

Professional Standards and Guidance for the Sale and Supply of Medicines

About this document

The Code of Ethics sets out seven principles of ethical practice that you must follow as a pharmacist or pharmacy technician. It is your responsibility to apply the principles to your daily work, using your judgement in light of the principles.

The Code of Ethics says that you must **‘Make the care of patients your first concern’**.

In meeting this principle you are expected to:

- Provide a proper standard of practice and care to those for whom you provide professional services.
- Seek all relevant information required to assess an individual’s needs and provide appropriate treatment and care. Where necessary, refer patients to other health or social care professionals or other relevant organisations.
- Seek to ensure safe and timely access to medicines and take steps to be satisfied of the clinical appropriateness of medicines supplied to individual patients.
- Encourage the effective use of medicines and be satisfied that patients, or those who care for them, know how to use their medicines.
- Be satisfied as to the integrity and quality of products to be supplied to patients.
- Ensure that you have access to the facilities, equipment and materials necessary to provide services to professionally accepted standards.

This document expands on the principles of the Code of Ethics to set out your professional responsibilities if you are involved in the sale and supply of medicines. It is designed to meet Society’s obligations under the Pharmacists and Pharmacy Technicians Order 2007 and other relevant legislation.

This document does not detail legislative requirements, but when selling or supplying medicines you must comply with relevant legislative and contractual requirements, including NHS terms of service.

Status of this document

Principle 6.6 of the Code of Ethics states that you must comply with legal requirements, mandatory professional standards and accepted best practice guidance.

This document contains:

- Mandatory professional standards (indicated by the word ‘must’) for all registered pharmacists and pharmacy technicians; and
- Guidance on good practice (indicated by the word ‘should’) which you should follow in all normal circumstances.

If a complaint is made against you the Society’s fitness to practise committees will take account of the requirements of the Code of Ethics and underpinning documents, including this one. You will be expected to justify any decision to act outside its terms.

1. PHARMACEUTICAL STOCK

STANDARDS

Patients, members of the public and other healthcare professionals are entitled to expect that medicines sold or supplied within the course of professional pharmacy practice are obtained from a reputable source and fit for the intended purpose. You must ensure that:

- 1.1** if you suspect you have been offered or supplied a counterfeit or defective medicine, this is reported to the Medicines and Healthcare products Regulatory Agency, the Royal Pharmaceutical Society, the Veterinary Medicines Directorate or the marketing authorisation holder as appropriate to the individual situation. Any such stock must be segregated from other pharmacy stock and must not be sold or supplied for the treatment of any person(s).
- 1.2** pharmaceutical stock is stored under suitable conditions, taking into consideration the stability of the drug.
- 1.3** particular attention is paid to protection of pharmaceutical stock from contamination, sunlight, atmospheric moisture and adverse temperatures. You must ensure that where you have concerns

about the stability of a medicine, it is segregated from the rest of the stock and not sold or supplied for patient use.

- 1.4** refrigerators used for pharmaceutical stock are capable of storing products between 2C and 8C. They must be equipped with a maximum/minimum thermometer, or other suitable alternative, which is checked on each day the pharmacy is open and the maximum and minimum temperatures recorded. Steps must be taken to rectify discrepancies in temperatures.
- 1.5** all stocks of medicines in the pharmacy have batch and expiry details. Medicines must be removed from blister or foil packs only at the time of dispensing to assist an individual patient.
- 1.6** date expired stock is segregated from the rest of the pharmacy stock and appropriately disposed of. Procedures must be in place to reduce the risk of short dated or out-of-date stock being accidentally supplied to a patient or member of the public. In the event of a pandemic flu, Level 6, date expired medicines may be supplied to patients, where this is in line with guidance issued by the Government and/or the RPSGB.¹
- 1.7** products that may be injurious to a person's health, for example tobacco products, alcoholic beverages and products intended to mask the signs of alcohol or drug consumption are not sold or supplied from registered pharmacy premises.
- 1.8** medicines returned to the pharmacy from a patient's home, a care home or a similar institution are not supplied to another patient. While awaiting disposal, these medicines must be clearly marked and segregated from other stock.¹ In the event of a pandemic flu, Level 6, patient returned medicines may be supplied to patients, where this is in line with guidance issued by the Government and/or the RPSGB.¹
- 1.9** within the hospital setting, all medicines returned to the pharmacy department from a ward or other hospital department are examined under the direction of a pharmacist to assess their suitability for being returned to stock. Patients' own drugs brought into hospital with them must not be returned to pharmacy stock or be supplied to another patient.¹

¹ The Society is currently considering its policy on the re-use of patient returned medicines. Until such time that this has been given full consideration 1.8 and 1.9 must be complied with. Any change in policy will be notified via the pharmacy press.

