

Service Standards for Medicines Management in Sexual and Reproductive Health Services



The Faculty of Sexual and Reproductive Healthcare (FSRH) is the largest UK professional membership organisation working in the field of sexual and reproductive health (SRH). We support healthcare professionals to deliver high quality healthcare including access to contraception. We provide our 15,000 doctor and nurse members with NICE-accredited evidence-based clinical guidance, including the UKMEC, the gold standard in safe contraceptive prescription, as well as clinical and service standards.

The FSRH provides a range of qualifications and training courses in SRH, and we oversee the Community Sexual and Reproductive Healthcare (CSRH) Specialty Training Programme to train consultant leaders in this field. We deliver SRH focused conferences and events, provide members with clinical advice and publish *BMJ Sexual & Reproductive Health* – a leading international journal. As a Faculty of the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK, we work in close partnership with the College but are independently governed.

The FSRH provides an important voice for UK SRH professionals. We believe it is a human right for women and men to have access to the full range of contraceptive methods and SRH services throughout their lives. To help to achieve this we also work to influence policy and public opinion working with national and local governments, politicians, commissioners, policy makers, the media and patient groups. Our goal is to promote and maintain high standards of professional practice in SRH to realising our vision of holistic SRH care for all.

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SERVICE STANDARDS FOR MEDICINES MANAGEMENT IN SEXUAL AND REPRODUCTIVE HEALTH SERVICES

Changes introduced since review

- ▶ Standard 4 Recommendation to restrict access to prescription pads stored to authorised personnel and where key code access systems are used to change these regularly.
- ▶ Standard 6 Reference to NICE Competency Framework both for individuals using PGDs and those developing them.

Introduction

Medicines Management is the clinical, cost effective and safe use of medicines to ensure patients receive the maximum benefit from the medicines they need, while at the same time minimising potential harm. The Safe and Secure Handling of Medicines, A Team Approach¹ published in March 2005 (currently under review), gives definitive and detailed guidance on medicines management within all healthcare organisations in the UK. Reference to this resource is made throughout this document. Although its scope does not include general practice or community pharmacy, we would commend the basic principles in these settings.

These standards relate to medicines and devices used within sexual and reproductive health care settings and apply equally to medicines and devices used in research trials. Throughout this document where the word 'patient' is used this refers to whomever the medication may be administered to, for example, patient, client, user or woman.

The term 'medicines management' has been interpreted to cover the processes and systems for providing medicines to patients within these areas. These standards reflect the process from prescribing through to dispensing, storage, administration and disposal. In this context the document does not include reference to evidence-based prescribing, for which readers should refer to the relevant Clinical Effectiveness Unit and NICE guidance.

These standards should be read in conjunction with Service Standards for Risk Management² and Service Standards for Record Keeping³.

¹ Royal Pharmaceutical Society of Great Britain (RPSGB)(2005). [The Safe and Secure Handling of Medicines: A Team Approach](#). A revision of the Duthie Report (1998) accessed March 2018.

² [Faculty of Sexual and Reproductive Healthcare \(February 2017\) Service Standards for Risk Management](#) accessed March 2018.

³ Faculty of Sexual and Reproductive Healthcare (2014) [Service Standards for Record Keeping](#). Accessed March 2018

1. Standard statement on the process of medicines management

A medicines management policy and related standard operating procedures (SOPs) should be in place in employing organisations and updated regularly.

- 1.1 Good medicines management should ensure a process for giving appropriate, safe and effective therapies to patients.
- 1.2 There should be a Medicines Policy for each employing organisation, which is accessible to staff and used in conjunction with these standards.
- 1.3 There should be an agreed process for deciding on medicines to be held in stock in clinical settings, and processes in place for the provision of other relevant medicines which are not held as stock.
- 1.4 Every service should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use. This is to ensure compliance with current legislation national and local guidance and professional standards and will promote safety, quality, consistency and security.
- 1.5 Guidelines for developing and implementing a SOPs can be found on the Home Office website.⁴
- 1.6 Appropriate pharmaceutical advice must be taken in the development of systems for the safe and secure handling of medicines.
- 1.7 Staff should understand the principles of safe and secure handling of medicines, including storage, handling, issuing, prescribing and disposal of drugs.
- 1.8 All medicine records including prescriptions, administration records, refrigerator monitoring etc. must be retained for a minimum period of time for legal, operational, and safety reasons.⁵ This should facilitate audit and be in line with the employing organisation's medicines and records policies.

