FSRH The Faculty of Sexual & Reproductive Healthcare

Service Standards for Medicines Management in Sexual and Reproductive Health Services

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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 14,000 doctor and nurse members with National Institute for Health and Care Excellence (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 everyone to have access to the full range of contraceptive methods and SRH services throughout their lives. To help 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 realise our vision of holistic SRH care for all.

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Changes introduced since review

- Standard 1: Addition of the reference to a locally held Medicines Formulary.
- Standard 2: Reworded to use the word ‘medicine’ instead of ‘treatment’ in the standard heading.
- Standard 3: Addition of the recommendation for stock lists to be subject to annual review.

  Addition of the recommendation to ensure the maintenance of the cold chain when transporting medicines requiring refrigeration.

  Addition of information regarding the need for regulatory-compliant locks on medicines cupboards.
- Standard 6: Addition of the need for those practicing under a PGD to be aware of the legal requirements of doing so.
- Standard 8: Removal of the statement that 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.

  Addition of the recommendation for the process of prescribing of a medicines and supply/administration by a single healthcare professional to be underpinned by risk assessment.

  Addition of information around accountability and responsibility when delegating supply and/or administration.
- Standard 9: Standard updated and re-written to include remote consultation, and to distinguish between remote prescribing and remote directions.

  Addition of the recommendation for healthcare professionals to consider whether or not informed consent can be obtained when consulting with a patient remotely.

  Addition of sub-sections on:
  - Remote supply under a PGD
  - Remote directions.
- Standard 10: Addition of a sub-section on the supply/administration of unlicensed medicines, and those used outside of their product licence, under a PGD.
- Other Sources of Information: Section updated throughout
- Glossary: Section newly added
- Audit Standards: Section newly added

SERVICE STANDARDS FOR MEDICINES MANAGEMENT IN SEXUAL AND REPRODUCTIVE HEALTH SERVICES

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 'Professional Guidance on the Safe and Secure Handling of Medicines'[1] gives definitive and detailed guidance on medicines management for all health professionals whose role involves handling medicines within all healthcare organisations in the UK. Reference to this resource is made throughout this document. It details the four core governance principles that underpin a framework for the safe and secure handling of medicines and can be used to develop working practices, policies, and procedures:

- Principle 1: Establish assurance arrangements – 'say what we do and why we do it'
- Principle 2: Ensure capacity and capability – 'train people and ensure they have the necessary competencies and resources'
- Principle 3: Seek assurance – 'do what we say and prove it'
- Principle 4: Continually improve – 'improve what we do'

The standards detailed in this document 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 medicine may be administered/supplied.

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 or supplying under a Patient Group Direction (PGD) through to dispensing, storage, administration, supply, 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 FSRH Service Standards for Risk Management[2] and Service Standards for Record Keeping[3]. Auditable standards are shown in ***bold italic*** font throughout this document.

[1]Royal Pharmaceutical Society (RPS) 2018 *Professional Guidance on the Safe and Secure Handling of Medicines.* Available at: https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

[2]Faculty of Sexual and Reproductive Health (FSRH) 2022 *Service Standards for Clinical Risk Management*. Available at: https://www.fsrh.org/standards-and-guidance/documents/service-standards-for-clinical-risk-management-in-srh-october/

[3]FSRH 2019 *Service Standards for Record Keeping*. Available at: https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-record-keeping-july-2019/

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 an up-to-date 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 which medicines are to be held in stock in clinical settings, and for managing the introduction of these. A comprehensive range of clinically appropriate medicines should be held. A locally held Medicines Formulary may support this.

- Processes should be in place to facilitate 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 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, for example, those for prescriptions, supplies and administration, and temperature monitoring, must be retained for a minimum period 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]Home Office 2013 *Guidelines for Standard Operating Procedures*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/480572/StandardOpProcedure.pdf

[5] NHS Transformation Directorate 2023 *Records Management Code of Practice.* Available at: https://transform.england.nhs.uk/information-governance/guidance/records-management-code/

2. Standard statement on access to medicines

Healthcare professionals should be able to provide medicines, or a prescription, to patients to meet their sexual and reproductive health needs, or signpost access to this.

2.1 Services should be able to provide access to, or a prescription for, a comprehensive and clinically appropriate range of medicines to meet their sexual and reproductive health need(s), or signpost access to this. This enables efficient provision of medicines, allows patient choice of provider, and underpins and enhances access to appropriate and timely services.

