may be necessary for some or all of the medicines to be administered by a Day Hospital Practitioner. In such situations the following should occur:

- Confirmation with the service user's carers and General Practitioner and inspection of the service user's own medicine
- Medicines that are to be administered are prescribed on the EPMA system and any medicines administered recorded in the EPMA system
- Recording in the electronic patient record of the complete list of medicines that the service user is receiving at other times
- Where a service user receives medicines other than those administered at day care, cross-reference must be made to those medicines via the trust EPMA system.

If for any reason a difference between the medicine provided by the service user and those prescribed within the trust EPMA system occurs the prescriber should be contacted to clarify the prescription.

If medicines are to be administered at the day hospital it is usual for the service user or home carers to provide the medicines from the service user's own supply. In some situations the medicines may be supplied from the hospital pharmacy. These situations include:

- When the service user or carer fails to provide a suitable supply.
- When a hospital prescriber wishes to initiate a short course of treatment or a new medicine.
- When arrangements for the General Practitioner to take over the responsibility for prescribing have not been completed.

Respite Care

For service users admitted for respite care, it is usual for the service user or home carers to provide the medicines from the service users' own supply. The nurse should:

- Confirm with the carers prior to admission that the necessary medicines to span the period of respite care will be provided by the carer.
- Confirm with the service user's General Practitioner prior to admission the medicines to be prescribed for the service user.
- Confirm with the hospital prescriber that the service users own supply agrees with the account provided by the carer and the General Practitioner. Once the confirmation has taken place the medicines will be prescribed via the EPMA system.

If all attempts to receive a supply from the carer fail or the supply of medicines is thought unsuitable to use an emergency supply will be made from the hospital pharmacy.

Appendix 10

MEDICAL GASES

All medical gases used in the Trust are Licensed Medicines and as such are subject to the Medicines Act and must be treated in the same way as any other medicines.

Before a medical gas is administered to a service user, written authority from a prescriber must be obtained. This authority must include the name, and concentration of the medical gas (where appropriate), the method of administration and the rate of flow. This can be achieved by:

- An inpatient prescription for an individual service user Patient
- Group Direction authorising the administration of a medical gas in an emergency.

A nurse or healthcare professional administering a medical gas to a service user must make a written record that treatment with the particular medical gas has been initiated on the trust EPMA system.

For use of oxygen therapy, further information and advice is contained within the Trust policy on oxygen therapy (C24)

Appendix 11

PROTOCOL FOR THE DISPOSAL OF UNIDENTIFIED SUBSTANCES

Introduction

This protocol is intended to provide guidance on what to do if unidentified substances that are suspected illicit drugs are either found on Trust Premises or a request is made by a service user or a carer/friend/member of the public to dispose of such a substance.

Where such substances are discovered then:

- The drugs must be sealed in a tamper proof evidence bag and kept securely until collection and transport to Pharmacy is arranged. The bag should be endorsed with the name of the ward and the date. No patient details should be documented on the evidence bag.
- This must be documented on an Eclipse form and witnessed by two members of staff.
- A senior Trust Manager must be informed of this action

1 Request to dispose of suspected illicit substances made at a venue other than Trust Premises, i.e. during a home visit or at a satellite clinic must not be accepted. The person-requesting disposal must be informed of the above procedures. The staff member must inform their line manager or another member of staff of this request.

2 If a request is made to Substance Misuse Services Staff to dispose of drugs they should encourage the person to either dispose of the drugs themselves or hand the drugs into the police. A senior member of staff should be informed of the request and it should be recorded on an Eclipse form.

3 If the person is unwilling to dispose of the drugs themselves or take the drugs to the police then Substance Misuse Staff can pass on the drugs to the Police or Pharmacy.

Appendix 12

RETURN OF CONTROLLED DRUGS TO PHARMACY STOCK

This procedure should not be followed where controlled drugs are destroyed on the ward. Only those controlled drugs that cannot be reused should be destroyed on the ward and only carried out by the Nurse in Charge in the presence of a pharmacist.

