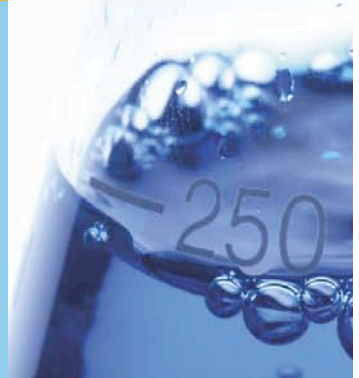


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# PROFESSIONAL STANDARDS AND GUIDANCE FOR PHARMACIST PRESCRIBERS



# PROFESSIONAL STANDARDS AND GUIDANCE FOR PHARMACIST PRESCRIBERS

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## ABOUT THIS DOCUMENT

The Code of Ethics sets out eight mandatory principles of ethical practice which a pharmacist must follow. It is therefore a framework for professional decision-making. It is the responsibility of the pharmacist<sup>1</sup> to apply these principles to daily work situations, using his professional judgement.

This document elaborates on the principles of the Code of Ethics for the purpose of explaining the pharmacist's responsibilities as a supplementary or independent prescriber. It is designed to meet the obligations required by the Pharmaceutical Society and its members.

This document applies to all settings in which a pharmacist may prescribe, both within and outside the Health Service, including primary care, secondary care, private sector, and care in the armed forces and H M Prisons. It should be read alongside other relevant documents from the Department of Health Social Services and Public Safety, Northern Ireland (DHSSPS).

The standards in this document aim to be consistent with those in place for other prescribing professions. A list of useful websites and supporting guidance can be found at the end of this document.

### 1. BACKGROUND

The main legislation that enables pharmacists to prescribe medicinal products for human use is the Prescription Only Medicines (Human Use) Order 1997, as amended in 2008 (No.464) and the Medicines (Pharmacy and General Sale – Exemption) Order 1980 as amended in 2005 (No.766). Pharmacists gained the right to achieve supplementary prescribing status in 2003 and independent prescribing status in 2006.

Legislation also allows qualified **Pharmacist Independent Prescribers to prescribe any licensed medicine for any medical condition with the exception of all Controlled Drugs**, until such time as there are changes to the Misuse of Drugs Regulations (Northern Ireland) 2002. **Pharmacist Independent Prescribers must only prescribe within their own level of experience and sphere of competence.**

<sup>1</sup> 'Pharmacist' will appear with the male pronoun but should be understood to mean the male/female gender.

## 1.1 TYPES OF PHARMACIST PRESCRIBING

There are currently two types of prescribing that may be undertaken as a pharmacist prescriber: supplementary and independent prescribing. Some pharmacists will be qualified as both, others as only a supplementary prescriber. A pharmacist independent prescriber can practise as either a pharmacist independent prescriber or pharmacist supplementary prescriber. The mode of prescribing practice will depend on the pharmacist's personal choice and practice circumstances. The pharmacist may practise solely in one practice mode or move between modes according to patient or practice circumstances.

### DEFINITIONS

#### SUPPLEMENTARY PRESCRIBING

A voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan (CMP) with the patient's agreement.

#### INDEPENDENT PRESCRIBING

Prescribing by a practitioner (e.g. doctor, registered nurse, pharmacist) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing.

#### GOOD PRACTICE GUIDANCE

Other methods for supplying and administering medicines include the use of **patient group directions, patient specific directions and minor ailments schemes**. Some of the standards and guidance outlined in this document will also apply to these practices.

## 1.2 WORKING WITHIN REQUIREMENTS

A pharmacist prescriber must comply with the relevant legislation and frameworks and should always be able to justify his decisions and actions.

Legal requirements for pharmacist prescribers:

- the pharmacist may prescribe only after successfully completing an education and training programme accredited by the Pharmaceutical Society of Northern Ireland (hereinafter known as the Society) or the Royal Pharmaceutical Society of Great Britain. His name must be annotated in the Society's practising register to reflect this;

- the pharmacist may prescribe only in relation to his prescribing status (independent or supplementary) and must comply with statutory requirements applicable to his prescribing practice;
- the pharmacist is legally accountable for his prescribing decisions, including actions and omissions, and cannot delegate this accountability to any other person. (The pharmacist is solely accountable as an independent prescriber (IP) and jointly accountable with the independent prescriber as a supplementary prescriber (SP). In the latter case a SP has joint responsibility with the IP for the content of the clinical management plan, but the SP is still solely responsible for the decision to prescribe);
- prescribing outside the legal parameters of either supplementary or independent prescribing is a criminal offence.