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, and 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, as appropriate.

3.2 All staff, whether clinical or non-clinical, should be trained in the parts of these procedures relevant to their duties.

3.3 ***Stock lists should be reviewed annually as a minimum to ensure they meet the needs of the clinic.***

3.4 ***A designated person should be responsible for ordering medicines from the pharmacy to maintain agreed stocks levels.***

3.5 Medicines arriving in the clinic should be promptly checked against the requisition by a designated person, who should record that the delivery is correct, follow up any discrepancies immediately, and ensure that the medicines are unpacked and stored appropriately. The registered healthcare professional in charge of a clinical area has the overall responsibility for the security and safekeeping of medicines in that area.

3.6 Where premises are shared, each service must be responsible for its own stock of medicines, which should be stored separately.

3.7 Storage should be sited for maximum security with access restricted to authorised staff.

3.8 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.

- Staff should carry out a risk assessment of the mode of transport, and the environment and area to 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. Care should be taken to maintain appropriate temperature control and, for items which require refrigeration, the cold chain is not broken.

3.9 All medicinal products issued by a healthcare professional must be over-labelled correctly.

Standard labelling requirements for all medicines issued to patients include:

- 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'[6].

3.10 All medicinal products must be stored in accordance with their Summary of Product Characteristics (SmPC) and any instruction on the label.

3.11 ***Lockable cupboards that comply with the relevant regulations should be used for the storage of medicines in the clinic or practice setting[7].***

- Metal cupboards should be used to ensure compliance with British Standard BS881, with a BS3621 compliant lock[8]. Cabinets for storing controlled drugs must additionally comply with Safe Custody Regulations[9].

3.12 If heat-sensitive products (such as vaccines) are kept, a dedicated medicines fridge fitted with a maximum and minimum thermometer must be available[10].

3.13 ***A logbook/record sheet of the ambient room temperature and, for heat-sensitive products, 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.

3.14 Medicines for clinical emergencies should be held in packs clearly marked 'for emergency use'[11]. 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.

[6] National Institute for Health and Care Excellence (NICE) 2023 *British National Formulary, Guidance on Prescribing.* Available at: https://bnf.nice.org.uk/medicines-guidance/guidance-on-prescribing/

[7] RPS 2023 *Professional Guidance on the Safe and Secure Handling of Medicines.* Available at: https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

[8] NHS England 2021 *Medicines Storage in Clinical Areas*. Available at: https://www.england.nhs.uk/wp-content/uploads/2021/05/HBN-14-02-Medicines-storage-in-clinical-areas.pdf

[9] The Misuse of Drugs (Safe Custody) Regulations 1973 https://www.legislation.gov.uk/uksi/1973/798/contents/made.

[10] UK Health Security Agency 2013 *Storage, distribution and disposal of vaccines: the green book, chapter 3*. Available at: https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

[11] RPS 2018 *Professional Guidance on the Safe and Secure Handling of Medicines.* Available at: https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

3.15 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 healthcare professional. The pharmacist should carry out inspections of the stock in the clinic, with reconciliation where necessary.

3.16 ***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.***

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

4. Standard statement on the 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, such as internal order forms.

4.2 ***Prescription pads must only be held by registered prescribers:***

- The healthcare professional must take responsibility for their security, which includes security of any prescription pads used outside of the clinic or practice setting, such as home visits.

4.3 ***Prescription pads and other controlled stationery must always be kept in secure location when not in use:***

- Access should be restricted to authorised users and, if an entry code is required to access this location, 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 ***Services should have a system that enables individual prescriptions to be accounted for and there should be an audit trail for numbered prescriptions.***

4.6 Appropriate procedures must be in place for the immediate reporting of any loss or theft of prescription stationery and staff should be aware of the actions to be taken if this occurs and/or fraud is suspected[12].