⁴ [Standard Operating Procedure Guidelines \(2007\)](#) Home Office Accessed March 2018

⁵ [NHS Records Management: Code of Practice for Health and Social Care \(2016\)](#). Accessed March 2018

2. Standard statement on access to treatment

All clinicians should be able to directly provide medication or a prescription to patients to meet their sexual and reproductive health needs.

- 2.1 Services should ensure that patients are able to directly access medication or a prescription which is appropriate to their sexual and reproductive health needs. This represents efficient treatment, endorses patient choice of provider and underpins and enhances access to appropriate and timely services.⁶

⁶ [FSRH Quality Standard for Contraceptive Services](#) (2014) Accessed March 2018

3. Standard statement on the process for safe and secure handling of medicines

The process of ordering, logging receipt, labelling, storage, transport, stock rotation and disposal of medicines should be in accordance with legislation, national and local guidance.

- 3.1 The SOPs for the management of medicines within the service must include reference to medicines that are heat and light sensitive, medicines for clinical emergencies, any medicines liable to misuse, and disposal of medicines no longer required.
- 3.2 All staff, whether clinical or non-clinical, should be trained in the parts of these procedures relevant to their duties.
- 3.3 A designated person should be responsible for ordering medicines from the pharmacy to maintain agreed stocks levels.
- 3.4 Medicines arriving in the clinic should be checked against the requisition by a designated person who should record that the delivery is correct and follow up any discrepancies immediately. The registered healthcare professional in charge of a clinical area has the overall responsibility for the security and safekeeping of medicines in that area.
- 3.5 Where premises are shared, each service must be responsible for its own stock of medicines, which should be stored separately.
- 3.6 Storage should be sited for maximum security with access restricted to authorised staff.
- 3.7 If an outreach worker takes medicines out of the clinic, that outreach worker is responsible for the safe and secure transport and storage of medicines.⁷
 - ▶ Staff should carry out a risk assessment of the environment, and the area in which they are transporting medicines, to determine the measures required for safeguarding the medicines and themselves.
 - ▶ Medicines must be transported in their original packaging in a locked box, bag or other suitable container and kept out of sight in the boot of a car.
- 3.8 All medicinal products issued by the practitioner must be over-labeled correctly. Standard labelling requirements for all dispensed items include:

⁷ Nursing & Midwifery Council (NMC) (2007). [Standards for Medicines Management](#). Accessed March 2018

- ▶ the name of the person to whom the medicine is to be supplied
- ▶ the date of issue
- ▶ the name and address of the service
- ▶ the name of the medicine
- ▶ directions for use
- ▶ precautions relevant to the use of the medicine
- ▶ the words 'keep out of reach of children'.⁸

- 3.9 All medicinal products must be stored in accordance with their summary of product characteristics (SPC) and any instruction on the label. Lockable cupboards that comply with the relevant regulations should be used for the storage of medicines in the clinic or practice setting.⁹ The current British Standard is BS2881 (1989).¹⁰
- 3.10 If heat-sensitive products are kept (e.g. vaccines), a suitable dedicated fridge must be available fitted with a maximum and minimum thermometer.¹¹
- 3.11 A log book/record sheet of the refrigerator temperature should be maintained with signed entries on each working day. There should be a policy in place with clear actions to be taken if the temperature is outside the recommended range.
- 3.12 Medicines for clinical emergencies, e.g. adrenaline for anaphylaxis, should be held in packs clearly marked 'for emergency use'.¹² They should be kept in a secure but accessible location and be available during the clinic session but locked away when the clinic is closed. They must be stored in tamper-evident packs and replaced immediately if used or signs of tampering are evident. Expiry dates of emergency medicines should be checked at least weekly and the check documented.
- 3.13 It should be the duty of a pharmacist to make sure that safe systems are in place to ensure that medicines are only supplied on the instruction of an authorised clinician. The pharmacist should carry out inspections of the stock in the clinic, with reconciliation where necessary.
- 3.14 There should be a local process of stock rotation of medicines to ensure that medicines closer to their expiry date are used in preference to those with a longer shelf life.

