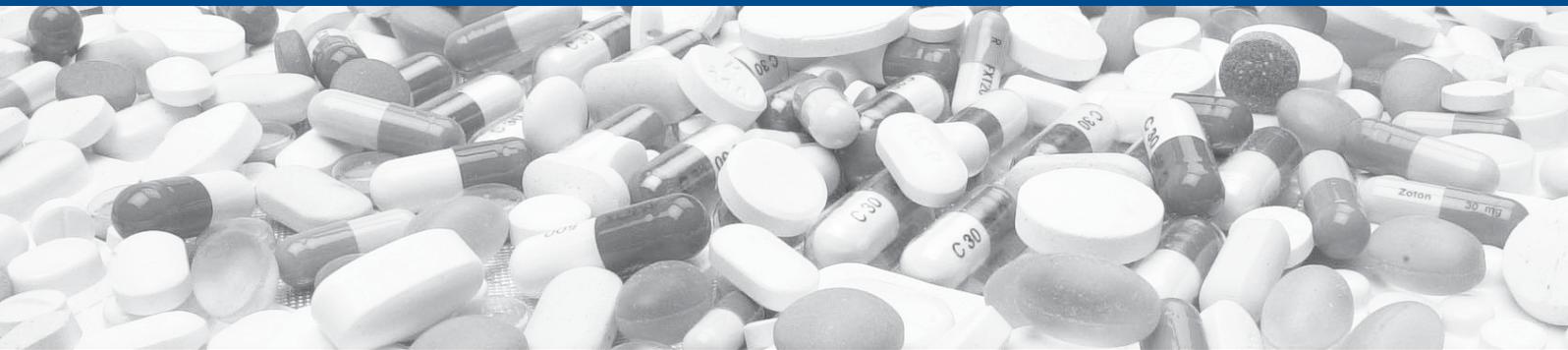


# Safe and Secure Handling of Medicines Within Primary Care





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Lead Author: Colette Byrne, Lead Pharmacist, Medicines Governance

*Produced in consultation with multidisciplinary teams across NHS GG&C.*

Responsible Director: Dr P Ryan

Approved by: Primary Care Clinical Governance Forum

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The document is available on both the NHS GGC Staffnet and externally via the NHS GGC Prescribing website ([www.ggcprescribing.org.uk](http://www.ggcprescribing.org.uk)). If any healthcare service area prints and stores copies of the document then any person referring to the document after the date of printing must refer to the online version to ensure they are using the most up-to-date guidance.

## Using this document

This document has been structured to allow quick reference to the relevant topic. The core areas of security, responsibility and the processes relating to ordering, receipt and storage of medicines in healthcare service areas are contained in chapter 4, within clear sub-sections. Further chapters cover distinct areas highlighted to the development team as areas requiring clarification and guidance. Please refer to the index in the first instance. A glossary of terms has been included at the end of the document. For further information or if you wish to comment on this document or request a review of any section please e-mail the dedicated "Safe and Secure Handling of Medicines" address on:

**sshm@ggc.scot.nhs.uk**

## Useful contacts

Contact	Phone number	E-mail address
NHS GGC Controlled Drugs Governance Team	0141 201 5348	audrey.thompson@ggc.scot.nhs.uk
NHS GGC Formulary and Therapeutics Handbook Team	0141 211 5433	roy.foot@ggc.scot.nhs.uk
Community Pharmacy Development Team	0141 201 5210	GG-UHB.cpdevteam@nhs.net
Lead for non-medical prescribing Addictions Team	0141 201 5312 0141 277 7660	jane.camp@ggc.scot.nhs.uk carole.hunter@ggc.scot.nhs.uk
Specialist pharmacists in Public Health	0141 201 4824	liz.mcgovern@ggc.scot.nhs.uk or pharmacypublichealth@ggc.scot.nhs.uk

### Lead Clinical Pharmacist for CH(C)Ps

CH(C)P	Pharmacist	email address	Work No
North East Sector – Glasgow CHP	Anne Thomson	annethomson2@nhs.net	0141 277 7452
North West Sector – Glasgow CHP	Sheila Tennant	stennant@nhs.net	0141 211 3983
South Sector – Glasgow CHP	Laura Hendry	laura.hendry@nhs.net	0141 276 6733
East Dunbartonshire	Carolyn Fitzpatrick	carolyn.fitzpatrick@nhs.net	0141 201 4271
East Renfrewshire	Lorna Brown	lornabrown2@nhs.net	0141 577 3354
West Dunbartonshire	Pamela Macintyre	pamela.macintyre@nhs.net	01389 812319
Renfrewshire CHP	Susan Love	susan.love1@nhs.net	0141 207 7752
Inverclyde CHP	Margaret Maskrey	margaret.maskrey@nhs.net	01475 506142
Lead Clinical Pharmacist – Care Homes / Elderly	Noreen Downes	noreen.downes@nhs.net	0141 232 7141
Lead Clinical Pharmacist – Interface	Rachel Bruce	rachel.bruce@nhs.net	0141 277 7602



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# Introduction

This document describes NHS Greater Glasgow and Clyde (NHS GGC) policy in relation to the safety and security of medicines during procurement, storage, distribution, dispensing, prescribing and administration within primary care environments. It is not intended to address the specific clinical issues that relate to therapeutic choice and medication efficacy.

The policy is applicable to all NHS GGC employees (substantive or sessional appointments) and holders of honorary contracts who handle medicines in any way during the course of their business. It is intended as a *guidance tool* for General Practitioners, Community Pharmacists, Dentists, Optometrists and any other independent NHS contractors, who are encouraged to adopt the principles in their own practice.

This document is not intended for use within NHS GGC acute hospital environments, for which there is a separate complementary policy, nor does it cover care homes, hospices or other premises e.g. schools or prisons.

All NHS healthcare service areas in primary care should have a system of standard operating procedures (SOPs) for the ordering, handling and use of medicines that ensure safety, security and efficiency. Much of the legislation concerning medicines has been written to avoid diversion or abuse. This document draws on relevant legislation, professional standards documents and established best practice to set out the core principles which should be addressed by local SOPs. This policy is intended to provide a framework for the review and / or preparation of the required detailed local procedures.

The Head of the Pharmacy and Prescribing Support Unit (PPSU), Medical Director and Director of Nursing are responsible for ensuring staff under their direction establish and maintain approved procedures to comply with current legislation and professional guidance. They must ensure the risks inherent to both staff and patients in the use of medicines are managed appropriately.

Certain medicines are classified as Controlled Drugs (CDs). These are listed in the current Misuse of Drugs Regulations and are subject to more stringent controls (see current BNF, section on Controlled Drugs and Dependence). The Accountable Officer for NHS GGC is ultimately responsible for ensuring the policies relating to Controlled Drugs are adhered to at all times. In some instances this responsibility may be delegated to appropriate senior personnel within the organisation.

This document is available on the NHS GGC StaffNet and NHS GGC Prescribing website. It is correct at time of first issue but the online version will be reviewed and updated on a regular basis in response to further guidance or changes in legislation. If versions of this document are printed and stored in service areas, any person referring to the document after the date of printing must refer to the online version to ensure they are using the most up-to-date guidance. This document supersedes all previously published guidelines in NHS GGC primary care settings that relate to safe and secure handling of medicines.

# 1. Definition of a Medicine, including Controlled Drugs (CDs)

Medicines are substances that are introduced into the body, or externally applied to the body, for the purpose of

- treating disease
- preventing disease
- diagnosing disease
- ascertaining the existence, degree or extent of a physiological condition
- contraception
- inducing anaesthesia
- otherwise preventing or interfering with the normal operation of a physiological function.