[12] NHS Counter Fraud Authority (2018) Management and control of prescription forms A guide for prescribers and health organisations. Available at: https://cfa.nhs.uk/resources/downloads/guidance/Management_and_control_of_prescription_forms_v1.0_March_2018.pdf

5. Standard statement on the 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 their registered professional body.

5.1 Prescribers should:

- Prescribe a medicine only with adequate, up-to-date awareness of its actions, indications, dose, contraindications, interactions, cautions and unwanted effects[13].
- Understand the potential for adverse effects and take steps to avoid, minimise, recognise, and manage them.
- Prescribe within relevant frameworks for medicine use as appropriate (such as local formularies, guidelines, care pathways, protocols) and within their clinical competence. Non-medical prescribers must ensure they prescribe in accordance with current regulations and guidance.
- Electronically generate or write legible, unambiguous, and complete prescriptions (or Patient-Specific Directions (PSDs)) which meet legal requirements.
- Effectively use the systems necessary to prescribe medicines (such as electronic prescribing, decision support, medicine charts) and tools to improve prescribing (feedback, audit, data analysis).
- Make accurate, legible, and contemporaneous records of prescribing decisions in clinical notes.
- Give clear, understandable, reliable, and accessible information about medicines to patients (and, where appropriate, carers), including how to take the medicine, duration of course, 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.
- Communicate information about medicines when sharing or transferring prescribing responsibilities/information.
- Keep up to date with emerging safety concerns related to prescribing, for example, MHRA alerts.
- Report prescribing errors, near misses, and critical incidents, and review and reflect on practice to prevent recurrence.
- Recognise when safe systems are not in place, take appropriate steps to ensure safe systems are implemented (following local policy), and document actions. If an error is made, take action to minimize any potential harm to the patient, follow the duty of candour and record the actions taken in the patient notes.

[13] RPS (2021) *Prescribing Competency Framework*. Available at: https://www.rpharms.com/resources/frameworks/prescribers-competency-framework

- Ensure confidence and competence to prescribe is maintained.
- Non-medical prescribers must undertake a programme of training approved by their professional body, and this must be annotated on the relevant professional register.
- Non-medical prescribers are permitted to prescribe black triangle* drugs provided that the drug in question falls within their field of competence and it is accepted practice to do so (for instance where such products are included in local formularies).
- Non-medical prescribers from some healthcare professions are prohibited from prescribing unlicensed drugs and/or (some) controlled drugs.

*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)[14]. 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 established (also see section 11.7).

[14] MHRA (2014) *The Black Triangle Scheme*. Available at: https://www.gov.uk/drug-safety-update/the-black-triangle-scheme-or

6. Standard statement on the process for supply or administration of a medicine under a Patient Group Direction (PGD)

Some registered healthcare professionals other than prescribers who have been appropriately trained and assessed as competent to do so 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"[15].

6.2 ***Any PGD in use must have been agreed through the authorising process within the relevant organisation[16].***

6.3 Anyone practicing under a PGD must be aware of the legal requirements of doing so[17,18, 19].

6.4 ***PGDs should only be used by registered healthcare professionals who have been assessed as competent to do so and whose name is identified within each document:***

- They must be competent in both the use of PGDs and the medicine in question. Competence should be assessed according to the NICE Competency Framework[20].

6.5 Staff involved in developing, reviewing, and updating PGDs should be assessed as competent in accordance with the NICE Competency Framework[21].

6.6 If a PGD cannot be used (for example where one has not yet been approved, or where some individuals fall outside the inclusion criteria), medicines can only be provided through a valid prescription or PSD.

6.7 Organisations must provide training, updating, and audit of those working under PGDs.

[15] MHRA (2017) *Patient Group Directions: who can use them.* Available at: https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them
[16] NICE (2017) *Patient Group Directions, Medicines Practice Guideline. Available at:* https://www.nice.org.uk/guidance/mpg2/resources
[17] RPS (2019) *Professional Guidance on the Administration of Medicines in Healthcare Settings.* Available at: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/SSHM%20and%20Admin/Admin%20of%20Meds%20prof%20guidance.pdf?ver=2019-01-23-145026-567
[18] *The Human Medicines Regulations. Available at:* https://www.legislation.gov.uk/uksi/2012/1916/contents/made
[19] MHRA (2017) *Patient Group Directions: who can use them.* Available at: https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them
[20] NICE (2017) *Patient Group Directions, Medicines Practice Guideline. Available at:* https://www.nice.org.uk/guidance/mpg2/resources
[21] NICE (2017) *Patient Group Directions, Medicines Practice Guideline. Available at:* https://www.nice.org.uk/guidance/mpg2/resources

6.8 PGDs should be reviewed and re-authorised according to local guidelines, particularly in the event of any changes in clinical guidance and practice.

6.9 Black triangle drugs (see 5.1) and medicines used outside the terms of the summary of product characteristics (off-label) (see 10.5) may be included in PGDs, provided that such use is exceptional and justified by current best clinical practice and provided that a direction clearly describes the status of the product.