## CLINICAL GOVERNANCE FRAMEWORK

Clinical and social care governance is the system through which the Health & Personal Social Services (HPSS) organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence will flourish.

All employing organisations must ensure that pharmacist independent prescribing is included within their overall clinical governance framework, to ensure that pharmacists practice safely and competently.

The Pharmaceutical Society of Northern Ireland has produced a clinical governance framework for pharmacist prescribers. The framework includes recommendations for Health Service organisations, employers and individual prescribers. It also includes indicators and examples of good practice. It is available at: <http://www.psnri.org.uk/pdfs/clincgovframeworkpharm.pdf>

## COMPETENCIES

The pharmacist must attain and maintain competencies specific to his role as a prescriber. The main competencies required are outlined in the National Prescribing Centre (NPC) document – *‘Maintaining Competency in Prescribing: An outline framework to help pharmacist prescribers’*. These competencies have been incorporated into the training courses for pharmacist prescribers. They are a useful tool as part of personal development plans and can help identify gaps and needs. The NPC document can be found at:

[http://www.npc.co.uk/pdf/pharmacist\\_comp\\_framework\\_Oct06.pdf](http://www.npc.co.uk/pdf/pharmacist_comp_framework_Oct06.pdf)

## **PRIVATE PRACTICE**

All pharmacists who prescribe privately must also follow the standards and guidance outlined in this document. Pharmacist prescribers should only prescribe within their sphere of competency. It is the responsibility of individuals to ensure that arrangements for good governance are in place.

## **LIABILITY AND INDEMNITY ARRANGEMENTS**

The Society requires that all activities pharmacists undertake be covered by professional indemnity arrangements. The pharmacist must ensure that he has professional indemnity arrangements in place which cover the scope of his prescribing practice regardless of whether he prescribes within or outside the Health Service.

For the purposes of indemnity within the Health Service (and similarly for other organisations) the pharmacist needs to ensure, along with his line manager, that the Health and Social Care (HSC) Trust and HSC Board has approved pharmacist prescribing at an appropriate level within the organisation and that this acquiescence has been recorded in the minutes of that meeting.

## **VETERINARY PRESCRIPTIONS**

Existing legislation permits pharmacists to dispense veterinary prescriptions and to sell certain classes of veterinary medicinal product over-the-counter. Pharmacists can also prescribe veterinary medicinal products classified as POM-VPS in accordance with the current Veterinary Medicines Regulations.

## **2. STANDARDS AND GUIDANCE FOR PHARMACIST PRESCRIBERS**

The professional standards and good practice guidance have been laid out under the eight mandatory principles of the Code of Ethics.

**The eight principles are,**

- 1 Make the safety and welfare of patients your prime concern.
- 2 Respect and protect confidential information.
- 3 Show respect for others.
- 4 Exercise professional judgement in the interests of patients and public.
- 5 Encourage patients (and/or their carers as appropriate) to participate in decisions about their care.
- 6 Maintain and develop professional knowledge and competence.
- 7 Act with honesty and integrity.
- 8 Provide a high standard of practice and care at all times.