Medicines may be categorised as follows:

1. Medicines and medicinal preparations that come under the provisions of the Medicines Act (1968). They can be classified as Prescription Only Medicines (POM), Pharmacy Medicines (P) or General Sales List (GSL) medicines and include medicines used in clinical trials, unlicensed medicines and medicated dressings. Please note – oxygen and other medical gasses should be treated as medicines and should be subject to the controls outlined in this document.
2. Controlled Drugs, (CDs), i.e. dangerous or otherwise harmful medicines controlled under the provisions of the Misuse of Drugs Act (1971) and Regulations made under the Act. Controlled Drugs are subdivided into different specifications as follows:

*Schedule 1: Includes drugs such as cannabis and lysergide, which are not used medicinally. Possession and supply are prohibited except in accordance with Home Office authority. Sativex® is a cannabis derivative product licensed for use in multiple sclerosis. It is the only medicinal drug in this class. There has been some use within NHS GGC. It may be reclassified to a different schedule by the Home Office and details will be circulated to relevant practitioners if this happens. It is subject to prescription writing requirements as for schedule 2 CDs.*

*Schedule 2: Includes drugs such as diamorphine (heroin), morphine, pethidine, secobarbital, amphetamine, and cocaine and are subject to the full CDs requirements relating to prescriptions, safe custody (except secobarbital), the need to keep register, etc. (unless exempted in Schedule 5).*

*Schedule 3: Includes barbiturates (except secobarbital, now Schedule 2), buprenorphine, diethylpropion, meprobamate, pentazocine, midazolam, temazepam and tramadol. They are subject to the special prescription requirements (except for temazepam) but not to the safe custody requirements (except for buprenorphine, diethylpropion, and temazepam) nor to the need to keep registers (although there are requirements for the retention of invoices for 2 years).*

*Schedule 4: Includes Part I benzodiazepines (except temazepam and midazolam which are in schedule 3) and zolpidem, which are subject to minimal control. Part II includes androgenic and anabolic steroids, clenbuterol, chorionic gonadotrophin (HCG), somatotrophin, somatrem, and somatrophin. Controlled Drug prescription requirements do not apply and Schedule 4 drugs are not subject to safe custody requirements.*

*Schedule 5: Includes those preparations which, because of their strength, are exempt from virtually all Controlled Drug requirements other than retention of invoices for two years.*

3. Alternative / complementary medicinal products e.g. herbal or homeopathic remedies that are used for therapeutic purposes.

Throughout the document the term 'medicine' will only cover categories 1 and 2 of medicines identified above. Where additional controls apply for Controlled Drugs these will be clearly identified.

## 2. Aims of Policy

- 2.1 To ensure safety in the procurement, storage, distribution and administration of medicines to patients in NHS GGC primary care healthcare service areas.
- 2.2 To ensure that medicines are purchased from approved suppliers and are of the required quality.
- 2.3 To ensure that medicines are available at the time they are needed.
- 2.4 To ensure that stocks of an appropriate range of medicines are kept at a level to minimise wastage and reduce stockholding costs.
- 2.5 To ensure that medicines used for research and clinical trials and unlicensed medicines are authorised for use.
- 2.6 To ensure that the quality and security of medicines are maintained during transportation.
- 2.7 To ensure that all medicines are transported with due attention to health and safety considerations.
- 2.8 To ensure that the quality and security of medicines is maintained in all primary healthcare service areas where medicines are stored or administered.
- 2.9 To ensure that all prescriptions for medicines are written according to legal requirements and accepted NHS GGC standards.
- 2.10 To minimise the risk of errors in the prescribing, administration and supply of medicines.
- 2.11 To ensure safe disposal of unwanted or expired medicines according to current legislation.
- 2.12 To prevent misappropriation of medicines by staff and / or patients and / or carers.

## 3. Core Policy Statements

- 3.1 All medicines issued or administered to patients within NHS GGC should be procured by and distributed through pharmacies (either community or hospital), or via approved wholesalers or homecare suppliers, in accordance with local standard operating procedures (SOPs).
- 3.2 Medicines must be stored securely in healthcare service areas in suitable cupboards, refrigerators and freezers or other secure storage facilities, as appropriate, to maintain their quality and security.
- 3.3 Medicines should be ordered, prescribed and administration recorded on approved stationery, which should be stored securely to prevent fraudulent use. Where electronic systems are in use there should be procedures in place to restrict access to computer terminals and pass codes and ensure a full audit trail is maintained.
- 3.4 Medicines should be prescribed with due reference to the NHS GGC Formulary.
- 3.5 In general, General Practitioners will not be required to prescribe unlicensed medicines. However, there may be circumstances where this is considered to be in the patient's best interests. Reference should be made to the NHS GGC Unlicensed Medicines Policy in these cases.
- 3.6 Qualified non-medical prescribers (NMPs) should follow local procedures relating to registration with NHS GGC prior to commencing prescribing duties. Job descriptions should be reviewed and updated (if necessary) at the time of registration to ensure NMP duties are reflected on the job description.
- 3.7 Medicines should be ordered, prescribed, or supplied to patients only by suitably trained and competent persons working within a legal framework, who can exercise professional accountability and judgement in the best interests of their patients. This includes persons operating within a Patient Group Direction, (PGD), or functioning as non-medical prescribers as well as medical prescribers.
- 3.8 Systems used for the transport of medicines should ensure their security, quality and integrity, and maintain the health and safety of the patient, staff and the public.
- 3.9 Disposal of medicines must be in accordance with legal requirements and health and safety regulations.
- 3.10 All clinical incidents (including near-miss events) involving medicines should be reported, documented and investigated (via the appropriate approved mechanism) and appropriate action taken to reduce the risk of recurrence.
- 3.11 Staff, whether employed directly by NHS GGC or working as contractors, are not permitted to acquire medicines purchased and supplied for patient-use for their own personal use or for use by their friends and family.
- 3.12 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 immediately.

## 4. The system to ensure safety and security in handling medicines in Healthcare Service Areas

### 4.1 Responsibility

- 4.1.1 The responsibility for establishing and maintaining a system for the security of medicines is that of the Senior Designated Pharmacist in consultation with relevant medical and/ or nursing staff or the Responsible Pharmacist in the community setting. In healthcare service areas where no Senior Designated Pharmacist is directly employed the responsibility lies with the Registered Manager or manager with designated responsibility for that area. Non-pharmacy personnel should seek appropriate pharmaceutical advice, where necessary, to establish and maintain a robust system.
- 4.1.2 The Registered / Designated Manager or Senior Designated Pharmacist or Responsible Pharmacist in the community setting may delegate some of the duties attached to these systems but the responsibility always remains with the appointed Registered / Designated Manager or Senior Designated Pharmacist or Responsible Pharmacist in the community setting.

### 4.2 Procedures

- 4.2.1 Healthcare service areas should review, amend and / or develop Standard Operating Procedures (SOPs) covering the various activities concerned with medicines use, including ordering, receipt, storage, administration, supply and destruction / disposal. The system, as a whole, should ensure that medicines are stored safely and securely and are fit for use at the point of clinical need.
- 4.2.2 All SOPs should be easily accessible to staff, reviewed regularly and a system for document control employed to ensure the most up to date version is in place and adhered to.
- 4.2.3 The procedures relating to Controlled Drugs must take account of current legal and good practice requirements. (Advice on Controlled Drugs within NHS GGC can be sought from the Controlled Drugs Governance Team).
- 4.2.4 The procedures relating to vaccines must take account of good practice recommendations (see section 4 of the NHS GGC immunisation resource pack (<http://www.nhsggc.org.uk/phpu>)).