6.10 Unlicensed drugs may not be supplied under a PGD.

6.11 Supplying under a 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. Healthcare professionals must not split prepared pre-packs.

6.12 ***The healthcare professional supplying the medicine under a PGD must undertake the whole episode of care.***

This includes:

- conducting an adequate clinical assessment and deciding on the suitability of the medicine to be supplied
- the handing over of the medicine to the individual/their representative (see also Standard 9.5)
- personally undertaking the packaging and posting/dispatch of the medicine
- personally undertaking the packaging of the medicine if it is to be collected at a later time[22].

[22] SPS (2023) *Delegation of supply or administration of medicines using a PGD*. Available at: https://www.sps.nhs.uk/articles/delegation-of-supply-or-administration-of-medicines-using-a-pgd/

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

Processes must be in place to ensure that the appropriate authorisation of a suitably qualified healthcare professional is obtained before medicines can be supplied or administered

7.1 The authorisation of a suitably qualified healthcare professional must be obtained before medicines can be supplied or administered to patients. This authority may be given in one of three ways:

- in accordance with a prescription or PSD completed by a medical or a Non-Medical Prescriber (NMP)
- in accordance with a PGD
- in accordance with another locally or nationally agreed clinical procedure, for example a National Protocol or Written Instruction.

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

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

8.1. ***Procedures for the supply and administration of medicines should be outlined in a local SOP[23].***

8.2. It is good practice for the actions of prescribing, supply and administration to be performed by separate healthcare professionals and for a second suitably qualified person to check the accuracy of the medicine provided in order to protect patient safety. However, this does not apply to medicines that have been labelled by a pharmacist, as these have already been dispensed and checked[24].

8.3. Exceptionally, where clinical circumstances make it necessary, and in the interests of the patient, the same healthcare professional can be responsible for the prescribing and supply and/or administration of medicines. Where this occurs, the process should be underpinned by risk assessment and clear accountability, and an audit trail and clinical governance arrangements must be in place to optimise patient safety, limit errors and ensure probity[25].

8.4. Non-medical prescribers who are both prescribing and supplying in community clinics or SRH services should be competent and familiar with all the medicines they prescribe.

8.5. Registered healthcare professionals who administer and/or supply medicines or, when appropriate, delegate the administration and/or supply, are accountable for their actions, non-actions, and omissions, and should exercise professionalism and professional judgement at all times.

- Delegated staff must act according to their level of competence and in accordance with the directions of the prescriber.
- It is the delegating healthcare professional's responsibility to ensure that a record is made when delegating the task of supplying or administering medicine.

8.6. Sufficient information about the medicine, as detailed in the authority to administer or

[23] FSRH (2019) *Service Standards for Record Keeping.* Available at: https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-record-keeping-july-2019/

[24] RPS (2021) *Prescribing Competency Framework*. Available at: https://www.rpharms.com/resources/frameworks/prescribers-competency-framework

[25] Royal College of Nursing and Royal Pharmaceutical Society. Guidance on Prescribing, Dispensing, Supplying and Administration of Medicines. March 2020/. Available at: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/SSHM%20and%20Admin/RCN%20RPS%20additional%20guidance.pdf?ver=2020-03-05-121229-987

supply, must be available to the staff and/or patient to enable identification and use of the product as intended.

8.7. 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/use the medicine and that the product is appropriately labelled. Only one healthcare professional needs to perform this task.

8.8. A record of administration and/or supply must be made in accordance with the FSRH Service Standards for Record Keeping[26]:

- Batch numbers and expiry dates should be recorded in accordance with local policy.
- The administering and/or supplying healthcare must be identified.

8.9. ***Where medicine is not given, for example, due to refusal, wastage or lack of availability, the reason for not doing so must also be recorded.***

8.10. If a second healthcare professional checks the administration of a medicine, the name and designation of the checking healthcare professional should also be recorded; however, the ultimate responsibility remains with the supplying/administering healthcare professional.

8.11. 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.

8.12. Wherever "take-home", pre-packed medicines are issued from the healthcare setting, the pharmacist is responsible for making sure that there is a system in place to ensure that all medicines are correctly over-labelled and issued to service users in accordance with the relevant legislation.

[26] FSRH (2019) *Service Standards for Record Keeping.* Available at: https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-record-keeping-july-2019/

9. Standard statement on remote consultation and remote prescribing and/or remote supply of a medicine under a PGD

When prescribing, or supplying, a medicine remotely, the healthcare professional must be satisfied that they can make an adequate, competent, and reliable assessment.