## 2.1 MAKE THE SAFETY AND WELFARE OF PATIENTS YOUR PRIME CONCERN STANDARDS

- 2.1.1 In order to prescribe for a patient the pharmacist must satisfy himself that he has undertaken an adequate assessment of the patient by taking a history, performing an appropriate examination and/or by accessing the appropriate parts of the patient's clinical records.
- 2.1.2 The pharmacist is accountable for his decision to prescribe and must prescribe only where he has relevant knowledge of the patient's health and medical history and of medicines required for treating his/her condition(s).
- 2.1.3 The pharmacist must ensure relevant physical examinations of the patient are carried out where appropriate or necessary, including any diagnostic tests in order to exclude contra-indications, clarify doses or note treatment cautions.
- 2.1.4 The pharmacist must prescribe only where there is a genuine, identifiable clinical need for treatment. The demands of a patient do not, on their own, constitute the basis for writing a prescription. The pharmacist should consider the use of non-pharmacological treatments where appropriate.
- 2.1.5 Independent pharmacist prescribers may prescribe both where a diagnosis has been made previously and also where no working diagnosis of the patient's condition has been made. If he is unable to reach a working diagnosis of the patient's condition he must refer him/her to an appropriate medical practitioner or other health professional.
- 2.1.6 If a pharmacist is carrying out a diagnosis of a patient's condition he must have the appropriate facilities and equipment to do this<sup>2</sup>. Any equipment used must undergo regular and appropriate quality assurance checks.
- 2.1.7 The pharmacist must ensure that an adequate clinical assessment has been undertaken in respect of the patient's current medicines or their medical condition(s) and include any risk of potential for confusion or interaction with other medicines.
- 2.1.8 When prescribing unlicensed medicines or medicines outside their licensed indications ('off-label') the pharmacist must be satisfied that it would serve the patient's needs more appropriately than a licensed alternative. Refer to appendix 1 of this document. Further information on "off-label prescribing" is available from, [http://www.gmc-uk.org/guidance/a\\_z\\_guidance/guidance\\_list/list\\_o.asp](http://www.gmc-uk.org/guidance/a_z_guidance/guidance_list/list_o.asp).

<sup>2</sup> Refer to NPA guide on "Making Best Use of Consultation Areas: A guide for NPA members in England and Wales."

He must ensure that the patient, or his/her representative, is aware that it is unlicensed or the indication for its use is outside its licence. In the case of unlicensed medicines patient consent must be obtained (see section 3.4 and 3.5 of document). (Refer to *Professional Standards and Guidance on Patient Consent*).

- 2.1.9 The pharmacist must provide clear dosage administration instructions to the patient or carer to avoid uncertainty for the patient, or any other health professional.
- 2.1.10 A retrievable audit trail of the pharmacist's prescribing actions must be maintained, for example, keeping records of his prescribing in the patient's notes.
- 2.1.11 The pharmacist must refer the patient to another prescriber where prescribing for the patient is outside his sphere of competency.
- 2.1.12 The pharmacist must adhere to safe prescribing standards as detailed in the British National Formulary, the DHSSPS publication on 'Use and Control of Medicines' and guidance from National Patient Safety Agency (NPSA).
- 2.1.13 The pharmacist must keep up-to-date with cost effective, evidence-based prescribing and adhere, where appropriate, to local practice formularies and local and national prescribing guidelines, for example, NICE, GAIN<sup>3</sup> (formerly known as CREST).

### GOOD PRACTICE GUIDANCE

- Whenever possible, when prescribing for a patient the pharmacist should have concurrent access to the patient's full health records;
- The maximum time allowed between writing the prescription and entering the details into the contemporaneous patient record should not exceed 48 hours, unless there are exceptional circumstances;
- The pharmacist should review the medications:
  - \* initiated for a patient,
  - \* any other concurrent medication including OTCs, or
  - \* medication for conditions within his sphere of competence.

<sup>3</sup> In August 2007 RMAG, NIRAAC and CREST became the Guidelines and Audit Implementation Network (GAIN) and will keep regional audit and guidelines in the forefront of service improvement. GAIN will have an important safety and quality improvement role in Health & Social Care Services throughout Northern Ireland through the commissioning of regional audit and guidelines as well as the promotion of good practice through the dissemination of audit results, and the publication and facilitation of implementation of regional guidelines. For more information on GAIN see [www.gain-ni.org](http://www.gain-ni.org)

This review should be done on each occasion the pharmacist prescribes for the patient. In certain circumstances it may be in the patient's best interest for the pharmacist prescriber not to prescribe medicines for him/her. The pharmacist prescriber should always consider stopping any unsuitable or unnecessary medicines;

- The dosage instructions should be written on the prescription unless the medicine has a variable dose regimen, in which case appropriate procedures should be put in place to ensure dose changes are accurately communicated to and understood by the patient. The instruction 'as directed' or other ambiguous instructions should be avoided.