### 4.3 Ordering Medicines

- 4.3.1 Healthcare service areas should have procedures in place that facilitates efficient and timely ordering of medicines.
- 4.3.2 Overall responsibility for ordering medicines is that of one senior designated staff member. They may delegate some of the duties but overall responsibility always lies with that designated person.
- 4.3.3 Orders should take the form of a permanent record. Electronic ordering systems must ensure that a permanent record of the order is maintained. All indents, requisitions and delivery notes should be retained for a minimum period of 2 years. (Further information on the administration and disposal of records can be located at <http://www.scotland.gov.uk/Publications/2012/01/10143104/0>).
- 4.3.4 Any paperwork that allows medicines to be ordered (e.g. requisition books / prescription pads) must be treated as controlled stationery and securely locked away when not in use. Electronic ordering systems must have similar levels of security (e.g. user specific passwords). The senior designated person with responsibility for ordering medicines must ensure security of medicines is maintained at all times and access to paperwork or electronic ordering systems is restricted to authorised staff only.
- 4.3.5 Qualified practitioners are responsible for the security and safe handling of their prescription pads.
- 4.3.6 Staff are not permitted to directly request medicine supplies from medical company representatives or supply / administer any medicine left by company representatives (e.g. "free" or "trial" samples). This includes free or trial samples of controlled drugs. The NHS GGC Code of Conduct (Section 18, Working with suppliers of clinical products) should be consulted for detailed information and a list of permitted products (e.g. medicine provided as part of a clinical trial).

## 4.4 Receipt and Records

- 4.4.1 Designated suitably qualified personnel should check that all medicines received into a healthcare service area are intended for that area, that it is sealed and has not been tampered with, before signing the relevant documentation (e.g. delivery note) to confirm receipt. The original order and delivery note should be checked with the item(s) supplied to ensure the correct medicine has been received.
- 4.4.2 The designated person should identify any items with specific storage requirements (e.g. fridge, controlled drugs cabinet) and ensure they are stored appropriately without delay.
- 4.4.3 The receipt and recording of Controlled Drugs must comply with current legal and good practice requirements (SOPs should be followed).

## 4.5 Security

- 4.5.1 Medicines should at all times be stored at a level of security appropriate to their proposed use and at a level appropriate to the staff present at any time. Cupboards / refrigerators used for medicine storage should be locked when not in use. (If cupboards etc are not used or are not lockable there should be an alternative means of ensuring security e.g. medicines in an area under constant staff supervision).
- 4.5.2 The Senior Designated Pharmacist or Registered / Designated Manager or Responsible Pharmacist in the community setting for the healthcare service area is responsible for ensuring all medicines are stored appropriately e.g. in secure cupboards, medicine trolleys or lockable refrigerators.
- 4.5.3 The Senior Designated Pharmacist or Registered / Designated Manager or Responsible Pharmacist in the community setting for the healthcare service area is responsible for ensuring a system is in place for the safekeeping of, and control of access to, all medicine stored in his or her area of control. In order to fulfil this any keys that allow access to medicines should be held by an assigned healthcare professional (e.g. nurse / pharmacist). Any keys that allow access to CDs should be kept separate from other keys and only given to approved staff when access to CDs is required.
- 4.5.4 The Senior Designated Pharmacist or Registered / Designated Manager or Responsible Pharmacist in the community setting for each area should carry out periodic checks according to locally agreed procedures to ensure all processes and security arrangements are appropriate and fit for purpose. In areas without a designated pharmacist the most appropriate pharmacist should be contacted for advice and review of security arrangements.
- 4.5.5 In general dental practices, the responsibility for the security of controlled drugs such as midazolam lies with the registered dentists. Controlled drugs can only be prescribed or administered under his/her authority. In those dental services which are managed directly by NHS GGC, the responsibility for security lies with the Registered / Designated Manager.

## 4.6 Storage of Medicines in Healthcare Service Areas

- 4.6.1 Medicines should at all times be stored at a level of security appropriate to their proposed use and at a level appropriate to the staff present at any time.
- 4.6.2 The responsibility for safekeeping of medicines lies with the Senior Designated Pharmacist or Registered / Designated Manager of the service area or Responsible Pharmacist in the community setting.
- 4.6.3 Drug cupboards, including CD cupboards, should not be marked to indicate their contents.
- 4.6.4 Medicines should be stored alphabetically by approved name as far as practically possible. They should be stored in their original packaging. Ampoules, vials, or blister packed tablets should not be removed from the original box during storage.
- 4.6.5 All cupboards, refrigerators, doctors' bags etc used for the storage of medicines must be kept locked when not in use. (If lockable cupboards etc are not in use there should be an alternative means of ensuring security e.g. medicines in an area under constant staff supervision).
- 4.6.6 Medicines should be separated and stored according to their specific requirements e.g. fridge, CD cupboard, emergency trolley, doctors' bag. Drug cupboards must comply with current British Standards (currently BS2881 1989 NHS Estates Building Note No.29).

- 4.6.7 When medicines require storage in locked refrigerators a temperature record must be maintained by a designated person. It is recommended that at least daily recording of current, maximum and minimum temperature (since the last reading) is carried out. If possible, twice daily records should be kept. Any temperature readings outside the recommended range must be investigated immediately and appropriate action taken and documented. All stock should be clearly marked "Do Not Use" until advice has been sought from appropriate pharmacy personnel regarding the suitability of using any stock stored outwith the recommended temperature range. Monthly review of fridge temperature charts should be undertaken. In the event of equipment failure arrangements must be made to move medicines to a suitable storage facility, until the equipment is repaired.
- 4.6.8 Oral medicines should be separated into solid oral dose preparations and liquid formulations as much as possible to minimise the risk of selecting the wrong preparation, and to facilitate efficient stock control and ordering. Other internal medicines given by non-oral routes, e.g. nebulisers / suppositories/topical preparations, should be kept clearly segregated from oral medicines to avoid inadvertent wrong route administration.
- 4.6.9 Regular expiry dates checks should be carried out for all medicines at an interval agreed by the Senior Designated Pharmacist or Registered / Designated Manager or Responsible Pharmacist in the community setting. Stock must be rotated according to the expiry date so that oldest stock is used first.
- 4.6.10 Where medicine storage facilities are shared by different healthcare providers each individual healthcare provider is responsible for their stock, which should be stored in a manner that allows clear segregation of stock between healthcare providers.
- 4.6.11 All incidents involving a breach of security that cause actual or potential loss or theft of medicines should be investigated and the appropriate corrective and preventative action taken in accordance with local SOPs. This may involve contacting the police.
- 4.6.12 All CDs, including dispensed prescriptions containing CDs awaiting collection and returned medicines, must be stored in areas that comply with current regulations. The CD storage facility must have its own dedicated key. The key for the CD storage facility should be kept in control of the assigned person in charge when not in use. This key should be kept separate from other medicine keys.
- 4.6.13 Doctors' bags containing CDs must be locked at all times when not in use. The person in lawful possession of this bag or an individual authorised by them should always retain the keys. Doctors' bags must be stored in a safe manner when not in use to prevent unauthorised access, i.e. not left unattended in an unlocked consulting room. Doctors' bags containing CDs should not be left in a vehicle overnight, or in a vehicle left unattended for long periods of time. If a bag is left unattended at any time in a car it should be locked and kept out of sight.
- 4.6.14 Out of date CD stock should be segregated from normal stock but remain in safe storage until an authorised person can destroy the product.
- 4.6.15 Out of date vaccine stock held in healthcare service areas that are not community pharmacies should be returned to the Pharmacy Distribution Centre (PDC) by prior arrangement (e.g. telephone to customer services). (Community pharmacies should have local arrangements in place to deal with expired stock).
- 4.6.16 Clinical areas that require access to medicines during a medical emergency (e.g. during cardiac arrest) should ensure that such emergency drug kits are -
- tamper evident.
  - held in a locked area or, if it is impractical for them to be locked up, they must be stored in an area with constant staff presence.
  - Manufactured / produced so that their contents are not obvious to the general public.
- 4.6.17 Once an emergency drug kit has been used it should be checked and missing items replaced as soon as possible. There must be a system of checks in place for emergency kits that are assembled and stored ready for use, to ensure that they are complete and any medicine included is correct and within its expiry date.