⁸ Royal Pharmaceutical Society (2017). [Medicines, Ethics and Practice: the professional guide for pharmacists](#). Edition 41. RPS London. Accessed March 2018

⁹ Royal Pharmaceutical Society of Great Britain (RPSGB) (2005). [The Safe and Secure Handling of Medicines: A Team Approach](#). A revision of the Duthie Report (1998). Accessed March 2018

¹⁰ Department of Health (2013). [Pharmacy and radiopharmacy facilities \(Health Building Note 14-01\)](#). DH: London. Accessed March 2018

¹¹ Immunisation Against Infectious Disease: [The Green Book, Chapter 3 for information on storage requirements for vaccines](#)

¹² Royal Pharmaceutical Society of Great Britain (RPSGB)(2005). [The Safe and Secure Handling of Medicines: A Team Approach](#). A revision of the Duthie Report (1998). Accessed March 2018.

- 3.15 There must be a policy agreed with the local pharmacy team for the safe disposal of expired and returned medicines.

4. Standard statement on process for security of prescription pads

Prescription pads and other controlled stationery must be kept securely.

- 4.1 There should be an agreed process for ordering and signed receipt of prescription pads and any internal employer prescription pads or other controlled stationery, e.g. internal order forms.
- 4.2 Prescription pads must only be held by qualified practitioners who are registered as such with their professional and regulatory bodies and who have been issued with them. The practitioner must take responsibility for their security, which includes security of any prescription pads used outside of the clinic or practice setting, e.g. home visits.
- 4.3 Prescription pads and other controlled stationery must be kept in secure locked cupboards at all times when not in use. Access should be restricted to authorised users and if an entry code is required to unlock the cupboard this should be changed regularly to maintain safety and security according to local policy.
- 4.4 Records of serial numbers of prescription pads received and issued should be retained for at least three years.
- 4.5 There should be an audit trail for numbered prescriptions. Services should have a system that enables individual prescriptions to be accounted for. Appropriate procedures should be in place for the immediate reporting of any loss or theft of prescription stationery and staff should be aware of what action they need to take if this occurs.¹³

¹³ NHS Security Management Service (2011 updated 2015). [Security of prescription forms guidance](#) (See 'Policy and Guidance' directory beneath 'Medicines Management'). Accessed March 2018

5. Standard statement on process for prescribing

All prescribers must have training and keep up-to-date in their area of practice in order to follow legal and professional frameworks as stated by the registered professional body.

Prescribers should:

- 5.1 Prescribe a medicine only with adequate, up-to-date awareness of its actions, indications, dose, contraindications, interactions, cautions and unwanted effects.¹⁴
- 5.2 Understand the potential for adverse effects and take steps to avoid, minimise, recognize and manage them.¹⁵
- 5.3 Prescribe within relevant frameworks for medicine use as appropriate (e.g. local formularies, guidelines, care pathways, protocols) and within their clinical competence. Non-medical prescribers must ensure they prescribe in accordance with current NHS guidance on independent and supplementary prescribing.^{16 17 18 19}
- 5.4 Electronically generate or write legible, unambiguous and complete prescriptions (or patient-specific directions) which meet legal requirements.
- 5.5 Effectively use the systems necessary to prescribe medications (e.g. electronic prescribing, decision support, medicine charts) and tools to improve prescribing (feedback, audit, data analysis).
- 5.6 Make accurate, legible and contemporaneous records of prescribing decisions in clinical notes.
- 5.7 Give clear, understandable, reliable and accessible information about medicines to patients/carers. Including how to take the medicine, duration of course or how to obtain further supplies, what to do if patients develop any side effects or concerns about their condition and processes for follow-up if needed.
- 5.8 Communicate information about medicines when sharing or transferring prescribing