9.1 Remote prescribing, or remote supply of a medicine under a PGD, are commonly used to facilitate access to sexual health and contraceptive services and have 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.

UK registered healthcare professionals are expected to follow 10 high level key principles of good practice when consulting and/or prescribing remotely.[27]

9.2 The healthcare professional must satisfy themselves that they can make an adequate, competent, and reliable assessment, establish a dialogue and obtain the patient's consent and that the principles of shared decision-making are upheld. They 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
- whether informed consent can be obtained
- the need for physical examination or other assessments, and
- whether they have access to the patient's medical records[28].

9.3 All services where remote prescribing or supply of medicines 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.

Remote Supply under a PGD

9.4 Remote consultation prior to making a supply under a PGD is permissible. A supply under a PGD can also be made in the absence of the patient, where the appropriate guidance is followed and appropriate safeguards are in place:

- Where it is not possible for the clinician to carry out the remote consultation directly (such as where an adult lacks capacity) then the assessment should include a consultation with

[27] GMC (2021) *Remote Prescribing High Level Principles.* Available at: https://www.gmc-uk.org/ethical-guidance/learning-materials/remote-prescribing-high-level-principles

[28] GMC (2021) *Good practice in prescribing and managing medicines and devices*. Available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices

a representative, if appropriate.

- A PGD can be used by a healthcare professional listed within the PGD legislation to make a supply following an online screening assessment completed by the individual. [29]

9.5 Where it is not possible for the healthcare professional who undertakes the remote consultation to be physically present to hand the medicine over to an individual or their representative, they must personally prepare the medicines being supplied under a PGD for dispatch (i.e. package the medicine in a sealed packaging showing only the required identifiable information such as name, date of birth, delivery address). Another appropriately trained registered healthcare professional who has been assessed as competent to do so can then identify the individual/their representative when they present to collect the medicine and hand over the sealed package.

Remote Directions (also referred to as Verbal Orders, Verbal Directions or Remote Orders)

9.6 Sexual health and contraceptive services often run without direct access to a prescriber and, in exceptional circumstances, it may be necessary for a remote direction to be requested from a prescriber to authorise another healthcare professional to administer or supply a medicine to a patient. A 'verbal order' from a healthcare professional not acceptable on its own; it must be supported by confirmation of the request communicated via an appropriately secure electronic method. This should be followed up by a written prescription within one working day (72 hours maximum over bank holidays and weekends).[30]

9.7 When issuing a remote direction, the prescriber is responsible for the assessment of the patient and the decision to supply/administer the medicine(s) in question.

9.8 The healthcare professional requesting authorisation to provide a medicine to a patient is accountable for ensuring all relevant information has been communicated to the prescriber.

9.9 The healthcare professional that receives the remote direction is the only person who may act on it. The prescriber must be satisfied that this individual has the qualifications, experience, knowledge and skills to provide the care or treatment involved.

9.10 The healthcare professional receiving the remote direction must make a clear, accurate and immediate record of reasons for contacting the prescriber,details of the remote direction and the name of the prescriber, and file the emailed direction in the patient's notes when received.

9.11 ***The use of remote directions must be monitored locally.***

[29] Specialist Pharmacy Service (SPS) 2022 *Patient Group Direction Use in Remote Consultations.* Available at: https://www.sps.nhs.uk/articles/patient-group-direction-use-in-remote-consultations/

[30] RPS (2019) *Professional Guidance on the Administration of Medicines in Healthcare Settings.* Available at: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/SSHM%20and%20Admin/Admin%20of%20Meds%20prof%20guidance.pdf?ver=2019-01-23-145026-567

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

The use of unlicensed medicines, and licensed medicines outside the manufacturer's licence (i.e. 'off-label'), should be explicit and follow national and professional guidance.

10.1. Off-label use of medicines becomes necessary if the clinical need cannot be met by the use of a licensed medicine within the marketing authorisation. Such use should be supported by appropriate evidence and experience and healthcare professionals should be aware that this may alter their professional responsibility and potential liability[31].

10.2 The General Medical Council (GMC) recommends that when prescribing a medicine 'off-label', healthcare professionals 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 medicine should be checked in the summary of product characteristics listed in the electronic Medicines Compendium (eMC)[32].
- The prescriber must be competent and operate within the professional code of ethics of their statutory bodies and the prescribing practices of their employers.