## 4.7 Authorisation to prescribe and administer medicines

- 4.7.1 Medicines can be prescribed by UK registered doctors, dentists, and registered supplementary / independent prescribers.
- 4.7.2 If medicines are not prescribed, they can only be administered or supplied to patients within the terms of a Patient Group Direction (PGD) or a Patient Specific Direction (PSD). (Certain healthcare professionals are exempt from this requirement in relation to specified medicines only, allowing them to supply and administer these medicines without the directions of a doctor e.g. Midwifery provision in the Prescription Only Medicines (Human Use) Order 1997. For specific advice relating to these exemptions please contact the NHS GGC Lead for Non Medical Prescribing).

- 4.7.3 Appropriate risk management arrangements must be followed for the prescribing of medicines that do not have a product licence or are prescribed outwith the terms of their product licence. (The NHS GGC Policy on Unlicensed Medicines should be consulted at <http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/GGC%20Formulary/Pages/MedicinesPolicies.aspx>).
- 4.7.4 A record of all medicines prescribed and administered to patients or supplied via PGD or PSD must be maintained in the relevant case notes or documentation e.g. nursing or medical notes. If the medicine is a CD then a record of administration must also be recorded in the Controlled Drugs Register.
- 4.7.5 Prescribers or other health professionals should not prescribe or obtain medicines for themselves or prescribe, administer or supply medicines to anyone with whom they have a close personal or emotional relationship, except in exceptional situations.
- 4.7.6 Qualified non-medical prescribers (NMPs) must follow local procedures relating to registration with NHS GGC prior to commencing prescribing duties. Job descriptions must be reviewed and updated (if necessary) at the time of registration to ensure NMP duties are reflected on the job description.
- 4.7.7 Non-medical prescribers can only prescribe using the appropriate prescription form (e.g. GP 10 P – see Appendix 1). The prescriber's unique cipher number must be recorded on the prescription form if not already pre-printed.
- 4.7.8 If a prescriber issues prescriptions to patients from a range of medical practices, then he / she requires a prescription pad for each practice. However, for some prescribers who prescribe on a CH(C)P basis, a single cipher number may be appropriate (please contact the NHS GGC Lead for Non Medical Prescribing for further information).
- 4.7.9 Prescribers should ensure separation of prescribing, dispensing and administration activities wherever possible.
- 4.7.10 Medicines can only be supplied or administered via a Patient Group Direction (PGD) that has current valid NHS GGC approval. Please contact the NHS GGC Lead for Non Medical Prescribing for further information on developing, reviewing or working with PGDs in NHS GGC or contact Community Pharmacy Development Team for information for use of PGDs in community pharmacies.

## 4.8 Prescribing Medicines

*(Please Note – this section refers to the technical / logistical aspects of prescribing and is not intended to deal with the complex issues associated with therapeutic choice).*

- 4.8.1 Prescriptions must be printed or written legibly in black ink or otherwise so as to be indelible. Prescriptions must be printed / written on the current approved prescription form appropriate to the prescriber. If any changes are required on a prescription form then consideration should be given to rewriting/reprinting it. If this is not feasible then changes must be written clearly and initialled by the prescriber. Under no circumstances should correction fluid e.g. Tippex® be used to change a prescription form.
- 4.8.2 Prescriptions must state the patient's full name and address, CHI number (if available) and their age if under 12. The prescription must be signed in indelible ink by the prescriber.
- 4.8.3 Medicine should be prescribed generically using the current British Approved Name (BAN), except where branded products of the same drug are known to have clinically significant differences in bioavailability (e.g. controlled release formulations of nifedipine, theophylline etc). For these medicines, the brand in use should be specified when prescribing.
- 4.8.4 Medicine names must be written clearly avoiding the use of abbreviations.
- 4.8.5 Medicine doses must be written in metric units. Only the following abbreviations may be used:  
g = gram  
mg = milligram  
ml = millilitre  
mmol = millimoles  
All other dose units must be written in full, e.g. microgram, litre and units for Insulin International Units.
- 4.8.6 The use of decimal points should be avoided, where possible. For example, 0.1mg should be written as 100 micrograms. If use of the decimal point is unavoidable, a zero should be written in front of the decimal point i.e. "0.5ml", not ".5ml".

4.8.7 The route of administration must be written in full except for the following approved abbreviations. Please note - Intrathecal must be written in full.

PO	oral	PEG	percutaneous endoscopic gastrostomy
IV	intravenous	RIG	radiologically inserted gastrostomy
IM	intramuscular	PEJ	percutaneous endoscopic jejunostomy
ID	intra dermal	NJ	nasojejunostomy
SC	subcutaneous	ETT	endotracheal
SL	sublingual	TOP	topical
NG	nasogastric	INHAL	inhaled
PR	per rectum	NEB	nebulised
PV	per vagina		

4.8.8 Where appropriate, the times and day(s) of administration should be specified. Particular attention should be paid when prescribing once weekly medicine, e.g. methotrexate for rheumatoid arthritis or bisphosphonates for osteoporosis.

4.8.9 The quantity to be supplied should be clearly stated either by directly writing the total quantity or by indicating the number of days treatment required (this requires a specific dose to be clearly stated).

4.8.10 Oxygen prescriptions should clearly state the administration device to be used, cylinder size, flow rate and how it is to be used (e.g. as required for palliative use or regular dosing for long term oxygen therapy).

4.8.11 Medicines should be prescribed, or authorised for administration or supply, according to agreed local policies, formularies and stock lists e.g. NHS GGC Formulary.

4.8.12 A record of all medicines prescribed and administered or supplied via PGD or PSD must be maintained in the relevant case notes e.g. nursing or medical notes.

4.8.13 All prescriptions for Controlled Drugs must take account of current legal and good practice requirements. (Advice on Controlled Drugs within NHS GGC can be sought from the Controlled Drugs Governance Team).

## 4.9 Administration of Medicine

4.9.1 Medicines can be administered to patients in healthcare service areas only in accordance with one or more of the following processes:

- Against an entry made in a Direction to Administer Sheet / GP Case Sheet / GP Clinical Record by a UK registered doctor, dentist, independent or supplementary prescriber
- Patient Group Direction (PGD)
- Patient Specific Direction (PSD)
- Medicines Act exemption (see Appendix 7 for Midwifery exemptions)
- Symptomatic Relief Policy

(Certain specified medicines can also be administered without the need for a prescription / PGD etc. for the purpose of saving a life).