2. SUPPLY OF OVER THE COUNTER (OTC) MEDICINES

STANDARDS

When purchasing medicines from pharmacies patients expect to be provided with high quality, relevant information in a manner they can easily understand. You must ensure that:

- 2.1** procedures for sales of OTC medicines enable intervention and professional advice to be given whenever this can assist the safe and effective use of medicines. Pharmacy medicines must not be accessible to the public by self-selection.
- 2.2** when a patient or their carer requests advice on treatment, sufficient information is obtained to enable an assessment to be made of whether self-care is appropriate, and to enable a suitable product(s) to be recommended.
- 2.3** if a sale is not considered suitable, the reasons for this are explained to the patient and they are referred to another healthcare professional where appropriate.
- 2.4** when an OTC medicine is supplied, sufficient advice to ensure the safe and effective use of the medicine is provided. You must take into account any other specific information such as safe storage, or short expiry dates that the patient may need to be counselled on.
- 2.5** all staff involved in the sale or supply of an OTC medicine are trained, or are undertaking the training required for their duties, and are aware of situations where referral to the pharmacist or other registered healthcare professional may be necessary. Consideration must be given to the types of OTC medicines that may require the personal intervention of a pharmacist e.g. those that have recently become available without prescription, those that may be subject to abuse or misuse, or where the marketing authorisation for non-prescription use is restricted to certain conditions and circumstances.

- 2.6** all persons involved in the sale of OTC products are aware of the abuse potential of certain OTC medicines and other products. You must be alert to requests for large quantities and abnormally frequent requests and refuse to make a supply where there are reasonable grounds for suspecting misuse.
- 2.7** particular care is exercised when supplying products for children, the elderly and other special groups or individuals, or where the product is for animal use.
- 2.8** requests for certain medicines such as emergency hormonal contraception are handled sensitively and the patient's right to privacy and confidentiality is respected.
- 2.9** any information provided about OTC medicines is up to date, accurate and reliable.
- 2.10** you keep up to date with developments regarding new products and policies for health promotion and are aware of local and major national and topical health promotion initiatives.

3. SUPPLY OF PRESCRIBED MEDICINES

STANDARDS

Patients are entitled to expect the dispensing service provided to be accurate, accessible and reasonably prompt. Appropriate standard operating procedures must be in place for the dispensing services you provide, or are responsible for and you must ensure that:

- 3.1** you seek to maintain adequate stock holdings.
- 3.2** every prescription is clinically assessed by a pharmacist to determine its suitability for the patient.
- 3.3** the patient receives sufficient information and advice to enable the safe and effective use of the prescribed medicine.
- 3.4** appropriate records of clinical interventions are maintained.
- 3.5** patients or their carers are informed if you are unable to dispense their prescription in its entirety and given the opportunity to take their prescription to another pharmacy.

- 3.6** when medication is outstanding, the patient, carer or their representative is provided with a legible note detailing the name and quantity of medicine outstanding and, where possible, informed when the balance will be available for collection. A record of the medicine owed must be kept in the pharmacy.
- 3.7** a product with a marketing authorisation is supplied where such a product exists in a suitable formulation and is available, in preference to an unlicensed product or food supplement.²
- 3.8** except in an emergency, a specifically named product is not substituted for any other product without the approval of the patient or carer and the prescriber, a hospital drug and therapeutics committee, or other similar locally agreed protocols.
- 3.9** when providing services for drug misusers you do not deviate from the instructions given on the prescription. Sugar and/or colour-free products have a greater potential for abuse than syrup based and coloured products and must not be dispensed unless specifically prescribed.
- 3.10** all solid dose and all oral and external liquid preparations are dispensed in suitable reclosable child resistant containers unless:
- the medicine is in an original pack or patient pack such as to make this inadvisable;
 - the patient has difficulty in opening a child resistant container;
 - a specific request is made by the patient, their carer or representative that the product is not dispensed in a child resistant container;
 - no suitable child resistant container exists for a particular liquid preparation, or
 - the patient has been assessed as requiring a compliance aid.
- 3.11** labelling of dispensed products is clear and legible and where appropriate includes any cautionary and advisory labelling recommended by the current British National Formulary.
- 3.12** appropriate systems and procedures are in place if you prepare monitored dosage systems.