- Contact pharmacy before any stock controlled drugs are returned (includes benzodiazepine and Z hypnotics)
- Pharmacy staff may sign out controlled drugs and return to Pharmacy. Where this is done, Pharmacy staff will sign the ward/team controlled drugs register.
- Where controlled drugs are returned to Pharmacy via the Pharmacy box then complete form – 'Authority for ward to return controlled drugs to pharmacy' and scan and e-mail to pharmacy – see attached
  - Pharmacy will scan and e-mail back a copy of the form, signed by a pharmacist
- Put one copy in pharmacy box with the controlled drugs to be returned and seal the box immediately
- Complete an entry in the controlled drugs register for the return of the medication – this must signed by two nurses
- Once pharmacy receive the returned medication they will sign the form and scan and e-mail it back to the unit including a reference number – this should be entered into the register and the form kept with register as proof of receipt at pharmacy.

Patients own medication

- Contact pharmacy before any service users own controlled drugs are returned (**excludes** benzodiazepines (except temazepam) and Z hypnotics) • Complete – 'Disclaimer for destruction of a service user's own medicine'
- Complete – 'Authority for ward to return controlled drugs to pharmacy' and scan and e-mail to pharmacy – see attached
- Complete an entry in the controlled drugs register for the return of the medication – this must signed by two nurses
  - Pharmacy will fax back a copy of the form, signed by a pharmacist
- Put one copy along with the disclaimer in the pharmacy box and seal the box immediately

  Once pharmacy receive the returned medication they will sign the form and scan and e-mail it back to the unit including a reference number – this should be kept on the ward for two years.

Birmingham and Solihull Mental *NHS* Foundation Trust – Pharmacy Services – Form HP 2802

Authority for wards to return CDs to Pharmacy

DO NOT return any Controlled Drugs to pharmacy without first obtaining a signed pharmacy authorisation. Ward and Team Managers and Leaders will be expected to account for returned medicines. This form provides an audit trail that helps to keep track of controlled drugs.

Name of Unit …….. Date ……

1	Name of Medicine	Strength	Quantity	If these are patients' own medicines, rather than Stock issued by the Trust, write patient details here	Pharmacy use

Step-by-step Instructions

Step **1.** Enter the details of the medicines that you wish to return in the form above – **DO NOT SIGN ANYTHING YET.**

Step **2.** Scan and e-mail the form to your local Pharmacy.

Step **3.** A pharmacist will sign on line 1 below and alert pharmacy "goods inward" to expect your CDs in the next box delivery received from you.

Step **4.** Pharmacy will scan and e-mail to you a copy of the authorisation – you should keep a copy as a record of authority to send CDs to pharmacy and send a copy with the CDs so that they can be tracked in pharmacy after receipt.

Step **5.** An appropriate trained nurse will SIGN ON LINE 5 when the CDs are put into the pharmacy box. FOR WARD STOCK ensure that an appropriate record of the return has been made in the controlled drug record book.

Step **6.** This procedure should be witnessed by a suitably trained person who must sign on line.6

Step **7.** On receipt in pharmacy the form sent with the drugs will be signed and given a number and scanned and e-mailed back so that the ward or manager or leader will have a receipt showing where the CDs have gone. THIS RECEIPT MUST BE FILED.

Step **8.** The receipt number (shown bottom right) should be entered in the CD record book.

3	Return of the above authorised by pharmacy Pharmacist's Signature	Name in Print	Date
5	Placed in Pharmacy Box and box sealed by Nurse's Signature	Name in Print	Date
6	Procedure witnessed and checked by Nurse's Signature	Name in Print	Date
7	CDs received in Pharmacy by Pharmacist's Signature	Name in Print	Date

Please be advised that there are no situations where medicines may be transferred from one pharmacy or manufacturer's container to another at unit level. If a unit returns a pack that started as 28 tablets, for example, with more than 28 tablets in it, all or some of the medicines may be destroyed and the unit will not be credited. This is a Consumer Protection matter. Patients may be exposed to risks if audit trails are compromised by unauthorised decanting.