10.3 Patients must be given sufficient information about the proposed medicine(s) to allow them to make an informed decision. The General Medical Council guidance[33] states that:

- Where prescribing unlicensed medicines, or medicines for use 'off-label', 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.

[31] GMC (2021) *Prescribing unlicensed medicines. Available at:* https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines#:~:text=When%20prescribing%20an%20unlicensed%20medicine%2C%20you%20must%3A%201,another%20suitable%20doctor%20to%20do%20so%20More%20items prescribers' responsibilities

[32] Electronic medicines compendium. Available at: https://www.medicines.org.uk/emc/

[33] GMC (2021) *Prescribing unlicensed medicines. Available at:* https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines#:~:text=When%20prescribing%20an%20unlicensed%20medicine%2C%20you%20must%3A%201,another%20suitable%20doctor%20to%20do%20so%20More%20items prescribers' responsibilities

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

10.4 All adverse reactions occurring during use of a medicine outside its licence should be reported on a Yellow Card to the Medicines and Healthcare Products Regulatory Agency (MHRA)[34] (see Section 11.7).

Supply and/or administration or unlicensed medicines or those for use 'off-label' under a PGD

10.5 Off-label use of a licensed medicine is permitted under PGD only when clearly justified by best clinical practice. Where this is the case, it must clearly be stated on the PGD when the medicine is being used outside the terms of the marketing authorisation and why this is recommended, with reference to the supporting evidence or guidance. In accordance with GMC guidance, consideration should be given to informing the patient or their carer that the use is off label[35].

10.6 **Unlicensed medicines cannot legally be supplied or administered under a PGD.**

[34] Medicines and Healthcare Regulatory Agency (MHRA) *Yellow Card Reporting Site. Available at:* https://yellowcard.mhra.gov.uk/

[35] GMC (2021) *Prescribing unlicensed medicines. Available at:* https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines#:~:text=When%20prescribing%20an%20unlicensed%20medicine%2C%20you%20must%3A%201,another%20suitable%20doctor%20to%20do%20so%20More%20items prescribers' responsibilities

11. Standard statement on the process for reporting adverse effects of medicines and for reducing errors when prescribing and supplying medicines.

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

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 the information in this and advice provided (e.g. in the case of off-label use).

11.3 Clinical history, including anaphylaxis, past side effects and concurrent medicine(s), 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. This should be recorded in the notes in line with local policy[36].

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 and selection errors at the point of supply/administration.

11.7 Adverse effects of a medicine, medical device or medicated device should be reported to the MHRA via the Yellow Card Reporting system, according to their guidelines[37], to the manufacturer, and to the 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[38]. The pharmacist and clinical lead or other designated person must be informed to commence appropriate investigation, improve practice, and reduce future risk. This also ensures that incidents and adverse effects are collated nationally by National Reporting and Learning System (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.

[36] FSRH (2019) *Service Standards for Record Keeping.* Available at: https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-record-keeping-july-2019/
[37] MHRA *Yellow Card Reporting Site. Available at:* https://yellowcard.mhra.gov.uk/
[38] RPS (2016) *Error Reporting Professional Standards.* Available at*:* https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Error%20Reporting/rslar-standards-nov-2016.pdf

Other Sources of Information

Service Standards on Confidentiality- Faculty of Sexual and Reproductive Healthcare (June 2020).

General Pharmaceutical Council (GPhC)

Royal Pharmaceutical Society (RPS)

Specialist Pharmacy Service

Medicines & Healthcare Products Regulatory Agency (MHRA)

Regulations for service providers and regulators- Care Quality Commission (updated January 23).

NICE Medicines and Prescribing Support.

Medicines Act 1968 (as amended).

The Medicines for Human Use (Miscellaneous Amendments) (No.2) Regulations 2009, SI 3063.

The Prescription Only Medicines (Human Use) Amendment Order 2003, SI 696.

The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013, SI 235.