² except where methadone mixture is prepared extemporaneously in accordance with Appendix 1

- 3.13** reimbursement claims for NHS or other professional services are honest and accurate.
- 3.14** procedures are in place to minimise the risk of dispensing errors or contamination of medicines. A record of errors or near miss incidents must be made and practices reviewed in light of such incidents.

GOOD PRACTICE GUIDANCE

- Where verbal information is provided about a prescribed medicine necessary records of this should be maintained, when clinically appropriate.

4. EXTEMPORANEOUS PREPARATION OR COMPOUNDING

STANDARDS

This standard is not intended to cover the reconstitution of dry powders with water or other diluents.

Patients are entitled to expect that products extemporaneously prepared in a pharmacy are prepared accurately and are suitable for use. If you wish to be involved in extemporaneous preparation you must ensure that:

- 4.1** a product is extemporaneously prepared only when there is no product with a marketing authorisation available³ and where you are able to prepare the product in compliance with accepted standards.
- 4.2** you and any other staff involved are competent to undertake the tasks to be performed.
- 4.3** the requisite facilities and equipment are available. Equipment must be maintained in good order to ensure that performance is unimpaired, and must be fit for the intended purpose.
- 4.4** you are satisfied as to the safety and appropriateness of the formula of the product.

³ except where methadone mixture is prepared extemporaneously in accordance with Appendix 1

- 4.5** ingredients are sourced from recognised pharmaceutical manufacturers and are of a quality accepted for use in the preparation and manufacture of pharmaceutical products. Where appropriate, relevant legislation must be complied with.
- 4.6** particular attention and care is paid to substances which may be hazardous and require special handling techniques.
- 4.7** the product is labelled with the necessary particulars, including an expiry date and any special requirements for the safe handling or storage of the product.
- 4.8** if you are undertaking large scale preparation of medicinal products, all relevant standards and guidance are adhered to.
- 4.9** records are kept for a minimum of two years. The records must include:
- the formula,
 - the ingredients,
 - the quantities used,
 - their source,
 - the batch number,
 - the expiry date,
 - where the preparation is dispensed in response to a prescription, the patient's and prescription details and the date of dispensing,
 - the personnel involved, including the identity of the pharmacist taking overall responsibility.

GOOD PRACTICE GUIDANCE

- Where possible, all calculations and measurements should be double checked by a second appropriately trained member of staff.

5. REPEAT MEDICATION SERVICES

STANDARDS

A repeat medication service is a service operated in co-operation with local prescribers, in which pharmacists will provide professional support to assist in the rational, safe, effective and economic use of medicines. In order to provide a repeat medication service, you must:

- 5.1** ensure the pharmacy operates a patient medication record system notified to the Information Commissioner's Office.
- 5.2** ensure that an audit trail exists to identify each request and supply.
- 5.3** establish, at the time of each request, which items the patient or carer considers are required and ensure that unnecessary supplies are not made. At this stage pharmacists must also use their professional judgement to decide whether concordance or other problems encountered by the patient may require early reference to the prescriber.
- 5.4** not request a repeat prescription from a surgery before obtaining the patient's or carer's consent. You may however institute a patient reminder system.
- 5.5** record all interventions in order to be able to deal with any queries that may arise.

6. DELIVERY SERVICES

STANDARDS

A delivery service is where the medicine is handed to the patient, their carer or other designated person other than on registered pharmacy premises. When providing medicines via a delivery service you still have a professional responsibility to ensure that patients or their carers know how to use the medication safely, effectively and appropriately and check that they are not experiencing adverse effects or compliance difficulties. You must ensure that:

- 6.1** on each occasion a delivery service is provided you use your professional judgement to determine whether direct face-to-face contact with the patient or their carer is necessary.