¹⁴ Royal Pharmaceutical Society (2016) [A Competency Framework for Prescribers](#). Accessed March 2018

¹⁵ Royal Pharmaceutical Society (2016) [A Competency Framework for Prescribers](#). Accessed March 2018

¹⁶ Department of Health (2006). [Improving patients' access to medicines: A Guide to Implementing Nurse & Pharmacist Independent prescribing in England](#). Accessed March 2018

¹⁷ NHS Scotland (2006). [Non-Medical Prescribing in Scotland](#). Accessed March 2018

¹⁸ Welsh Assembly Government (2011). Non-Medical Prescribing in Wales: A guide for implementation.

<http://www.wales.nhs.uk/sitesplus/documents/861/Non%20medical%20prescribing%20guidance%202011.pdf> Accessed March 2018

¹⁹ Department of Health (Northern Ireland). [Prescribing by Non-medical Healthcare Professionals](#). Accessed February 2018

responsibilities/information.²⁰

- 5.9 Keep up-to-date with emerging safety concerns related to prescribing e.g. MHRA alerts.
- 5.10 Report prescribing errors, near misses, critical incidents and review and reflect on practice to prevent recurrence.
- 5.11 Recognise when safe systems are not in place and take appropriate steps to maintain safety, following local policy, and document actions. If an error is made, take action to prevent any potential harm to the patient, follow the duty of candor and record their actions in the patient notes.
- 5.12 Ensure confidence and competence to prescribe is maintained.²¹
- 5.13 Non-medical prescribers must undertake a programme of training approved by their professional body, and this must be recorded in the relevant professional register.^{22 23 24 25}
- 5.14 Non-medical prescribers are permitted to prescribe black triangle* drugs as long as it is accepted practice to do so, for instance where such products are included in local formularies.

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*A black triangle is assigned to any drug or vaccine if it meets any of the following criteria:

- ▶ a new active substance or biosimilar medicine
- ▶ a new combination of active substances
- ▶ administration via a novel route or drug delivery system
- ▶ an established medicine which is being used for a new population or new indication
- ▶ The black triangle symbol (▼) appears next to the name of the relevant product in the British National Formulary (BNF).²⁶ These drugs are monitored closely for a minimum of two years and the black triangle symbol is not removed until the safety of the drug is well established²⁷ (also see section 11.8).

²⁰ Royal Pharmaceutical Society (2016). [A Competency Framework for Prescribers](#). Accessed March 2018

²¹ Royal Pharmaceutical Society (2016) [A Competency Framework for Prescribers](#). Accessed March 2018

²² Department of Health (2006). [Improving patients' access to medicines: A Guide to Implementing Nurse & Pharmacist Independent prescribing in England](#). Accessed March 2018

²³ NHS Scotland (2006). [Non-Medical Prescribing in Scotland](#). Accessed March 2018

²⁴ Welsh Assembly Government (2011). Non-Medical Prescribing in Wales: A guide for implementation. <http://www.wales.nhs.uk/sitesplus/documents/861/Non%20medical%20prescribing%20guidance%202011.pdf> Accessed March 2018

²⁵ Department of Health (Northern Ireland) (no date) [Non-Medical Prescribing](#). Accessed February 2018

²⁶ [British National Formulary \(BNF\)](#)

²⁷ Medicines and Healthcare Products Regulatory Agency (MHRA) (2017). [Black Triangle Scheme](#). Accessed March 2018

6. Standard statement on process for supply or administration using a Patient Group Direction (PGD)

Health care professionals other than doctors who have completed additional training and competency-based assessments may be authorised to supply or administer medicines using a locally agreed PGD.