4.9.2 Medicines may be administered in healthcare service areas to patients by authorised NHS practitioners, e.g. registered doctors, registered nurses and midwives. (Other suitably qualified and trained persons may also administer medicines - this will involve local risk assessment and approval of procedures). NB – this refers to medical personnel administering medicine and does not refer to patient / carer administration within their own home.

4.9.3 Staff and / or patients (or the patient's carer) must have sufficient information about the medicine available to them to allow identification and appropriate use of the medicine. Information should be in a format that is accessible for the patient / carer and if the patient or carer's first language is not English an interpreter should be used. (Please refer to the NHS GGC Accessible Information Policy and the NHS GGC Interpreter Policy for further information).

4.9.4 Locally agreed SOPs should be followed during medicines administration and staff should have completed any necessary training, if applicable, before undertaking administration duties.

- 4.9.5 A record of administration should be kept that allows identification of the person administering the medicine and what medicine(s) and doses were administered. If a second staff member checks the preparation or administration of the medicine their identity should be recorded (but the overall responsibility still remains with the administrator). Local administration procedures should be followed, where available, to record administration of medicines in patients own homes (e.g. administration charts used to record palliative care medicines).
- 4.9.6 Student nurses and midwives, who have received the appropriate level of training, may participate in the administration of medicines providing they are adequately supervised.
- 4.9.7 Some drug administrations require complex calculations to ensure that the correct volume or quantity of medication is administered. In these situations, it is good practice for a second practitioner to check the calculation in order to minimise the risk of error.
- 4.9.8 It is unacceptable to prepare substances for injection in advance of their immediate use or to administer medication drawn into a syringe or container by another practitioner when not in their presence. An exception to this is a licensed ready-made injectable product, an already established infusion which has been instigated by another practitioner following the principles set out above, or medication prepared under the direction of a pharmacist from a central intravenous additive service and clearly labelled for an individual patient.
- 4.9.9 Where practically possible, the preparation and administration of CDs should be performed by two practitioners, i.e. registered nurse / midwife, student nurse / midwife and / or doctors or dentists. One will be the administrator and the other the witness. Those roles should be performed by the same named members of staff throughout the procedure, i.e. roles cannot be swapped mid-way.
- 4.9.10 Registered doctors, nurses and midwives who have successfully completed a registered intravenous therapy training programme or equivalent may prepare and administer intravenous injections. Ongoing training needs should be identified at annual PDP review.
- 4.9.11 Infusions should be completed within 24 hours of preparation (or sooner if microbial contamination / chemical instability is a problem). If the infusion is required for more than 24 hours a fresh infusion should be prepared and any unused portion destroyed. In exceptional cases, infusions, it may be acceptable to use infusions for longer than 24 hours without preparing a fresh infusion. A formal risk assessment should be undertaken for infusions being used for longer than 24 hours and approval for this practice granted by the lead clinician and appropriate pharmacist.
- 4.9.12 Injections or infusions prepared in the clinical area or patients home should be prepared immediately before administration. They should not be prepared in advance and stored in the clinical area or home. If this is not possible for operational reasons, a risk assessment should be undertaken in conjunction with pharmacy, and the action taken to minimise any identified risks documented.
- 4.9.13 Injections prepared and administered in healthcare service areas or a patient's home should be administered only by those individuals who were involved in the preparation. (Except in the case of licensed ready-made injectable products and medication prepared under the direction of a pharmacist from a central intravenous additive service and clearly labelled for an individual patient).

## 4.10 Supply of medicine to patients from NHS clinics / healthcare service areas

- 4.10.1 If local systems are in place that allow the issue of "pre-pack" medicines that have been pre-labelled with dosage instructions then locally agreed SOPs must be followed (e.g. medication supplied under a valid PGD).
- 4.10.2 A full record of medicines supplied to patients must be maintained and regular stock reconciliation carried out by a designated staff member.
- 4.10.3 If non-clinical staff are involved in the supply of medicine to patients they must follow agreed SOPs and have documented evidence of appropriate training.

## 4.11 Return and disposal of medicine

- 4.11.1 All medicines returned to pharmacies or other healthcare service areas must be disposed in strict accordance with procedures relevant to the type of waste.

- 4.11.2 Waste medicines returned to community pharmacies by patients should be placed in the containers provided by NHS GGC (or the company contracted to uplift waste on behalf of NHS GGC). Waste is routinely uplifted on a quarterly basis (every two months for Health Centre Pharmacies). Any community pharmacy in Glasgow needing an uplift outwith this schedule can request an ad hoc uplift by contacting the Community Pharmacy Development Team. Pharmacies in Clyde should contact the Transport and Waste department at Inverclyde directly. While pharmacists are not expected to remove medicines from their packaging before destruction, common sense should be used to minimise excess packaging in the containers.
- 4.11.3 Clinical waste generated by GPs and dentists should be placed in the containers provided by the company contracted to uplift waste on behalf of NHS GGC and disposed of as part of the standard uplift schedule.

## 5. Guidance on the transport or posting of medicines

### 5.1 General principles

- 5.1.1 A record must be kept at each step where a medicine changes hands in the transportation chain.
- 5.1.2 The person responsible for the medicine at each point of the transportation chain must be identifiable.
- 5.1.3 Medicine containers and packages should be kept securely or under surveillance whilst awaiting collection or in transit between points.
- 5.1.4 Medicine containers and packages awaiting collection or in transit should be kept in the appropriate secure storage conditions to maintain the quality of their contents. This includes maintaining the cold chain where required.
- 5.1.5 All medicines must be transported in sealed tamper evident containers or packages, e.g. securely stapled bags.
- 5.1.6 All containers and packages must be clearly labelled with the final destination and also with any relevant warning labels e.g. Store in Fridge.
- 5.1.7 Vaccines may only be transported to peripheral clinics, care homes or patients own homes using validated cool boxes.
- 5.1.8 Staff employed by NHS GGC involved in transporting medicines should have an understanding of the need for security and knowledge of any appropriate NHS GGC procedures, including action to be taken in the event of physical threat. Staff involved in the transportation of medicines should carry official identification (e.g. photographic ID badge).
- 5.1.9 All incidents involving a breach of security must be documented and investigated.
- 5.1.10 Local SOPs will apply for the transport of high-risk medicines e.g. vaccines, cytotoxic chemotherapy.
- 5.1.11 All nursing staff ordering routine medicines should have the required knowledge and competence to order and safely store medicines within the clinical area.

### 5.2 Transport of medicines from community pharmacy to patients and healthcare service areas.

- 5.2.1 Medicines must be transported in a sealed, tamper evident package. They must be clearly labelled with the destination and accompanied by a note of what has been supplied. Deliveries to patients should be clearly labelled with the patient's name and address which must be verified with the patient (or their representative) on receipt. The recipient should always sign appropriate documentation to confirm receipt of the medication. Healthcare service areas should identify suitably qualified personnel to receive and sign for their medicines.
- 5.2.2 The Community Pharmacist is responsible for ensuring the individual transporting the medicine is aware of any specific requirements relating to the safe and secure transport of a medicine, e.g. maintaining cold chain, and that transport arrangements will comply with these requirements.
- 5.2.3 The individual transporting the medicine is responsible for the safe and secure handling of the medicine while in transit and for ensuring appropriate documentation confirming receipt is signed and returned to the community pharmacy. The person must have adequate means to identify themselves to the patient/carer, especially if a delivery is being made out with normal working hours.
- 5.2.4 Medicine in transit must not be left unattended unless for a brief period only and appropriate steps are taken to make it secure e.g. locked out of sight in a vehicle.
- 5.2.5 The relevant community pharmacist must be informed immediately of any suspected or actual breaches in safety or security arrangements.
- 5.2.6 If access cannot be gained to a patient's home or healthcare premises for delivery of the medicines they should be brought back to the community pharmacy. Information should be left for the patient or healthcare service regarding collection or re-delivery. Under no circumstances should medicines be pushed through a letterbox, left unattended or left with a neighbour unless specific arrangements, agreed previously, are in place to manage deliveries if the patient is unable to answer the door and relies on carers for support.