You should obtain new copies of this form from the Intranet **Home Page > Forms > Pharmacy**	**8**	Pharmacy Receipt No

Appendix 13

SELF-ADMINISTRATION OF MEDICATION

Self-administration of medication is considered by the Trust to be an important aspect of rehabilitation. Taking responsibility for own medication can increase independence, confidence and compliance. Consequently, a clear process is needed to aid relevant staff and service users.

The NMC/RPS (2019) supports and welcomes the selfadministration of medication within safe, secure parameters.

The aim is that service users are able to administer their own medication safely and to the level of independence required when discharged or to allow some autonomy with medications for service users resident on a long term unit.

It is expected that any programme will consist of several stages, allowing the service user to gradually progress within a safe and supported environment.

It is also anticipated that local teams may have their own specific programme. A written protocol must be agreed with pharmacy (a copy should be forwarded to Deputy Director of Nursing). The following points must be adhered to:

1. ASSESSMENT

The assessment will involve:

- Current medication – is it appropriate or does it need changing/rationalising?
- Service user's attitude towards the medication.
- History of non-compliance with medication.
- History of risk relating to medication.
- Disabilities affecting service user's ability to self-administer, e.g. vision; dexterity; swallowing difficulties; confusion.

The decision for a service user to enter a self-administration programme must be based on an MDT-discussion, including the service user (and carer, if appropriate).

The nature and purpose of the programme must be fully explained to the service user.

2. STORAGE.

- The principles of the Medicine Code must be adhered to at all times.
- Medication for self-administration must be locked in individual cabinets, boxes or drawers. These must be approved by pharmacy.
- All controlled drugs must be stored in the controlled drug cupboard.
- At an appropriate stage, agreed by the MDT, the service user may be issued with their own individual key. A master key will be held by the Nurse in Charge.
- If compliance aids are used, these should be filled by pharmacy. In the event that pharmacy service is not available, this can be done by an appropriately trained nurse. Consideration should be given to

the type of aid used and whether the same type will be used by the supplying local chemist, on discharge.

(See Appendix 14 for further details on compliance aids).

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3. RECORDING

As with any other administration of medication, recording must be clear and accurate.

Assessment and decision for the service user to commence the self-administration programme must be recorded in the care records.

The EPMA record must clearly indicate that the service user is self medicating.

4. ORDERING AND DISPENSING

Ordering through pharmacy will be as agreed within the local protocols.

Medication for self-administration will be ordered and dispensed like TTO's, in individually labelled bottles (or compliance aid, if used).

Appendix 14

MEDICINES ADHERENCE/CONCORDANCE/COMPLIANCE

Up to half of all service users with long term conditions are known not to take their medicines as intended. In schizophrenia rates of non-compliance around 50% are consistently found. The following guidance has been developed to assist clinical staff in adopting a more consistent and collaborative approach with service users to apply a range of strategies to maximise concordance. For further information refer to NICE clinical guideline 76 Medicines adherence issued January 2009. The Trust also has a medication management 5 day module which can be accessed via corporate nursing as part of an overall package of training for nurses and other professional staff within the trust.

Documentation

Concerns that service users are not taking their medication must be recorded in the patient's Electronic Care Record by the care co-ordinator and the team advised in the daily handover. Additionally the care plan must be amended to address issues of non-compliance. Any discussions about choice, benefits and risks of medication and the provision of information such as the Choice and Medication leaflets should also be documented in the notes.

What can be done to improve compliance?

1. Involve service users in decisions about medicines

a) Engage service users, communicate effectively and have a good relationship with the service user. Adapt your consultation style to the service users' need and encourage them to ask questions.

