



PROFESSIONAL STANDARDS AND GUIDANCE FOR THE SALE AND SUPPLY OF MEDICINES



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STATUS OF THIS DOCUMENT

This guidance is addressed to pharmacists but may also help patients and the public understand what they can expect when medicines are either purchased over the counter or supplied on prescription.

Principle 8.8 of the Code of Ethics states that the pharmacist must comply with legal requirements, mandatory professional standards and accepted best practice guidance.

This document contains:

- mandatory professional standards (indicated by the word ‘must’ and ‘have to’) for all registered pharmacists;
and
- guidance on good practice (indicated by the word ‘should’, ‘might’, ‘may’, ‘would’, ‘will’ and ‘could’) which the pharmacist should follow in all normal circumstances.

Serious or persistent failure to follow this guidance will put a pharmacist’s registration at risk. The pharmacist¹ must, therefore, be prepared to explain and justify his actions.

If a complaint is made against a pharmacist, the Pharmaceutical Society of Northern Ireland’s (hereinafter named the Society) Fitness to Practise process will take account of the requirements of the Code of Ethics and underpinning documents, including this one. The pharmacist will be expected to justify any decision to act outside the terms set down in these documents.

ABOUT THIS DOCUMENT

The Code of Ethics sets out eight principles of ethical practice that a pharmacist must follow. It provides a framework for professional decision-making and it is the pharmacist’s responsibility to apply the principles to daily work situations, using his professional judgement. The guidance is not meant to be exhaustive, nor can it be.

Principle 1 of the Code of Ethics states that the pharmacist must ***‘Make the safety and welfare of patients your prime concern’***.

¹ ‘Pharmacist’ appears with masculine pronoun and is understood to refer to male/female gender

In adhering to this principle, the pharmacist is expected to:

- ensure the provision of a high standard of professional service by him or those working under his direct supervision;
- provide appropriate treatment and care based on relevant information he has available to him. Where appropriate, consult with other agencies and signpost or refer patients to other health and social care professionals and/or relevant organisations;
- ensure as far as possible the clinical appropriateness of medicines supplied to patients and their safe and timely access to them;
- promote the safe, effective and rational use of medicines by controlling the sale or supply of all medicinal and related products, especially those with a potential for abuse or dependency;
- purchase medicines only from suppliers and sources known to be reputable to ensure the safety, quality and efficacy of products supplied to patients;
- ensure he has the facilities, equipment and materials necessary to provide services to professionally acceptable standards; and
- ensure he records patient consent either in writing or electronically before providing a professional service.

This document expands on the principles of the Code of Ethics to set out the pharmacist's professional responsibilities if he is involved in the sale and supply of medicines. It is designed to meet Society's obligations under relevant legislation.

This document does not detail legislative requirements, but when selling or supplying medicines the pharmacist must comply with relevant legislative and contractual requirements, including Health Service terms of service where appropriate.

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, that appropriate distribution processes are followed and that the medicines are fit for the intended purpose.

The pharmacist must ensure that:

- 1.1 if he suspects he has been offered or supplied a counterfeit or defective medicine, this is reported to the Medicines and Healthcare products Regulatory Agency (MHRA), the Department of Health Social Services and Public Safety (DHSSPS) Inspectorate, the Pharmaceutical Society of Northern Ireland (PSNI), the Veterinary Medicines Directorate (VMD) 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) or animal(s);
- 1.2 pharmaceutical stock is stored under suitable conditions, taking into consideration the stability of the drug and any manufacturers recommendations;
- 1.3 particular attention is paid to protection of pharmaceutical stock from contamination, sunlight, atmospheric moisture and adverse temperatures;
- 1.4 in cases of concern about the stability of a medicine, it must be segregated from the rest of the pharmacy stock and not sold or supplied for patient or animal use;
- 1.5 refrigerators used for pharmaceutical stock must be capable of storing products between 2°C and 8°C, thereby ensuring the maintenance of the “cold chain” and integrity of fridge lines supplied. 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 temperature recorded. Steps must be taken to rectify discrepancies and to appropriately dispose any pharmaceutical stock that has been subjected to temperatures outside the terms of SPC recommendations;
- 1.6 the labelling of all stocks of medicines in the pharmacy with batch and expiry details;
- 1.7 the removal of medicines from blister or foil packs only, where required, at the time of dispensing, to assist an individual patient. In so doing, the integrity of the medicine must not be impaired;
- 1.8 the segregation of date-expired stock from the rest of the pharmacy stock and its appropriate disposal;
- 1.9 the installation of procedures to reduce the risk of short dated or out-of-date stock being accidentally supplied to a patient or member of the public;

- 1.10 a ban on the sale or supply of products, from registered pharmacy premises, 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;
- 1.11 the segregation and appropriate disposal of medicines returned to the pharmacy from a patient's home, a care home or a similar institution; these medicines must not be supplied to another patient.
- 1.12 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. This also includes ensuring patients' own medicines brought into hospital with them are not returned to pharmacy stock or supplied to another patient. (Refer to "Use and Control of Medicines" (DHSSPS) 2004 and the "Duthie Report, UK.")

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.