### Controlled Drugs : Additional Requirements

- 5.2.7 Where CDs are delivered to a patients home the guidance issued by the NHS GGC Controlled Drugs Governance team must be followed.

- 5.2.8 CDs delivered to healthcare service areas must be handed to an authorised person and not left unattended at any time. A full audit trail must be maintained.

## 5.3 Transport of medicines by healthcare practitioners

- 5.3.1 Authorised healthcare practitioners may be required to carry medicines in the course of their duty. The practitioner is responsible for ensuring the safe and secure handling of medicines while in transit, ensuring the requirements described in this policy are complied with e.g. maintaining cold chain, safe custody of controlled drugs.
- 5.3.2 Practitioners working within Mental Health Service areas should follow local Policy and Practice guidance on the Transportation of Medicines in the Community.
- 5.3.3 Professionals who routinely utilise and transport medicine in the course of their work (e.g. GPs on home visits / Community Midwives / District Nurses) must ensure all medicines are transported and stock replenished in an appropriate manner. A stock list should be available and be reviewed and updated regularly to ensure it meets the needs of the healthcare professional and the patient. Systems should be in place to ensure medicines are replenished when used, that medicines are regularly date-checked and are of appropriate quality.
- 5.3.4 All medicines and equipment (e.g. sharpsafe containers) should be stored securely, out of sight, during transportation in an appropriate container provided for this purpose. Containers should not display any medical or NHS logos.
- 5.3.5 Wherever possible, patients and / or carers should be encouraged to obtain new medication or return any unwanted medication to their local community pharmacy themselves. In some situations it may be necessary for healthcare practitioners to carry out these duties on a patient's behalf. At all times the practitioner should follow local procedures, ensuring that safety and security issues are considered and that appropriate documentation is kept to ensure a clear and transparent audit trail is maintained. (E.g. mental health practitioners utilise a "Return of Patients Medicines" form, which is signed by the community pharmacist receiving the returned medication and a copy made available to the patient / carer).

## 5.3 Maintaining the cold chain

- 5.4.1 Sensitivity to changes in temperature varies depending on the medicine. Community pharmacies should ensure that medicines sensitive to temperature change are identified and staff involved in the transport of these products are aware of these items and any special storage / transport arrangements that must be followed.
- 5.4.2 If medicines that are sensitive to temperature changes are to be transported on an occasional basis, the following good practice should be followed:
- The medicines sensitive to temperature change must be clearly labelled with appropriate warnings (e.g. "Store in Fridge").
  - The medicine must be held outwith the recommended storage temperature for the minimum time possible. Maximum exposure time allowed depends on the sensitivity of the product.
  - Cold boxes or expanded polystyrene boxes should be used for medicines identified as being likely to deteriorate with even short-term temperature changes. Validated cool boxes should be used for vaccine transportation.
  - If gel packs are used, they should be evenly distributed. Direct contact with the medicines should be avoided by using bubble-wrap between the medicines and the gel packs. Using partially frozen gel packs further reduces the risk of the medicine freezing.
- 5.4.3 Medicines should not be removed from refrigerators until the individual transporting the medicine is available and ready to go.

## 5.5 Taxis and couriers

- 5.5.1 Only in exceptional circumstances should taxis or couriers be used for transportation of medicines.
- 5.5.2 Taxi and courier use should be in accordance with the NHS GGC Protocol "Ordering and Use of Taxis and Couriers" (available on Staffnet).
- 5.5.3 An approved courier service is available for urgent delivery of medicines to patients receiving palliative care when there are no other means of delivery or collection. Details of how to access this service are available from palliative care pharmacies, NHSGGC out of hours service or out of hours district nursing centres serving NHS GGC.

- 5.5.4 Taxis must not transport other passengers while transporting medicines, unless they are authorised staff accompanying the medication.
- 5.5.5 All packages must be sealed and tamper evident and the driver or courier must sign for collection of the medicines to be transported. Taxi drivers must record their unique call number.
- 5.5.6 Drivers must be advised of procedures to follow in the event of an accident / spillage when transporting high risk medicines e.g. cytotoxic drugs.
- 5.5.7 Drivers must be advised of any specific storage and handling requirements to maintain the safety and security of the medicine and be advised whom to contact if there is any breach to the safety and security arrangements.

## **5.6 Posting medicines**

- 5.6.1 Medicines must be posted only when the patient or the patient's representative cannot collect them, and there is no suitable alternative means of delivery e.g. community pharmacy delivery service, taxi, courier.
- 5.6.2 Patients' medicines may provide confidential information about their condition and treatment, and this must be considered before posting medicines.
- 5.6.3 Cytotoxic chemotherapy is classified as prohibited or restricted material by the Postal Service and must therefore not be sent by routine post. Special arrangements are required and the carrier must be made aware of the hazardous contents. Storage, handling and packaging requirements must be agreed. (The Royal Mail may be contacted for further information on 08457 740 740).
- 5.6.4 Medicines should be posted using Recorded Delivery or Registered Mail (unless a formal risk assessment has been undertaken to demonstrate that standard mail is appropriate).
- 5.6.5 Where medicines are posted, a record must be kept of the date, name and address of the recipient, contents of the package, and person responsible for posting.

## 6. Arrangements for the supply of medicines “out of hours”

### 6.1 General principles

- 6.1.1 ‘Out of hours’ refers to any time a GP practice is closed (usually from 6pm until 8am Monday-Friday, all weekend and public holidays) and the NHS GGC out of hours service is in operation in conjunction with NHS 24.
- 6.1.2 Community pharmacies are often open at times GP practices are closed and should be utilised in the first instance. A list of pharmacy opening times is available from the Community Pharmacy Development Team (or via NHS 24/ libraries for the public) and on the NHS GGC website at [www.nhsggc.org.uk](http://www.nhsggc.org.uk).
- 6.1.3 Community pharmacies may supply repeat medication prescribed by the patient’s doctor under the Community Pharmacy Unscheduled Care Service (CPUS).
- 6.1.4 NHSGGC out of hours medical service is based in nine centres across the Board area. Services are accessed from NHS 24 or community pharmacies. All medical emergencies should be directed to Accident and Emergency Departments.
- 6.1.5 NHS 24 operate an advice and triage service for patients and will direct relevant people to the out of hours service or to their local community pharmacy for advice on medicines or to access repeat medication using the approved patient group direction.
- 6.1.6 On the rare instances when prescriptions are marked as “urgent” by the prescriber or are required urgently, the patient will be able to have their medication dispensed using the pharmacy emergency dispensing service. Patients should contact NHS 24 to be referred to their nearest out of hours centre. The out of hours centre will contact a pharmacist from the agreed list who will dispense the required item(s).
- 6.1.7 Palliative care medicines can be accessed in the same manner from one of the palliative care network pharmacies.