## **2.2 RESPECT AND PROTECT CONFIDENTIAL INFORMATION STANDARDS**

- 2.2.1 The pharmacist must gain patient's consent to share information about him/her with other health and social care professionals. Only where there is real or perceived danger of harm to the patient or anyone else may information be shared without patient consent. (Refer to *Professional Standards and Guidance on Patient Consent*).
- 2.2.2 If a patient's consent to share information is not forthcoming the pharmacist must offer an explanation of the possible risks to his/her health and safety in not doing so. If the patient continues to refuse to give consent this must be documented in his/her records.

## **2.3 SHOW RESPECT FOR OTHERS STANDARDS**

- 2.3.1 The pharmacist must explain his role as a non-medical prescriber to the patient or his/her representative.
- 2.3.2 The pharmacist must be aware of cultural and religious differences in so far as these apply to prescribing.
- 2.3.3 The pharmacist must obtain the patient's consent for the prescribing process and for any physical examinations or diagnostic testing undertaken. This can be verbal or written consent. In either case, consent should be documented on the patient's record. (Refer to *Professional Standards and Guidance on Patient Consent*).
- 2.3.4 The pharmacist must inform anyone else who may be in a position to prescribe for that patient of his actions, where relevant and possible, and where consent to do this has been obtained. This is most likely to be the patient's general medical practitioner but in principle, may also include

non-medical prescribers and other health/social care professionals. The main way to do this is to enter any interventions and actions in the common prescribing record. Where there is no common prescribing record the pharmacist must inform the primary prescriber.

Please Note: A common prescribing record would not communicate prescribing actions from a hospital admission or an out-patient episode. These would ordinarily be communicated on a discharge summary or an out-patient letter. Therefore it is important to routinely check with the patient if they have had any recent hospital appointments or are attending the hospital for any treatment. Then refer to the patient's GP where appropriate.

For more information on consent refer to the Society's *Professional Standards and Guidance for Patient Consent* and refer to DH guidance at:

Reference Guide for Consent for examination, treatment or care (Department of Health, Social Services & Public Safety, Northern Ireland, 2003)

<http://www.dhsspsni.gov.uk/consent-referenceguide.pdf>

## **2.4 EXERCISE YOUR PROFESSIONAL JUDGEMENT IN THE INTERESTS OF PATIENTS AND PUBLIC STANDARDS**

2.4.1 The pharmacist's prescribing practice must, wherever possible, be evidence-based and be in accordance with relevant national and local guidelines. Deviations from these policies must be justifiable and be in the best interest of the patient.

### **GOOD PRACTICE GUIDANCE**

- The pharmacist should be familiar with current guidance published in the British National Formulary (including the use, side effects and contra-indications of the medicines which he prescribes) as well as having access to a wider range of information. Where local policy varies from current national guidelines, the pharmacist should seek guidance through clinical governance structures in respect of his vicarious liability within his employing organisation (Health and Social Care (HSC) Trust, HSC Board, head office of a multiple, pharmacy company etc);

- In some cases the pharmacist may be working at the margins of established practice, or in an area where the available evidence base is poor. In these circumstances there may not be any evidence available for the medicines prescribed and decisions should be based on current thinking and peer opinion.

## 2.5 ENCOURAGE PATIENTS (AND/OR THEIR CARERS AS APPROPRIATE) TO PARTICIPATE IN DECISIONS ABOUT THEIR CARE

### STANDARDS

- 2.5.1 When prescribing, the pharmacist must take the views of the patient (and /or their carers as appropriate) into account, in order to create an environment where shared-decision making is the norm. This will include taking into account the patient's personal views and beliefs when discussing their treatments.