Glossary

Term	Definition
Non-medical Prescriber (NMP)	Prescribers from a range of healthcare professions, other than a doctor or dentist, who are able to prescribe within their scope of practice once they have completed an approved education programme. NMPs may be independent prescribers or supplementary prescribers: ▶ Independent non-medical prescribers are responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and can make prescribing decisions to manage the clinical condition of the patient*. ▶ Supplementary prescribers prescribe in partnership with a medical prescriber i.e. a doctor or dentist in accordance with an agreed written Clinical Management Plan. *N.B. There are certain prescribing restrictions for prescribers from each healthcare profession which may prohibit the prescription of, for example, controlled drugs and/or unlicensed and/or off label medicines.
Off-label (use of a drug)	Use of a licensed medicine outside the terms of the licence, for example, outside the defined indications, doses, routes of administration, or contrary to listed warnings as detailed in the Summary of Product Characteristics.
Overlabelled pack	Small packs of licensed medicines with labels already attached, to allow issue against a prescription or under a PGD without further pharmacy involvement. The labels give patients instructions for use that have been specified by the prescriber for a specific patient group in accordance with local clinical governance policy and have space for the patient's name and date of issue to be added by the clinic staff.
Patient Group Direction (PGD)	A written direction that allows the supply and/or administration of a specified medicine or medicines, by a named authorised health professional, to a well-defined group of patients requiring treatment for a specific condition.
Patient Specific Direction (PSD)	The traditional written instruction, signed by a prescriber, for medicines to be supplied and/or administered to a named individual after the prescriber has assessed that individual on a one-to-one basis. In practice, a PSD is commonly referred to as a prescription by those who write them or use them as the legal basis to administer a medicine, because this indicates that it is written by a prescriber.
Prescription	An instruction written by a medical practitioner that authorises a patient to be issued with a medicine or treatment.
Summary of Product Characteristics (SmPC)	A monograph for a medicine, written and updated by pharmaceutical companies based on their product research and knowledge, which outlines important information about a medicine such as form, clinical parameters and pharmacological properties. SmPCs are checked and approved by the UK or European medicines licensing agency, the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA).

Term	Definition
Unlicensed Drug	A drug without a marketing authorisation or product licence defining the medicine's terms of use. Such drugs have not been subject to the rigorous testing of a licensed drug, and hence will not have been assessed for efficacy and safety and will lack assurance that it has been manufactured to appropriate quality standards. It may not be accompanied by appropriate product information and labelling when placed on the market.

Audit Standards

Component (Standard Number)	Auditable Outcome Measure	Standard
Medicines management (1.2)	There should be an up-to-date Medicines Policy for each employing organisation, which is accessible to staff and used in conjunction with these standards.	97%
Safe and secure handling of medicines (3.3)	Stock lists should be reviewed annually as a minimum to ensure they meet the needs of the clinic.	97%
Safe and secure handling of medicines (3.4)	A designated person should be responsible for ordering medicines from the pharmacy to maintain agreed stocks levels.	97%
Safe and secure handling of medicines (3.11)	Lockable cupboards that comply with the relevant regulations should be used for the storage of medicines in the clinic or practice setting.	97%
Safe and secure handling of medicines (3.13)	A logbook/record sheet of the ambient room temperature and, for heat-sensitive products, refrigerator temperature, should be maintained with signed entries on each working day.	97%
Safe and secure handling of medicines (3.16)	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.	97%
Safe and secure handling of medicines (3.17)	There must be a policy agreed with the local pharmacy team for the safe disposal of expired and returned medicines.	97%
Security of prescription pads (4.2)	Prescription pads must only be held by registered prescribers.	97%
Security of prescription pads (4.3)	Prescription pads and other controlled stationery must always be kept in a secure location when not in use.	97%
Security of prescription pads (4.4)	Records of serial numbers of prescription pads received and issued should be retained for at least three years.	97%
Security of prescription pads (4.5)	Services should have a system that enables individual prescriptions to be accounted for.	97%
Supply and/or administration under a PGD (6.2)	Any PGD in use must have been agreed through the authorising process within the relevant organisation.	97%
Supply and/or administration under a PGD (6.4)	PGDs should only be used by registered healthcare professionals who have been assessed as competent to do so and whose name is identified within each document.	97%
Supply and/or administration under a PGD (6.12)	The healthcare professional supplying the medicine under a PGD must undertake the whole episode of care.	97%

Audit Standards

Component (Standard Number)	Auditable Outcome Measure	Standard
Supplying and administering medicines to patients (8.1)	Procedures for the supply and administration of medicines should be outlined in a local SOP.	97%
Authorising and recording of medicines supplied and/or administered (8.9)	Medicine that is not given due to refusal, wastage or lack of availability must be recorded.	97%
Remote consultation and prescribing/supply under PGD (9.11)	The use of remote directions must be monitored locally.	97%