### 6.2 Unscheduled Care service from community pharmacies.

- 6.2.1 Unscheduled care can be described as NHS care which cannot reasonably be foreseen or planned in advance of contact with the relevant healthcare professional, or is care which, unavoidably, is outwith the core working period of NHS Scotland. It follows that such demand can occur at any time and that services to meet this demand must be available 24 hours a day.
- 6.2.2 A Patient Group Direction (PGD) for urgent provision of repeat medicines and appliances has been developed by NHS 24 on behalf of NHS Scotland, and implemented by NHS Boards.
- 6.2.3 The PGD enables pharmacists to supply up to one normal prescription cycle for those drugs included within the PGD on a CPUS form for patients registered with a GP in Scotland.
- 6.2.4 All pharmacists must read and sign the relevant version of PGD before supplying repeat medicines in this way.
- 6.2.5 The PGD is operational when the GP practice is closed, the out of hours service is operating or the GP is otherwise unobtainable.
- 6.2.6 A copy of the CPUS form is provided to the patient’s GP for the GP-held patient records..
- 6.2.7 Patients cannot access two supplies in concurrent periods using this service.
- 6.2.8 If a request for medication is not covered by the PGD then emergency supply regulations should be employed. Please note that this guidance permits up to 30 days supply of medication (excluding Schedule 2 and 3 controlled drugs) to be issued to any patient from any EEA country and Switzerland who has been prescribed the medication at least once previously. In this instance, patients must meet the full cost of the supply.

### 6.3 Arrangements for supply of medicines from Out of Hour Centres

- 6.3.1 NHS GGC out of hour centres’ hold a small supply of agreed medicines for supply to patients.
- 6.3.2 This stock should be reviewed, monitored and replenished using a GP 10A stock order form fulfilled by a community pharmacy or written order from a hospital pharmacy.

## 7. Medication incidents

*Many medication incidents occurring in the primary care setting cannot be reported through the Datix system as this facility can only be accessed within the managed service. Individual contractors are encouraged, as a principle of good governance, to maintain records of incidents and share these as part of a learning culture to prevent reoccurrence. Incidents occurring in the managed service require to be recorded on to the Datix system which brings an additional element of review*

### 7.1 General principles

- 7.1.1 Medication incidents (and 'near-misses') can be clinical (e.g. administration of the wrong medicine to a patient, inappropriate prescribing choice, incorrect label on product, expired product supplied) or non-clinical (e.g. medicine refrigerator turned off in error). When a medication incident or 'near-miss' is discovered, it should be investigated and appropriate corrective action taken. It should be formally reported in order to ensure further preventative action is implemented, if appropriate, and to ensure systematic learning throughout the organisation.
- 7.1.2 Datix is a web-based reporting mechanism for NHS GGC which is currently implemented in all NHS GGC acute hospitals, divisions and partnerships. Contractors are required to have their own reporting mechanisms, although some incidents involving contractors may be recorded on the Datix system.
- The NHS GGC Policy on the Management of Significant Clinical Incidents and the NHS GGC Incident Reporting and Management policy outline the requirements for incident management including reporting and investigation.
- Incidents may be multifactorial and involve a number of breakdowns in the medication supply process. Usually incidents which reach the managed service in any way (e.g. patient is admitted to hospital because of incorrect prescription or dispensing in the community) will be recorded on Datix to facilitate NHS GGC learning.
- Other processes in place in primary care include:
1. Community pharmacists reporting incidents using the MI recording form for anonymous reporting to the Community Pharmacy Development Team.
  2. Medication incidents submitted to NES in the context of Significant Event Analysis.
  3. Local GP systems for incident reporting and investigation.
  4. Reporting to the respective Pharmacy Superintendent's Office within a pharmacy organisation, e.g. in a multiple or body corporate.
- 7.1.3 The person who discovers a medication incident or 'near-miss' must ensure the immediate remedial action is carried out, ensure the incident is reported, and inform the appropriate senior member(s) of staff in charge of the patient.
- 7.1.4 Any medicine may produce unwanted or unexpected adverse reactions or side effects. Any such confirmed or suspected adverse reaction to medicine (including vaccines and herbal remedies), blood products and radiographic contrast media should be reported via the UK wide 'Yellow Card' scheme (guidance on reporting can be found at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) or in the BNF). Healthcare staff should report not only adverse drug reactions but also harm / potential harm to a patient resulting from a medication error where there may be a need to share the issue more formally beyond NHS GGC. Examples of this include medication errors where the product packaging contributed to the error; errors where a wider educational intervention regarding the correct use of the product is identified; any errors causing serious harm or death.
- 7.1.5 Any medicines that have been consumed by or administered to a patient at or shortly before a significant clinical incident should be held safely and securely, be clearly labelled to indicate they are not for use, and the person in charge of the investigation informed of their whereabouts. If the medication is a patient's own property then permission should be sought from the patient or their representative(s) and consent to quarantine the medicine clearly documented in the patient notes. (If these medicines are later not required or are not clinically suitable for return to the patient then permission should be sought from the patient or their representative(s) for destruction to take place and this should also be documented in the patient notes or other paperwork used for this purpose locally). If the patient or their representative(s) refuse to give consent for the medicine to be quarantined and / or destroyed advice should be sought from an appropriate senior colleague (e.g. GP / pharmacist).

## 8. Defective medicines

*This section relates to the actions to be taken when national alerts about a defective medicine are issued and the appropriate action to be taken locally if NHS GGC staff believe any medicine in their healthcare service area may be defective*

### 8.1 General principles

- 8.1.1 Official notification of a defective medicine is issued as a Drug Alert from the Scottish Government or the Medicines and Healthcare products Regulatory Agency (MHRA) or the manufacturer / supplier.
- 8.1.2 The Senior Designated Pharmacist and / or Registered / Designated Manager or Responsible Pharmacist in the community setting must ensure that there are systems in place to check if the defective medicine is in use within their healthcare service area. They should also facilitate withdrawal of the defective medicine from use, if appropriate, (in conjunction with GP practice staff / other staff), within the required timescale for action.
- 8.1.3 If any member of staff has reason to believe that a medicine is defective, he or she must inform their line manager immediately and action taken to identify if the medicines is defective. This should involve discussion with the Senior Designated Pharmacist or staff at the site who supplied the pharmaceutical product (e.g. PDC) and / or the Community Pharmacy Development Team, who will advise on further appropriate actions to be taken.
- 8.1.4 The person who discovers the defect must ensure that the product, container and other packaging are retained. If the defect has been discovered following reconstitution or mixing with another preparation, then the mixture, remaining unmixed constituents, and all containers and other packaging must also be retained. All retained materials must be placed in a sealed container, clearly marked "Do Not Use", and stored in a secure place.
- 8.1.5 The Senior Designated Pharmacist and / or Registered / Designated Manager or Responsible Pharmacist in the community setting should ensure that there are systems in place to investigate local reports of defective medicines, to withdraw from use other affected stock ,if appropriate, and to inform the Specialist Pharmacist in Public Health in the first instance.
- 8.1.6 If any staff member suspects that a package containing medicines has been tampered with prior to them receiving it then he / she should refuse to accept it and contact the appropriate Senior Designated Pharmacist and / or Registered / Designated Manager or Responsible Pharmacist in the community setting.
- 8.1.7 Local SOPs for the reporting and monitoring of such defects must be followed.