- explain the pros and cons of treatment
- clarify what the service user hopes treatment will achieve
- talk and listen to the service user and note any non-verbal cues
- help service users make decisions based on likely benefits and risks rather than misconceptions
- accept that service users may have different views from healthcare professionals about risks, benefits and side-effects

b) Understanding the service users perspective

- ask what they know and believe about medicines and their need for medication
- ask about general and specific concerns and address these
- remember to discuss what will happen if they don't take medication, treatment options, reducing or stopping medication and fitting medicines into their routine

c) Provide information

- The choice and medication website is an excellent source of information and has been designed for use by both service users and mental health professionals www.choiceandmedication.org.uk/bsmhft
- Document what information is given and record a summary of the discussion

2. Supporting compliance

a) assess compliance

- ask service users if they have missed any doses recently (e.g. in the last week) and about medicine-taking habits
- monitor side-effects as a sign of compliance- rating scales such as LUNSERS or GASS can be used. Where they are, document in the electronic care record
- ask for empty compliance aids, medicine boxes/bottles and any untaken medicines etc
- consider taking blood samples for antipsychotic levels. Further information is available on the pharmacy and medicines Connect pages
- check the service user has been collecting their prescription from their GP and having them dispensed at a pharmacy if medicines are obtained from primary care

b) interventions to increase compliance

- assess if non-compliance is intentional or unintentional
- discuss any beliefs or concerns service users have about their medicines
- undertake a critical medicines review to simplify the number of medicines taken, address side effects and maintain or improve overall effectiveness (see 3. below)
- possible interventions include: service users recording their medicine taking (the pharmacy can provide stickers that can be placed on medicine boxes/bottles which can be ticked when a dose has been taken), simplify the regimen, use alternative packaging or a compliance aid, phone/text reminders to take medicines, staff to supervise medicine taking, consider compliance therapy/motivational interviewing
- If side-effects are a problem: discuss benefits versus side-effects and how the service user might deal with these, suggesting strategies for managing side-effects, e.g. consider adjusting the timing or dosage or switching to an alternative medication
- If prescription charges are a reason for non-compliance medication may be obtained from the Trust pharmacy service

3. Review medicines

- Critically review the service user's medicines including any medicines they may be receiving from their GP. This may be a carried out if necessary as part of a multidisciplinary review of the service user. This should include a clear indication, assessment of the medicine's effectiveness, checking of the service users understanding of the medicines they are prescribed, doses, side effects and how to manage them, interactions between medicines and any changes required.
- Review the service users' knowledge, understanding, experiences and concerns about their medicines and whether they think they still need them
- Ask about compliance when reviewing medicines. Clarify reasons for non-compliance and agree any action with the service user
- Ask service users if they have their own way of assessing medication e.g. by stopping and starting treatment

After the medicines review, assess the effectiveness of the medicines review and if necessary, tailor the approach in line with the service users needs

4. Improve communication between healthcare professionals

Many service users have some or all of their medication prescribed in primary care thus any reviews carried out by the Trust must be communicated with other prescribers involved with the service users care. The following information should be communicated:

- The outcome of any medication review

- A list of the psychiatric medicines the service user should be taking including the indications for each
- State any new medicines that have been started
- State any medicines that have been changed or stopped with reasons
- Information on duration of treatment
- Any known adverse drug reactions and allergies
- Any difficulties with adherence and any actions taken (e.g. compliance aid)

5. Practical Interventions to aid adherence

The table overleaf gives solutions to some problems that service users may encounter.

Problem	**Action**
Difficulty reading labels	Possible solutions include • Large print • Colour coded bottles • Use numbers and not words • Use symbols • Translation into different languages
Difficulty opening and closing bottles	Use non child resistant tops, or winged tops
Difficulty handling boxes and bottles	Use larger bottles or boxes Consider compliance aid where this will improve handling
Half tablet dose	Pharmacy will halve tablets if appropriate
Difficulty pushing tablets out of blister pack	Pharmacy can de-blister if appropriate
Difficulty with liquid measurements	Provide alternative formulation
Difficulty swallowing	Change formulation. Many tablets may be dispersed in water where a liquid formulation is not available. Further advice is available from the Trust Pharmacy
Is service user confused	Synchronise doses to daily events Reduce frequency of doses, if possible all medicines to be taken at same time of day A supplementary medication administration chart with tick boxes may help Supply medicines on a weekly basis, rather than monthly

Does service user forget to take medicines	Simplify regime Organise support, e.g. with carer Supply a system for reminding service user such as an alarm or chart Consider a compliance aid
Understand the risks associated with not complying Unacceptable side effects	Educate and support. Provide verbal and written information. Identify side effects Improve therapy to minimise side effects. Use of slow release preparations if available, changing times of administration. Treat side effects
Have poor or no motivation	Provide education about benefits
Understand the need for the medicine	Provide education and consider treatment regime and support.