- 6.1 The legal definition of a PGD is: “a written instruction for the supply and / or administration of a licensed medicine (or medicines) in an identified clinical situation, signed by a doctor or dentist and a pharmacist. It applies to groups of patients who may not be individually identified before presenting for treatment.”²⁸
- 6.2 Any PGD in use must have been agreed through the authorising process within the relevant NHS organisations.^{29 30}
- 6.3 PGDs should only be used by registered healthcare professionals who have been assessed as competent and whose name is identified within each document. Competence should be assessed according to the NICE Competency Framework.³¹ Anyone involved in the delivery of care within a PGD must be aware of the legal requirement.^{32 33 34 35 36 37}
- 6.4 Staff involved in developing, reviewing and updating PGDs should be assessed as competent in accordance with the NICE Competency Framework.³⁸

²⁸ Medicines and Healthcare Products Regulatory Agency (MHRA) (2017) [Patient Group Directions in the NHS](#). Accessed March 2018

²⁹ [The National Treatment Agency \(Abolition\) and the Health and Social Care Act 2012 \(Consequential, Transitional and Saving Provisions\) Order 2013, SI 235](#). Accessed March 2018

³⁰ [NICE Competency Framework MPG2 Patient group directions \(published 2013, updated 2017\)](#) Accessed March 2018

³¹ [NICE Competency Framework MPG2 Patient group directions \(published 2013, updated 2017\)](#) Accessed March 2018

³² Nursing & Midwifery Council (NMC)(2007). [Standards for Medicines Management](#). Accessed March 2018

³³ [The Human Medicines Regulations 2012, SI 1916](#). Accessed March 2018

³⁴ [Patient Group Directions \(2017\)](#). Accessed March 2018

³⁵ NHS Scotland. [Patient Group Directions](#). Accessed March 2018

³⁶ Medicines and Healthcare Products Regulatory Agency (MHRA). [Patient Group Directions in the NHS](#). Accessed March 2018

³⁷ [NICE Competency Framework MPG2 Patient group directions \(published 2013, updated 2017\)](#) Accessed March 2018

³⁸ [NICE Competency Framework MPG2 Patient group directions \(published 2013, updated 2017\)](#) Accessed March 2018

- 6.5 If a PGD cannot be used (for example where one has not yet been approved, or where some individual fall outside the inclusion criteria), medication can only be provided through a valid prescription.
- 6.6 Training, updating and audit of those working to PGDs must be provided.³⁹
- 6.7 PGDs should be reviewed and re-authorised according to local guidelines, particularly in the event of any changes in clinical practice.
- 6.8 Black triangle drugs (see under 5.5), and medicines used outside the terms of the summary of product characteristics (off-label) may be included in PGDs provided such use is exceptional, and justified by current best clinical practice and provided that a direction clearly describes the status of the product.⁴⁰ An example of off-label use is supplying a double dose (3mg) of levonorgestrel for emergency contraception when a woman is using an enzyme inducing drug.
- 6.9 Unlicensed drugs, e.g. those used in clinical trials, may not be supplied under a PGD.
- 6.10 Supplying under PGD must be done from the manufacturers' original packs or over labelled pre-packs. The patient's details, date of supply and any necessary additional instructions must be added to the label at the time of supply. Practitioners must not split prepared pre-packs.⁴¹

³⁹ [NICE Competency Framework MPG2 Patient group directions \(published 2013, updated 2017\)](#)
Accessed March 2018

⁴⁰ Medicines and Healthcare Products Regulatory Agency (MHRA). [Patient Group Directions in the NHS](#). Accessed March 2018

⁴¹ Nursing & Midwifery Council (NMC) (2007). [Standards for Medicines Management](#). Accessed March 2018.

7. Standard statement on the authorisation and recording of medicines supplied or administered to patients

Processes must be in place to ensure that medicines are supplied or administered to patients by clinicians accurately and safely.