## 9. Medicines for use in Research and Clinical Trials

- 9.1 Researchers wishing to undertake research should approach the local Research and Development Office for all clinical investigations involving human volunteers or patients, as appropriate. Guidance will be given by the Research and Development Office.
- 9.2 Where medicines are to be used for research or as part of a clinical trial, the study must have the appropriate management, regulatory and ethics committee approval prior to the start of any research activity. Other approvals may be required depending on the nature of the research.
- 9.3 Where a study is blinded, there must be appropriate local mechanisms in place to allow for the prompt unblinding of treatment allocation. Similarly, there must be processes in place to facilitate the local recall of medicines from study subjects should the need arise. Consideration should also be given to ensuring that there are appropriate arrangements in place to ensure that subjects can access the investigator or other trained individuals for advice should the need arise.
- 9.4 Although it is the sponsor's responsibility to ensure that any medicines supplied as part of a clinical trial meet the required quality standards, the investigator, or their designee should maintain an understanding of the necessary quality standards and ideally have systems in place in order to ensure that the standards are met and maintained at all times.
- 9.5 Where medicines are to be used as part of a clinical trial, it is the responsibility of the investigator, or their designee, to ensure that there is appropriate accountability of any medicines in accordance with Good Clinical Practice. The investigator is also responsible for ensuring that any medicines are used on in accordance with the study protocol and that study subjects receive sufficient information to allow the safe and correct use of the medicine. During the study the investigator should ensure that the study subject continues to follow the instruction provided.
- 9.6 Where medicines are to be stored on a site as part of a clinical trial or research study, they must be stored in accordance with the instructions provided by the sponsor and in accordance with any other regulatory requirements or local requirements for safe storage of medicines. Access to these medicines should be restricted. Any deviations in storage conditions must be investigated and discussed with the sponsor prior to their supply to study subject. Any monitoring equipments such as temperature monitoring equipment, should be calibrated on a routine basis.
- 9.7 Where study subjects are required to return medicines for accountability purposes, these must be stored securely in a segregated area that is clearly marked for this purpose. Medicines should not be retained where retention may pose a hazard to either study subjects or staff. This should be agreed with the study sponsor prior to the start of the research project.
- 9.8 A site file meeting the sponsor's and organisation's requirements must be held by the investigator. This should ideally include local processes for the safe management of the medicines to be used within the study. Records of training in the study processes for the management of medicines used in the clinical trial or study should also be maintained.
- 9.9 Clinical trial medicines should be prescribed only by prescribers trained in the specific clinical trial. The patient's study number should be included in addition to standard information.
- 9.10 There may be additional ordering, receipt and storage requirements to that described for non-trial materials. This should be documented within the trial-specific site file.

The information contained within this section may change and it suggested that you contact the following for further information:

NHS GGC R&D Pharmacy Team  
1st Floor Tennent Institute  
Western Infirmary  
38 Church Street  
Glasgow G11 6NT

Tel: 0141 211 8554  
[www.nhsggc.org.uk/r&d](http://www.nhsggc.org.uk/r&d)

## Glossary of terms

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<b>Accountable Officer</b>	The Officer in an NHS Board, and independent hospital or a hospice, who is responsible for the safe management and effective use of controlled drugs. Their appointment is required by Controlled Drugs (Supervision and Management of Use) Regulations 2006.
<b>Audit trail</b>	A system whereby all transactions regarding a specific medicine can be traced from the act of purchase to the point of use.
<b>Authorised person / authorised healthcare practitioner</b>	A person who is authorised by their line manager to carry out defined tasks. This may involve a competency assessment, which should be documented.
<b>Authorised prescriber</b>	A system whereby all transactions regarding a specific medicine can be traced from the act of purchase to the point of use.
<b>Authorised Nurse / Midwife</b>	A person who is authorised to undertake independent or supplementary prescribing according to current legislation and local NHS GGC policies.
<b>Community Pharmacy</b>	A retail pharmacy (i.e. not attached to an NHS hospital) in contract with the Board to provide pharmaceutical care services under NHS terms of service
<b>Controlled Drugs</b>	Medicines classified into different schedules (defined in the current Misuse of Drugs Regulations) depending on their therapeutic use and potential for harm. Each schedule has different requirements with respect to storage, handling and record keeping.
<b>Controlled Stationery</b>	All stationery that could be used to obtain medicines fraudulently e.g. prescription pads.
<b>Healthcare Service Area</b>	Any clinical area where medicines are stored, supplied, prepared or administered to patients or are available for patients to purchase (e.g. Community pharmacy, GP surgery or a defined part of that surgery).
<b>Medicine</b>	A substance defined in Section 30 of the Medicines Act as a medicinal product i.e. a substance administered by mouth, applied to the body, or introduced into the body for the purpose of treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, contraception, inducing anaesthesia or otherwise preventing or interfering with the normal operation of a physiological function.
<b>Medicines liable to misappropriation</b>	Those medicines whose potential for misappropriation is high. This may include family planning products and steroids as well as recognised drugs of abuse (benzodiazepines etc).
<b>Misappropriation</b>	Removal of medicines for unauthorised use, theft.
<b>Patients</b>	Service users, clients, consumers or customers of the health services.
<b>Patient Group Direction (PGD)</b>	A written instruction to enable a healthcare professional to supply and / or administer a medicine to groups of patients who may not be individually identified before presentation for treatment.
<b>Patient Specific Direction (PSD)</b>	A written instruction from a doctor, dentist or appropriate independent prescriber to enable medicines to be supplied or administered to a named patient.
<b>Registered / designated manager</b>	The person with designated responsibility for a defined healthcare service area.

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<b>Responsible Pharmacist</b>	The pharmacist in charge of a registered pharmacy premises at any given day and time, with responsibility for ensuring the safe and effective running of the pharmacy.
<b>Senior designated pharmacist</b>	Pharmacist (registered with the General Pharmaceutical Council) with designated responsibility for a defined healthcare service area.

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## Appendix 1 - Prescription Forms in use within NHS Scotland

Prescription Form ID	Colour	Issued By	Issued To/For
CP1	Yellow	Community Pharmacist – MAS (hand written)	Exempt Patients
CP2	Yellow	Community Pharmacist – MAS (computer generated)	Exempt Patients
CPUS	Buff	Community Pharmacist – Urgent Supply of Repeat Medication	General Practice Patients
GP10	Peach	Medical Prescriber	General Practice Patients
GP10 (SS)	Peach	Medical Prescriber (computer Generated)	General Practice Patients
GP10A	Pink	Medical Prescriber	GP Stock Orders
GP10N	Lilac	Nurse Prescriber	General Practice Patients
GP10N (SS)	Lilac	Nurse Prescriber	General Practice Patients
GP10 P	Yellow	Supplementary/Independent Pharmacist Prescriber	General Practice Patients
GP14	Yellow	Dental Prescriber	Dental Patients
HBP	Blue	Hospital Based Prescriber	Hospital Outpatients
HBPA	Pink	Hospital Based Drug Addiction Clinic Prescriber	Drug Addict Patients
HBPA (SS)	Pink	Hospital Based Drug Addiction Clinic Prescriber	Drug Addict Patients
HBPN	Lilac	Hospital Based Nurse Prescriber	Hospital Outpatients
HBPP	Yellow	Hospital Based Supplementary Independent / Pharmacist Prescriber	Hospital Outpatients
PPCD	Buff	Private Prescribing of CDs	Private Patients
CDRF	Buff	Private Prescribing of CDs	Private Patients

Similar formats are in use in England and Northern Ireland and may be presented for dispensing in pharmacies in Scotland. NHS scripts issued in Jersey, Guernsey and the Isle of Man cannot be dispensed by community pharmacies in Scotland. It should be noted that the community pharmacist will not be reimbursed for items dispensed when the wrong script format has been used by a prescriber, e.g. GP using a Nurse Prescriber form