6. Compliance Aids

For some people a compliance aid may assist them to continue self-medication and remain out of hospital. However, there is little strong evidence that compliance aids improve adherence and they will not improve poor compliance in those who have deliberately chosen not to take their medication. Neither will they improve compliance in those who do not have the cognitive skills to use the aid nor will they improve the memory of those who forget to take medication. Many medicines are not suitable to be repackaged into a compliance aid and this again can limit the usefulness of these devices.

Transferring medicines to a compliance aid is not covered by the medicines marketing authorisation and this is therefore an unlicensed use of the medicine.

The Trust has published guidance on assessing the suitability of using compliance aids, which should be followed. This guidance includes forms that must be completed and sent to Pharmacy prior to the first dispensing. Pharmacy will not fill compliance aids where forms have not been completed or when there is no justifiable reason for using a compliance aid.

Filling of compliance aids may involve re-dispensing or secondary dispensing. This may be done by Authorised Pharmacy Staff, community pharmacists or nurses. Nurses must have received secondary dispensing training (See Appendix 8). This additional responsibility must also be agreed by the team manager in consultation with the relevant programme lead pharmacist and lead nurse.

In addition

- Service users may be assisted to fill their own compliance aids.
- Service users may be assisted to use a compliance aid as part of a ward based rehabilitation scheme.

The Trust Pharmacy service has a list of medicines that are not compatible with compliance aids. Where nurses are undertaking the filling of compliance aids via secondary dispensing, the compatibility of all medicines must be confirmed before commencing the first dispensing. **All medicines supplied via a compliance aid are normally given an expiry date of a maximum of SIX weeks from dispensing.**

The following preparations should not be put in a compliance aid

Effervescent tablets

Sublingual tablets

Buccal tablets

Chewable tablets

Oro-dispersible tablets

Hygroscopic tablets and medicines requiring a desiccant

'When required' doses and variable doses (dose dependent upon biochemistry e.g. warfarin)

Further information is available from the Trust Pharmacy service.

Risks associated with compliance aids

Medidose and nomad systems are not child resistant

Other systems may be difficult to open

Swapping from one system to another will be confusing

Filling compliance aids is time consuming and subject to errors. The medicines are removed from their packaging thereby removing the batch number, the expiry date and the Patient Information Leaflet.

Some compliance aids are not sealed after filling and there is opportunity for tablets to be added or removed. The aid may be dropped spilling all the tablets.

Service users may obtain medicines from the mental health service and from the GP. It is difficult to ensure that all the medicines are in the one compliance aid.