- 7.1 The authorisation of a suitably qualified practitioner (i.e. doctor or non-medical prescriber) should be obtained before medicines can be supplied or administered to patients. This authority is given in one of three ways:
- ▶ a prescription completed by a doctor or a Non-Medical Prescriber
 - ▶ in accordance with locally agreed clinical procedures, e.g. for off-label medicines
 - ▶ in accordance with Patient Group Directions (PGD) or Patient Specific Directions (PSD).
- 7.2. Sufficient information about the medicine must be available to the staff and/or patient to enable identification and correct use of the product.
- 7.3. A record of administration must be made, and the administering practitioner identified (e.g. an entry in the medicines record or electronic health record).⁴²
- 7.4. Medication that is not given due to refusal, wastage or lack of availability must also be recorded.
- 7.5. If a second clinician checks the administration of a medicine, the identity of the checking clinician should also be recorded; however, the ultimate responsibility remains with the administering healthcare professional.

⁴² Nursing & Midwifery Council (2009, updated 2016) [Record keeping guidance for nurses and midwives](#). Accessed March 2018.

8. Standard statement on process for supplying or administering medicines to patients

Only a qualified healthcare professional can supply or administer medicines that have been prescribed or supplied using a locally agreed PGD for an individual patient.

- 8.1. Prescription-only medicines may only be dispensed, supplied or administered by a qualified health care professional (e.g. doctor, nurse, midwife, pharmacist) and procedures should be outlined in a local SOP.⁴³
- 8.2. It is good practice to ensure separation of prescribing and dispensing whenever possible but where separation has not occurred, a second suitably qualified person should check the accuracy of the medication provided. Clear accountability, audit and clinical governance arrangements must be in place to ensure patient safety and probity.⁴⁴ However, this does not apply to medications that have been labelled by a pharmacist, as these have already been dispensed.⁴⁵
- 8.3. Non-medical prescribers who are both prescribing and supplying in community clinics or SRH services should be competent and familiar with all the medication they prescribe.⁴⁶
- 8.4. When supplying or administering a medicine, the healthcare professional has a duty to check the patient's identity, that the patient is not allergic to the product, that there are no contraindications, that they consent to take the medication and that the product is appropriately labelled. Only one healthcare professional needs to perform this task. This process should be outlined in a local SOP.⁴⁷
- 8.5. When a medicine is supplied or administered, the dosage, method of delivery and expiry date should be checked and a clear, accurate and immediate record made.⁵ Where medication is not given, the reason for not doing so must also be recorded. It is the practitioner's responsibility to ensure that a record is made when delegating the task of administering medicine.

⁴³ Nursing & Midwifery Council (NMC)(2007). [Standards for Medicines Management](#). Accessed March 2018.

⁴⁴ Department of Health (2006), [Improving Patients Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the NHS in England](#). Accessed June 2018.

⁴⁵ Nursing & Midwifery Council (NMC) (2006). [Standards of proficiency for nurse & midwife prescribers](#). Accessed March 2018.

⁴⁶ Nursing & Midwifery Council (NMC) (2006). [Standards of proficiency for nurse & midwife prescribers](#). Accessed March 2018.

⁴⁷ Nursing & Midwifery Council (NMC) (2007). [Standards for Medicines Management](#). Accessed March 2018.

- 8.6. Where contraindications to the prescribed medicine are discovered or where assessment of the patient indicates that the medicine is no longer suitable, an authorised prescriber should be contacted.
- 8.7. Wherever "take-home", pre-packed medication is issued from the health care setting, the senior pharmacist is responsible for making sure that there is a legal system to ensure that all medicines issued to service users are recorded and correctly over-labelled.
- 8.8. Records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

9. Standard statement on remote prescribing

When prescribing remotely, the prescriber must satisfy themselves that they can make an adequate, competent and reliable assessment.