- 6.2** you obtain consent from the patient or their carer to provide the delivery service on a single occasion or for a set period of time.
- 6.3** delivery to a person other than the patient or carer is undertaken only where they have been specifically designated by the patient or their carer.
- 6.4** you maintain appropriate records of requests for the service.
- 6.5** the delivery mechanism used:
- enables the medicine to be delivered securely and promptly to the intended recipient with any necessary information to enable safe and effective use of their medicine;
 - caters for any special security/storage requirements of the medicine;
 - incorporates a verifiable audit trail for the medicine from the point at which it leaves the pharmacy to the point at which it is handed to the patient, their carer or other designated person, or returned to the pharmacy in the event of a delivery failure;
 - safeguards confidential information about the medication that a patient is taking.

GOOD PRACTICE GUIDANCE

- Wherever possible a signature should be obtained to indicate safe receipt of the medicines.
- Systems should be in place to inform a patient who is not at home that delivery was attempted.

7. PRESCRIPTION COLLECTION SERVICE

STANDARDS

A prescription collection service encompasses any scheme where a pharmacy receives prescriptions other than directly from the patient, their carer or their representative. When providing such a service you must:

- 7.1** obtain consent to receive patients' prescriptions. The request for the ongoing service must be from the patient or their carer and procedures must exist for maintaining records of the initial request for the service.
- 7.2** explain fully to patients, or their carers, what the service involves, including the time period required to collect/receive and dispense their prescription.
- 7.3** ensure that any members of staff who collect prescriptions are acting in accordance with your directions.
- 7.4** take all reasonable steps to ensure patient confidentiality and the security of prescriptions.
- 7.5** make sure that requests for repeat prescriptions are initiated by the patient or their carer. A reminder system may be instituted but a prescription must not be requested from a surgery before obtaining the patient's or their carer's consent.
- 7.6** on receipt of prescriptions, including electronic prescriptions, be satisfied that you are authorised to receive and dispense them. Any prescription received for which you do not have the authority, must be returned to the surgery for collection by the patient or carer, or be directed to the pharmacy authorised to receive it.

8. COMPLEMENTARY THERAPIES AND MEDICINES

STANDARDS

You must ensure that you are competent in any area in which you offer advice on treatment or medicines. If you sell or supply homoeopathic or herbal medicines, or other complementary therapies, you must:

- 8.1** assist patients in making informed decisions by providing them with necessary and relevant information.
- 8.2** ensure any stock is obtained from a reputable source.
- 8.3** recommend a remedy only where you can be satisfied of its safety and quality, taking into account the Medicines and Healthcare products Regulatory Agency registration schemes for homoeopathic and herbal remedies.

9. EMERGENCIES

STANDARDS

There may be occasions when you are required to assist members of the public or patients in an emergency. In such situations you must:

- 9.1** where appropriate, consider using the exemption in legislation that allows pharmacists to make an emergency supply of medicines if a patient has an urgent need for them. You must consider the medical consequences, if any, of not making the supply and be satisfied that your decision will not lead to patient care being compromised.
- 9.2** advise the patient on how to obtain essential medical care where you do not consider an emergency supply to be appropriate.
- 9.3** assist persons in need of emergency first aid or medical treatment whether by administering first aid within your competence or by summoning assistance.

10. PATIENT GROUP DIRECTIONS

STANDARDS

If you are involved in the supply and/or administration of a medicine under a patient group direction (PGD) you must:

- 10.1** be satisfied that the PGD is legally valid and that it has been approved by the relevant authorising body.
- 10.2** ensure that when supplies are made the agreed protocol is followed and the information specified in the PGD is recorded. These records must include the identity of the pharmacist assuming responsibility for each supply.
- 10.3** ensure you have up-to-date knowledge relating to the clinical situation covered by the PGD, the medicine and its use for the indications specified.
- 10.4** ensure that you have undertaken any training required for operation of the PGD.