Appendix 15

DRAFT STANDARD OPERATING PROCEDURE FOR USE OF PATIENTS OWN

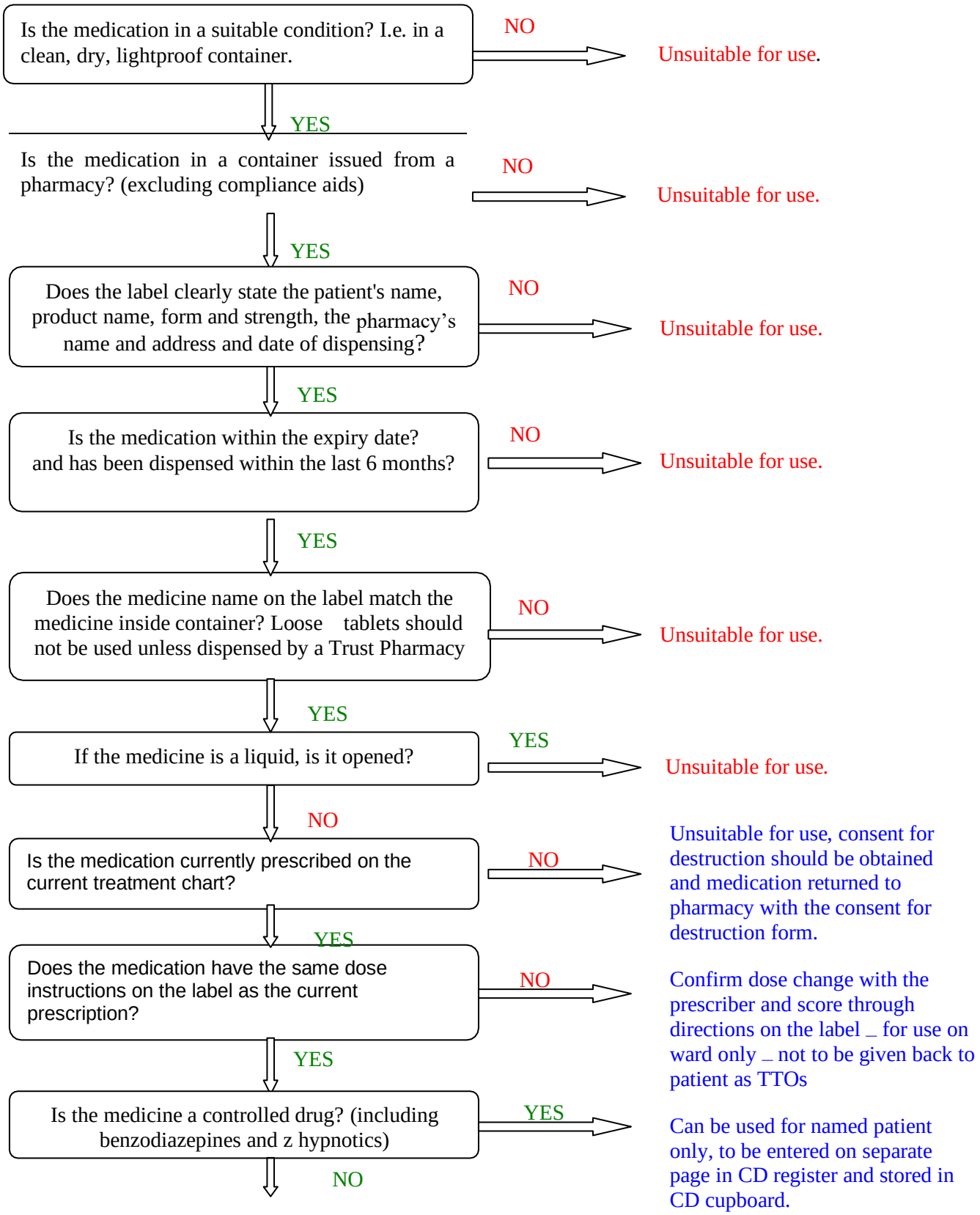
MEDICATION ON AN IN-PATIENT UNIT

SOP:	Use of Patients Own Medication on an In-patient Unit	
Scope:	To reuse patients own medication safely on an in-patient unit	
Applicable to:	All pharmacy technicians and pharmacists	
Procedure:	NB: Nursing staff can use service users own medication prior to screening by pharmacy staff, using the attached flow chart as guidance .PODs will be screened by a technician and a pharmacist will then provide a second check to confirm suitability. In the absence of a technician a pharmacist can confirm suitability alone.	
Technician/ Pharmacist	A1.	Check the service users own medication using the attached flow chart to confirm suitability for use.
	A2.	Quarantine medication that is unsuitable for use. Return medication to pharmacy for destruction once a 'Destruction for Patients Own Medication Disclaimer' has been completed. This will require the service user's or carers' consent
	A3.	Place the medication once it is deemed suitable for use in the trolley/cupboard/controlled drugs cupboard for use for that named service user on the ward. Ensure controlled drugs (including benzodiazepines and z hypnotics) are entered into the controlled drugs register on a separate page for each service user
	A4.	Complete the attached form with details of the service user's own medication that is suitable for use.
	A5.	Annotate the treatment chart with 'Patient's Own' and initial and date.
	A6.	Order any medication needed as per SOP ??
	A7.	Inform ward pharmacist of service user's own medication that requires a second check using the attached form.
Pharmacist or Accredited Pharmacy Technician	B1.	At next ward visit check each service user's own medication for suitability using the attached flow chart
	B2.	Initial the treatment sheet to confirm the item has been double checked
	B3.	Store the form in the ward top up folder for audit purposes