The pharmacist must ensure that:

- 2.1 procedures for sales of OTC medicines enable intervention and professional advice to be given whenever this can assist in the safe and effective use of medicines;
- 2.2 Pharmacy (P) medicines are not accessible to the public by self-selection;
- 2.3 for a patient or their carer who 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;
- 2.4 if a sale is not considered suitable, the reasons for this are explained to the patient and he/she is referred to another healthcare professional where appropriate;
- 2.5 on supplying an OTC medicine, sufficient verbal advice is given to ensure its safe and effective use, including specific information on aspects such as safe storage, or short expiry dates;
- 2.6 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;

- 2.7 consideration is given to the types of OTC medicines that may require the personal intervention of a pharmacist, for example, those that have recently become available without prescription, those that may be subject to abuse or misuse², or where the marketing authorisation for non-prescription use is restricted to certain conditions or circumstances;
- 2.8 all persons involved in the sale of OTC products are aware of the abuse potential of certain OTC medicines and other products including being alert to requests for large quantities and abnormally frequent requests, and knowing to refuse to make a supply where there are reasonable grounds for suspecting misuse and/or abuse;
- 2.9 the exercise of particular care when supplying products for children, the elderly and other special groups or individuals, or where the product is for animal use;
- 2.10 the sensitive handling of requests for certain medicines such as emergency hormonal contraception and the respecting of the patient's right to privacy and confidentiality;
- 2.11 any information provided about OTC medicines is up-to-date, accurate and reliable;
- 2.12 he keeps up to date with developments regarding new products and policies for health promotion and is aware of local and major national health promotion initiatives.

GOOD PRACTICE GUIDANCE

- Medicines should not be sold to children under 16 years except in exceptional circumstances.

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 (SOPs) must be in place for the dispensing services the pharmacist provides³, or is responsible for.

² For more detailed information refer to:

- Substances of Misuse. RPSGB. February 2008.
- Letter on "Sale and Supply of Medicines Liable to Abuse," by Dr Michael Mawhinney, Head of Inspection and Investigation, DHSSPSNI, posted to all registrants and dated 4 July 2008

³ It is **mandatory** for a pharmacist to have SOPs in the pharmacy covering all stages of the 'prescription journey'. Members of the National Pharmacy Association (NPA) can download a "Guide to writing SOPs – step by step, for community pharmacists." Template SOPs are also available from <http://www.npa.co.uk>.

With the introduction of Responsible Pharmacist Regulations from 1 October 2009, the responsible pharmacist must establish (where these are not already in place) pharmacy procedures designed to ensure the safe and effective running of the pharmacy. These procedures will need to be maintained and regularly reviewed. Refer to www.psni.org.uk/responsiblepharmacist.

The pharmacist must ensure that:

- 3.1 adequate stock holdings are maintained;
- 3.2 a clinical assessment of every prescription is undertaken, by a pharmacist, to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency 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 the patient's prescription can not be dispensed in its entirety and are 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. The supply of controlled drugs must be completed within 28 days of the date of issue of the prescription or other appropriate date as indicated by the prescriber on the prescription;
- 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;
- 3.8 except in an emergency, a specifically named product is not substituted for any product without the approval of the patient or carer and the prescriber, a hospital drug and therapeutics committee, or other similar locally-agreed protocols and a record is made in the Patient Medication Record (PMR);
- 3.9 when providing services for drug misusers the pharmacist does 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 re-closable 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, computer-generated and where appropriate includes any cautionary and advisory labelling recommended by the current British National Formulary (BNF);
- 3.12 appropriate systems and procedures are in place if he prepares monitored dosage systems;
- 3.13 reimbursement claims for Health Service 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 and a record of errors and ‘near-miss’ incidents must be made and practices reviewed in light of such incidents.
- 3.15 a patient information leaflet (PIL) is issued with a medicine at the time of dispensing.

GOOD PRACTICE GUIDANCE

- Where verbal information is provided to a patient about a prescribed medicine a record 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 the pharmacist chooses to be involved in extemporaneous preparation he must ensure that:

- 4.1 a product is extemporaneously prepared only when there is no product with a marketing authorisation available and where he is able to prepare the product in compliance with accepted standards;
- 4.2 the pharmacist and any other staff involved are competent to undertake the tasks to be performed;
- 4.3 the requisite facilities and equipment are available and the equipment is maintained in good order to ensure that it is fit for the intended purpose;

- 4.4 he is satisfied as to the safety and appropriateness of the formula of the product and its suitability for the patient;
- 4.5 ingredients are sourced from recognised pharmaceutical manufacturers and are of an acceptable quality for use in the preparation and manufacture of pharmaceutical products, in compliance with relevant legislation;
- 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 he is undertaking large scale preparation of medicinal products, all relevant standards and guidance must be followed;
- 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;
 - the patient's and prescription details; and the
 - date of dispensing, the personnel involved, including the identity of the pharmacist taking overall responsibility.
- 4.10 the manufacture of nostrums should take account of guidance issued by the Society, DHSPPS and other professional bodies and comply with all legal requirements.