If you are involved in writing and/or approving patient group directions (PGD) you are accountable for their content and must ensure that:

- 10.5** you are familiar with your role and responsibilities and the government advice set out in relevant guidance.
- 10.6** only PGDs which comply with legal requirements are approved.
- 10.7** the staff training specified will enable safe operation of the PGD.
- 10.8** the appropriate people have been involved in the drafting, approval and signing of the PGD.
- 10.9** you have up-to-date knowledge relating to the clinical situation being covered by the PGD, the medicine and its use for indications specified in the PGD.

Guidance that supports this document

We have produced documents or guidance bulletins on the following which should be considered in conjunction with these standards:

- Code of ethics for pharmacists and pharmacy technicians
- Professional standards and guidance for patient consent
- Professional standards and guidance for patient confidentiality
- Emergency first aid; guidance for pharmacists
- Patient group directions: a resource pack for pharmacists
- The safe and secure handling of medicines: a team approach (The Duthie Report)
- Emergency supplies guidance (Law and Ethics Bulletin)
- Safe storage of medicines in patient's homes (Law and Ethics Bulletin)

You can download these documents and more copies of this document from our website (www.rpsgb.org) or you can telephone us on 020 7735 9141.

Other sources of Society advice

Further information or advice on the professional or legal obligations of the pharmacy profession can be obtained by contacting the Society's legal and ethical advisory service on 020 7572 2308 or e-mail leadvice@rpsgb.org.

EXTEMPORANEOUS PREPARATION OF METHADONE MIXTURE

You must supply a product with a marketing authorisation, where such a product exists in a suitable formulation and is available, in preference to an unlicensed product or food supplement. You must only prepare a product extemporaneously if there is no product with a marketing authorisation available and where you are able to prepare the product in compliance with accepted standards.

An exception to these requirements, to permit the extemporaneous preparation of methadone mixture in circumstances where a licensed product is available, will be granted provided the following requirements are adhered to:

STANDARDS

(a) If a licensed product is available, methadone mixture may only be prepared extemporaneously if the quantity of methadone dispensed on a regular basis is large enough to preclude storage of sufficient quantities of the licensed product within the pharmacy, in accordance with the safe custody requirements of the Misuse of Drugs legislation.

(b) In addition to the standard operating procedures (SOPs) required for dispensing, a SOP must be in place for the extemporaneous preparation of methadone. The SOP must ensure safe systems and provide a verifiable audit trail. Adherence to the SOP must be ensured.

(c) Extemporaneous preparation must only be carried out by persons who are appropriately trained and competent to do so.

(d) All quantities of methadone powder and diluent, and any colourings, flavourings and stabilisers, must be accurately measured. You must not rely on the accuracy of the quantities of powder, diluent etc stated on the manufacturer's packs.

(e) The equipment used to measure and prepare extemporaneous methadone products must be appropriate and be maintained in good order to ensure that performance is unimpaired.

(f) Equipment must be properly cleaned between each batch of extemporaneously prepared product to ensure that no residue from previous batches remains.

(g) Visual checks must be made to ensure the methadone powder has fully dissolved in the diluent.

(h) Stock bottles must not be reused.

(i) The product must be labelled with the necessary particulars, including:

- The name and strength of the product
- The quantity of medicinal product in the container
- Any special handling and storage requirements (eg, store in safe custody)
- The batch expiry date
- A batch reference number

(j) For each batch of extemporaneous methadone mixture prepared a record must be maintained for a minimum of two years of:

- The formula
- The ingredients and quantities used
- The source, batch number and expiry date of the ingredients
- The batch number and expiry date of the extemporaneously prepared mixture
- The persons involved in preparing the product, including the identity of the pharmacist assuming overall responsibility

(k) Extemporaneously prepared methadone mixture must be stored in a cabinet, cupboard or room that meets the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973.

(l) Extemporaneous preparation of methadone mixture, when a licensed product is available, carries increased liability and must be covered by indemnity insurance arrangements.

GOOD PRACTICE GUIDANCE

- Running balances of methadone powder and the resulting extemporaneously prepared methadone mixture should be maintained.
- The prescriber and the patient should be informed that the methadone product being supplied does not have a marketing authorisation.
- Wherever possible all measurements should be checked by a second person.