- 9.1 Remote prescribing is commonly used to access sexual health and contraceptive services and has been shown to improve patients' access to advice and treatment. It can provide a safe alternative to a face-to-face consultation when risks are recognised and effectively managed through appropriate service design and delivery.^{48, 49}
- Before prescribing for a patient remotely, the prescriber must satisfy themselves that they can make an adequate, competent and reliable assessment, establish a dialogue and obtain the patient's consent.
- 9.2 The prescriber may prescribe only when they have adequate knowledge of the patient's health, and are satisfied that the medicines serve the patient's needs. They must consider:
- ▶ the limitations of the medium through which they are communicating with the patient
 - ▶ the need for physical examination or other assessments
 - ▶ whether they have access to the patient's medical records.⁵⁰
- 9.3 Contraceptive services often run without direct access to a doctor and it may be necessary for a doctor to 'remotely' prescribe a medicine. A 'verbal order' to supply medication to a patient is not acceptable on its own: the use of information technology (such as fax, text message or email) must confirm the prescription before it is administered. This should be followed up by a written prescription within one working day (72 hours maximum – bank holidays and weekends).^{51,49}
- 9.4 When prescribing remotely the prescriber is responsible for the assessment of the patient and the decision to supply/administer the medicine(s) in question.

⁴⁸ General Medical Council (2013). [Good Practice in Prescribing and Managing Medicines and Devices](#). Accessed March 2018.

⁴⁹ Royal Pharmaceutical Society (2016), [Position Statement: Access to Medicines](#). Accessed June 2018.

⁵⁰ General Medical Council (2013). [Good Practice in Prescribing and Managing Medicines and Devices](#). Accessed March 2018.

⁵¹ Nursing & Midwifery Council (NMC) (2007). [Standards for Medicines Management](#). Accessed March 2018.

- 9.5 When prescribing remotely the healthcare professional must ensure all relevant information has been communicated to the prescriber.⁵²
- 9.6 When prescribing remotely the healthcare professional must ensure that all communications that have taken place are accurately documented.
- 9.7 The prescriber must be satisfied that the person to whom practice is delegated has the qualifications, experience, knowledge and skills to provide the care or treatment involved.⁵³
- 9.8 Where an order to supply and administer a medicine has been given by text message or e-mail, there should be a second signature recorded in the patient record, ideally by another registered healthcare professional (if this is not possible another appropriately qualified employee), to confirm the documentation agrees with the text message. The text message must be regarded as a clinical contact and should be documented in the patient notes and include the complete text message, telephone number (it was sent from), the time sent, any response given, and date/time when received. All received text messages should be deleted once documentation has been completed to maintain patient confidentiality.⁵⁴
- 9.9 All services where remote prescribing is undertaken should have policies in place to ensure that any products/software used for consulting remotely are secure, provide a robust audit trail and comply with clinical and information governance standards.

⁵² Nursing & Midwifery Council (NMC)(2007). [Standards for Medicines Management](#). Accessed March 2018.

⁵³ Care Quality Commission. [Nigel's Surgery 19 PGDs and PSDs](#). Accessed March 2018.

⁵⁴ Nursing & Midwifery Council (NMC)(2007). [Standards for Medicines Management](#). Accessed March 2018.

10. Standard statement on the process for prescribing unlicensed medicines and for the use of medicines outside the manufacturer's licence (off-label prescribing)

The use of unlicensed medicines, and licensed medicines outside the manufacturer's license, should be explicit and follow national and professional guidance.

- 10.1. Off-label prescribing of medicines becomes necessary if the clinical need cannot be met by licensed medicines within the marketing authorisation. Such use should be supported by appropriate evidence and experience and prescribers should be aware that this may alter their professional responsibility and potential liability.⁵⁵
- 10.2 The General Medical Council (GMC) recommends that when prescribing a medicine 'off label', doctors should:
- ▶ Be satisfied that such use would better serve the patient's needs than an authorised alternative (if one exists).
 - ▶ Be satisfied that there is sufficient evidence/experience of using the medicine to show its safety and efficacy, seeking the necessary information from appropriate sources.
 - ▶ Record in the patient's clinical notes the medicine prescribed and, when not following common practice, the reasons for the choice.
 - ▶ Take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring the effects of the medicine.
 - ▶ Prior to any prescribing, the licensing status of a medication should be checked in the summary of product characteristics listed in the [electronic Medicines Compendium](#).⁵⁶
 - ▶ The prescriber must be competent and operate within the professional code of ethics of their statutory bodies and the prescribing practices of their employers.⁵⁷
- 10.3 Patients must be given sufficient information about the medicines proposed to be prescribed to allow them to make an informed decision. The General Medical Council produced the guidance document 'Good Practice in prescribing Medicines' in February 2013.⁵⁸ This document states that:
- ▶ Where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population.