GOOD PRACTICE GUIDANCE

- Where possible, all calculations and measurements should be double-checked by a second appropriately trained member of staff.
- Where possible, try to validate the formula for the product being prescribed before dispensing from an appropriate source, for example, contact Victoria Pharmaceuticals, Royal Victoria Hospital, Belfast.

5 REPEAT MEDICATION SERVICES STANDARDS

A repeat medication service is 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, the pharmacist must:

- 5.1 ensure consent is obtained from the patient or carer before requesting a repeat prescription from a surgery. The pharmacist may himself establish a patient reminder system;
- 5.2 ensure the pharmacy operates a patient medication record system notified to the Information Commissioner's Office⁴;
- 5.3 ensure that an audit trail exists to identify each request and supply;
- 5.4 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 the pharmacist must also use his professional judgement to decide whether concordance or other problems encountered by the patient may require early reference to the prescriber;
- 5.5 record all interventions in order to be able to deal with any queries that may arise. It is good practice to keep records of interventions for up to a year after the intervention occurs.

6 DELIVERY SERVICES STANDARDS

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

The pharmacist must ensure that:

- 6.1 on each occasion a delivery service is provided he uses his professional judgement to determine whether direct face-to-face contact with the patient or their carer is necessary;
- 6.2 he obtains consent from the patient to provide the delivery service, confirms consent on each occasion, as appropriate, and maintains appropriate records of requests for the service;
- 6.3 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 his medicine;

- provides 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 or their carer, 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.
- Refer to the HSC Board's *Guidance on Collection and Delivery services*.

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 the pharmacist must:

- 7.1 obtain consent to collect/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 on his behalf are acting in accordance with his directions;
- 7.4 take all reasonable steps to ensure patient confidentiality and the security of prescriptions;
- 7.5 ensure he obtains consent from the patient or carer before requesting a repeat prescription from a surgery. The pharmacist may himself establish a patient reminder system;
- 7.6 on receipt of prescriptions, including electronic prescriptions, be satisfied that he is authorised to collect/receive and dispense them. Any

prescription for which he does 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;

- 7.7 where more than one pharmacy is involved in supplying prescriptions a SOP must be in place with detailed governance arrangements.

8 COMPLEMENTARY THERAPIES AND MEDICINES STANDARDS

The pharmacist must ensure that he is competent in any area in which he offers advice on treatment or medicines.

If the pharmacy sells or supplies homeopathic or herbal medicines, or other complementary therapies, the pharmacist 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 he can be satisfied of its safety and quality, taking into account the MHRA registration schemes for homeopathic and herbal remedies. (Refer to www.mhra.org.uk).

9 EMERGENCIES STANDARDS

There may be occasions when the pharmacist is required to assist members of the public or patients in an emergency.

In such situations the pharmacist must:

- 9.1 give consideration, where appropriate, to using the provision that allows pharmacists to make an emergency supply of medicines in line with the Medicines Act legislation;
- 9.2 give consideration to the medical consequences, if any, of not making the supply and be satisfied that his decision will not lead to patient care being compromised;
- 9.3 make relevant records in relation to emergency supplies in the PMR and in the '*prescription only record*' book;
- 9.4 advise the patient on how to obtain essential medical care where he does not consider an emergency supply to be appropriate;
- 9.5 assist persons in need of emergency first aid or medical treatment whether by administering first aid within his competence or by summoning assistance.

10 PATIENT GROUP DIRECTIONS (PGDS)

The legal definition of a PGD is:

'a written instruction for the sale, supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment.'

Guidance⁵ issued along with this definition sets the overall context in which PGDs should be viewed:

'the majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability.'

STANDARDS

If the pharmacist is involved in the **supply and/or administration of a medicine** under a patient group direction (PGD) he must:

- 10.1 be satisfied that the PGD is legally valid and that it has been approved by the relevant authorising body for the organisation in which it is being used;
- 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 that he has 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 PGDs are reviewed, updated and re-authorised, in line with changes to clinical practice;
- 10.4 ensure that he has undertaken any training required for operation of the PGD;
- 10.5 ensure that the staff training specified will enable safe operation of the PGD.

If the pharmacist is involved in **writing and/or approving PGDs** the pharmacist is accountable for the content and must ensure that:

- 10.6 he is familiar with his role and responsibilities and the advice set out in relevant guidance⁵;

⁵ Patient Group Directions: A practical guide and framework of competencies for all professionals using patient group directions. March 2004. www.npc.co.uk/pdf/pgd.pdf

- 10.7 only PGDs which comply with legal requirements are approved;
- 10.8 the appropriate people have been involved in the drafting, approving and signing of the PGD. The PGD must be signed by:
- the doctor and pharmacist involved in developing the PGD;
 - the authorising body for the organisation in which it is being used.

GUIDANCE THAT SUPPORTS THIS DOCUMENT

The Society has produced documents or guidance on the following which should be considered in conjunction with these standards:

- Code of Ethics for pharmacists
- Professional Standards and Guidance for Patient Consent
- Professional Standards and Guidance for Patient Confidentiality.

These documents can be downloaded from the Society's website www.psn.org.uk or telephone us on 02890 326 927 for more information or a hard copy(ies).

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RPSGB



