NHSGGC Safe and Secure Handling of Medicines	
Guidance Section 1	
Procurement of Medicines	
Approved by: ADTC Safer Use of Medicines Committee	October 21
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1.1 General principles

- 1.1.1 The Director of Pharmacy will delegate responsibility to specified senior pharmacy staff within GGC to negotiate contracts for medicines with suppliers on behalf of NHSGGC. Designated senior staff will have authority to purchase non contract medicines as required, including unlicensed medicines, in line with current policy and Standing Financial Instructions (SFIs).
- 1.1.2 Information on medicine costs is confidential within NHSGGC and is referred to only in the most general terms by NHSGGC personnel, except during direct negotiations of agreements and contracts.
- 1.1.3 All medicines must be obtained through pharmacy, except for patients' own drugs.
- 1.1.4 Medicines used for research and clinical trials, expanded access medicines and newly licensed medicines must have the appropriate management approval and / or committee approval.
- 1.1.5 Appropriate risk management arrangements are followed for the procurement of medicines that do not have a product licence in the United Kingdom (see section 1.6, Unlicensed Medicines).
- 1.1.6 If any staff member involved in the procurement, prescribing, preparation or administration of medicines has concerns about the quality of the product or any clinical concerns regarding the use of the medicine in individual patients they should advise the relevant senior professional (e.g. Consultant / Assigned Nurse in Charge / Senior Pharmacist).
- 1.1.7 Defective medicines or potentially defective medicines are withdrawn from use in an appropriate timescale to minimise risk to patients, and the Defective Medicine policy followed. (Link to this policy is here located on ggcmedicines.org.uk site).

1.2 Company medical representatives

1.2.1 Company medical representatives must observe the current Association of British Pharmaceutical Industry (ABPI) Code of Practice and any local NHSGGC guidance. Employees of NHSGGC must observe relevant guidance on conduct with business representatives (i.e. as laid out in the GGC Code of Conduct for Staff (link <u>here</u> – located on NHSGGC Staffnet >Corporate Services site).

- 1.2.2 Only medicines approved for use by NHSGGC Area Drug and Therapeutics Committee (ADTC) may be promoted to staff working within NHSGGC.
- 1.2.3 Information may be requested on any product from a medical representative, irrespective of whether the medicine is on the NHSGGC Formulary.
- 1.2.4 The presence of medical representatives must not disrupt work in clinical areas.
- 1.2.5 Junior pharmacists, medical staff and ward nursing or other staff may not be approached directly by medical representatives unless authorised to do so by a senior pharmacist, lead nurse / midwife or consultant. Any meetings with medical representatives must have a clear educational objective. Consultants, specialist registrars, nurses /midwives and pharmacy staff must see representatives by appointment only.
- 1.2.6 Sponsorship of meetings by medical representatives may be accepted only if the meeting has a clear educational objective.
- 1.2.7 Staff must not disclose information on medicine costs to representatives.
- 1.2.8 Representatives must not leave samples of medicines in wards or other clinical areas or in the pharmacy.
- 1.2.9 Representatives from companies promoting an unlicensed medicines manufacturing / distribution service should contact the Regional Quality Assurance Pharmacist prior to making initial contact with individual hospital sites.

1.3 Ordering and stock control of medicines by hospital pharmacy staff

- 1.3.1 All medicines must be procured in accordance with current pharmacy computer stock control procedures for procuring drugs, which have been approved by the external auditors and finance department.
- 1.3.2 A purchase order will be raised, in accordance with current contracts, to an appropriate supplier (e.g. local wholesaler) by a suitably trained staff member and approved by a pharmacy authorised signatory for medicines, in accordance with NHSGGC Standing Financial Instructions.
- 1.3.3 In some instances it may be necessary to procure medicines from other hospitals or community pharmacies. Such requests must be authorised by the Sector Chief Technician / Lead Clinical Pharmacist or delegated deputy, dependent on local policy. Out of hours, this request will be dealt with by the On-Call Pharmacist. Local standard operating procedures (SOPs) will apply.
- 1.3.4 In exceptional circumstances medicines may need to be ordered from suppliers outwith normal opening hours. Local SOPs will apply.

1.3.5 Stock levels must be reviewed regularly to ensure medicines are available on site when they are needed and to minimise wastage.