Patients Own medication Suitable for Use on Ward……

Date	Patient Name	Medication (including strength and form)	Quantity	Pharmacy initial	Comments

Use of Patients Own Medication on an In-Patient Ward



Appendix 16

Draft Standard Operating Procedure For Destruction of Controlled Drugs on wards

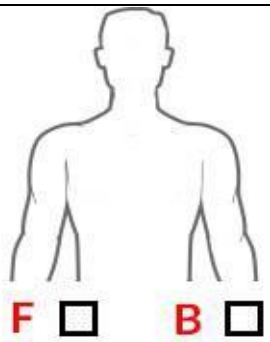
Purpose:	To ensure stock controlled drugs are denatured and rendered irretrievable before being disposed of safely and appropriately.	
Applicable	Nurses in Charge, Pharmacists,	
Procedure:	1.	Destruction of controlled drugs returned by a patient, expired or unusable controlled drugs may be undertaken by the Nurse in Charge and witnessed by a pharmacist.
	2.	The pharmacist should wear disposable apron and gloves throughout the process.
	3.	The Pharmacist should obtain a controlled drug destruction kit. These are supplied as stock to wards
	4.	The destruction kit should be shaken to loosen the granules.
		For each controlled drug, select the item that is to be denatured/destroyed. Sign the register to confirm the item has been denatured. The pharmacist should also sign as confirmation. Different formulations of medication should be destroyed in the following order:
	5.	Tablets and capsules should be removed from bottles/blisters packs and added to the destruction kit. .
	6.	Powders may be added to the destruction kit directly.
	7.	Ampoules containing dry powders should be crushed before adding to destruction kits. Safety precautions, such as covering with a paper towel should be exercised at all times. Ampoules containing liquids should be opened and the contents emptied into a controlled drug destruction kit. The empty ampoules should then be disposed via a sharps container. Use ampoule snappers wherever possible to break open the ampoules.
	8.	Patches should have the backing removed and the patch folded back on itself and may be placed directly into the denaturing kit.
	9.	Liquids may be added to the destruction kits directly but should be added last as this will cause the contents of the kit to solidify.
	10.	The kit should only be filled to the capacity indicated on the container with controlled drug. It should then be filled with either potable water or a liquid controlled drug for destruction.
	11.	Replace the lid securely
	12.	The kit should be shaken thoroughly and left to set.
	13.	The sealed container should be placed into a blue-lidded pharmaceutical waste container.

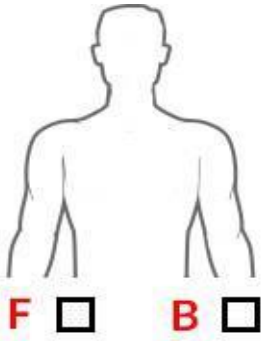
Written By:		XXXX/XXXX
Approved by:		XXXX
Date:		August 2020
Review Date:		

Appendix 17

Patch Application Record

Name of resident		**Date of birth**	

Drug name:				**Strengths(s):**	**No. of Patches:**
	**DAY**	**DATE**	**TIME**	**ACTION/COMMENT**	**SIGNATURES**
	1				
	2				
	3				
	4				
	5				
	6				
	7				

Drug name:				**Strengths(s):**	**No. of Patches:**
	1				
	2				
	3				
	4				
	5				

	6				
	7				

The old patch should be removed before applying the new patch. The old patch must be folded in half and stuck together before disposal.
The site of application should be rotated in accordance with the manufacturer guidance.
Use a cross (x) to indicate where the new patch has been applied.
Use a new section each time patches are applied.
The patch should be checked on a daily basis to make sure it is still in place.