⁵⁵ Medicines and Healthcare Products Regulatory Agency. [Off-label use or unlicensed medicines: prescribers' responsibilities](#). Drug Safety Update 2009. Accessed March 2018.

⁵⁶ [Electronic Medicines Compendium](#). Accessed March 2018.

⁵⁷ Medicines and Healthcare Products Regulatory Agency. [Off-label use or unlicensed medicines: prescribers' responsibilities](#). Drug Safety Update 2009. Accessed March 2018.

⁵⁸ General Medical Council (2013). [Good Practice in Prescribing and Managing Medicines and Devices](#). Accessed March 2018.

- ▶ Questions from patients about medicines should be answered fully and honestly.
- ▶ If it is intended to prescribe an unlicensed medicine which is not routine or if there are suitably licensed alternatives available, this should be explained to the patient, along with the reasons for doing so.
- ▶ Health care professionals should be careful about using medical devices for purposes for which they were not intended.

10.4 Any medication provided in this way as a 'named patient prescription' should have an audit trail.

10.6 Adverse reactions occurring during use of a medicine outside its license should be reported on a [Yellow Card](#) to the Medicines and Healthcare Products Regulatory Agency (MHRA).⁵⁹

⁵⁹ Medicines and Healthcare Products Regulatory Agency (MHRA). [Yellow Card Scheme](#). Accessed March 2018.

11. Standard statement on the process for reporting adverse effects of drugs and for reducing errors in prescribing or supplying medication.

Systems should be in place to identify and learn from incidents and adverse events related to medication.

- 11.1 Details of the patient using the medicine should be checked before supply or administration.
- 11.2 The name of the medicine should be checked with the patient prior to administration or supply. The patient should be made aware of the patient information leaflet and if there are any differences between this and any other leaflets provided, e.g. those from the Family Planning Association.⁶⁰
- 11.3 Clinical history, including anaphylaxis and past side effects, and concurrent medication, should be checked and updated at each visit.
- 11.4 Dose, administration instructions, expiry date and batch numbers should be checked on the label and contents and recorded in the notes as recommended by local policy.⁶¹
- 11.5 Warnings to identify contraindications to medicines should be clearly identifiable in the records.
- 11.6 Where packaging is similar for different medicines, these supplies should not be kept adjacent to each other. Systems should be employed to minimise the risk of confusion between the different medicines.⁶²
- 11.7 Adverse effects of a medicine, medical device or medicated device should be reported to the MHRA, according to their guidelines⁶³, to the manufacturer and to local pharmacy governance lead.
- 11.8 Any incident (including medicines errors, adverse effects, and theft of supplies or prescriptions), should be reported on local clinical incident forms.⁶⁴ The pharmacist and clinical lead or site manager for the area must be informed to commence appropriate investigation, improve practice and reduce future risk. This also ensures that incidents / adverse effects are collated

⁶⁰ [Family Planning Association. Help, Advice and Information for You](#). Accessed March 2018.

⁶¹ [Faculty of Sexual and Reproductive Healthcare \(2014\) Clinical Standards Record Keeping](#). Accessed March 2018.

⁶² Royal Pharmaceutical Society (2017). [Medicines, Ethics and Practice: the professional guide for pharmacists](#). Edition 41. RPS London. Accessed March 2018.

⁶³ Medicines and Healthcare Products Regulatory Agency (MHRA). [Yellow Card Scheme](#). Accessed March 2018.

⁶⁴ Royal Pharmaceutical Council (2016). [Professional Standards For The Reporting, Learning, Sharing, Taking Action and Review of Incidents](#). Accessed June 2018

nationally by NRLS and used to inform national policy with regard to patient safety.

- 11.9 To determine potential risks to service users and staff, drug products and procedures involving drugs (including the use of delivery devices) should be subject to risk assessment in accordance with the local risk management policy.

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