1.4 Receipt of medicines into pharmacy

- 1.4.1 When any medicines are delivered to pharmacy the driver's identity must be confirmed. If the driver enters the pharmacy to deliver goods / obtain signatures he/she must be escorted at all times. He/she must report to the appropriate pharmacy delivery area where a pharmacy staff member will sign for the delivery either by signing "Received unchecked" or will check the medicines against the delivery note prior to signing for receipt.
- 1.4.2 Completed delivery notes must be presented to a suitably trained staff member to mark up on the computerised stock control system. There must be clear separation of the 'procurement', 'goods received' and 'mark up' processes, with at least two suitably trained staff members involved.
- 1.4.3 A "Medicines Returned to Pharmacy Form" must accompany all medicines returned from clinical areas, wards, theatres or departments (including prescriptions not issued to patients and patients own drugs no longer required). Returned medicines assessed as suitable for reuse must be entered into the computerised stock control system and the destruction of any medicines documented.

Controlled Drugs : Additional Requirements

- 1.4.4 When a CD is delivered to pharmacy the driver must report to the appropriate pharmacy delivery area and their identity must be confirmed. A pharmacist or authorised pharmacy technician will sign for the delivery and check the CDs against the delivery note.
- 1.4.5 All CDs received in pharmacy, from suppliers or returned from wards, must be stored in a designated CD storage facility which should be kept locked at all times when not in use.
- 1.4.6 All CDs received in pharmacy, either from suppliers or returned from wards, must be recorded in the appropriate section of the pharmacy Controlled Drug Register. The following particulars must be recorded:
 - Date on which received
 - Name and address of supplier (wholesaler, manufacturer or ward)
 - Amount received and new total balance
 - Form in which received
 - Signature of pharmacist or authorised pharmacy technician recording receipt
- 1.4.7 All CDs received into the pharmacy department must be written into the pharmacy Controlled Drug Register within 24 hours of receipt. If any

discrepancies are found the wholesaler or pharmacist returning the CDs from ward /clinical areas should be informed immediately.

- 1.4.8 Pharmacy CD balances must be checked when goods are received into stock and after each issue.
- 1.4.9 The balance in the register must be reconciled with the computer stock balance periodically, at least monthly, by pharmacy staff, with ad hoc spot checks being conducted on a regular basis. If any discrepancies are found a thorough investigation must be carried out. This must be fully documented, including any actions taken. The Sector Chief Technician and/or Lead Clinical Pharmacist must be informed. If a discrepancy cannot be resolved a report should be sent to the Accountable Officer.

1.5 Approval of medicines for procurement / Non-Formulary medicines

Please refer to GGC policies on Access to Medicines on the GGC Medicines site (link here - located on ggcmedicines.org.uk site).

1.6 Unlicensed medicines

Please see the NHSGGC Unlicensed Medicines Policy (link <u>here</u> – located on ggcmedicines.org.uk site).

1.7 Medicines for use in research and clinical trials

- 1.7.1 Researchers wishing to undertake research must approach the local Research and Innovation Department for all clinical investigations involving human volunteers or patients. (Additional approval may be required, depending on the nature of the individual trial – guidance will be given by the Research and Innovation Department.)
- 1.7.2 A Clinical Trials Authorisation (CTA) must be submitted to the Medicines and Healthcare Products Regulatory Agency (MHRA) for all clinical trials involving an investigational medicinal product.
- 1.7.3 If the investigation involves the administration or supply of medicines the Research and Innovation Department should liaise with the relevant Lead Clinical Pharmacist(s) / Sector Chief Technician(s) prior to trial approval.
- 1.7.4 Medicine supplies for research and clinical trials must be distributed through the pharmacy unless risk assessed and approved by the local Senior Clinical Trials Pharmacist as suitable for out of pharmacy storage and distribution.
- 1.7.5 A pharmacy file meeting current Research and Innovation regulatory requirements must be held in the pharmacy and a local dispensing procedure approved.

1.7.6 The clinical trial may commence only following formal Research and Innovation management approval, MHRA and ethical approval.

Controlled Drugs : Additional Requirements

1.7.7 All requirements regarding storage, record keeping and destruction apply to clinical trial drugs classified as CDs in addition to any trial documentation that may be required