The National Prescribing Centre (NPC) ([www.npc.co.uk](http://www.npc.co.uk)) has produced the following document which may be used as a tool for shared decision making with patients. "*Maintaining Competency in Prescribing: an outline framework to help pharmacist prescribers*" (January 2007). (available at, [http://www.npc.co.uk/publications/maint\\_compt\\_presc/maint\\_compt\\_presc.htm](http://www.npc.co.uk/publications/maint_compt_presc/maint_compt_presc.htm))

### GOOD PRACTICE GUIDANCE

- There will be occasions when the patient's views cannot be fully accommodated. In these circumstances, the pharmacist needs to ensure, as far as practicable, that the patient complies with the treatment and should explain to the patient why he has made a particular choice.

## 2.6 MAINTAIN AND DEVELOP PROFESSIONAL KNOWLEDGE AND COMPETENCE

### STANDARDS

- 2.6.1 The pharmacist must prescribe only within his level of expertise and sphere of competence and not outside his clinical knowledge of either the condition, or the medicines required to treat that condition.
- 2.6.2 The pharmacist must refer the patient to an appropriate prescriber if he is not competent to prescribe in disease areas with which the patient may present.
- 2.6.3 If the pharmacist moves to another area of practice (a different sector of pharmacy, a different therapeutic area or a different geographical area)

he must consider the requirements of expertise and competence associated with any new role. The pharmacist requires the approval of his employer for this new role and may need to undertake additional training to ensure he is competent to prescribe, in addition to the educational course which allows him to prescribe. This may also affect the pharmacist's professional indemnity arrangements.

- 2.6.4 It is the pharmacist's responsibility to remain up to date with the knowledge and skills to enable him to prescribe competently and safely within his area of expertise.
- 2.6.5 A pharmacist registered as a prescriber, must ensure that part of his continuing professional development (CPD) directly addresses his role as a prescriber. This includes keeping up to date with relevant changes in the law and safe prescribing practice, as well as the therapeutic areas in which the pharmacist prescribes.

## **2.7 ACT WITH HONESTY AND INTEGRITY STANDARDS**

- 2.7.1 The pharmacist must inform anyone who needs to know about any restrictions placed on his prescribing practice. In particular, other practitioners with dispensing responsibilities need to know about this. For example, the pharmacist must inform his HSC Trust or Board if he has restrictions placed upon his prescribing. The HSC Trust or Board is obliged to inform the relevant people using the systems it has developed for this purpose.
- 2.7.2 The pharmacist should not normally both prescribe and dispense medicines, except in exceptional circumstances, for example, where the need for the medicine is urgent and not to dispense would compromise patient care. The pharmacist must have robust procedures in place to demonstrate the separation of prescribing and dispensing.
- 2.7.3 Where the pharmacist is involved in both prescribing and dispensing a patient's medication, a second suitably competent person should be involved in checking the accuracy of the medicines provided, and wherever possible, carrying out a clinical check.
- 2.7.4 The pharmacist must make his choice of medicinal product for the patient based on clinical suitability and clinical and cost effectiveness. The decision must not be based on potentially biased information, fraud or commercial gain.

- 2.7.5 The pharmacist must maintain a declaration of interest, which he must produce on request if required for audit purposes to his employer. The pharmacist must adhere to local policy in this regard.
- 2.7.6 The pharmacist must not prescribe for himself.
- 2.7.7 The pharmacist must not prescribe for anyone with whom he has a close personal or emotional relationship, except in exceptional circumstances such as when no other person with the legal right to prescribe is available and only then if that treatment is necessary to:
- save a life,
  - avoid serious deterioration in the patient's health, or
  - alleviate otherwise uncontrollable pain.
- 2.7.8 The pharmacist must be able to justify his actions and must document his relationship and the exceptional circumstances that required him to prescribe for someone close to him.
- 2.7.9 If the pharmacist has concerns about the competence, behaviour or conduct of a professional colleague, which impacts on patient safety, he must take appropriate action to raise this as a concern. (Refer to *Guidance for Pharmacists on Raising Concerns*).

### GOOD PRACTICE GUIDANCE

- The Medicines (Advertising) Regulations 1994 govern the supply, offer or promise of gifts to healthcare professionals, including pharmacists, by drug manufacturers and distributors. Pharmacists accepting items such as gift vouchers, bonus points, discount holidays, sports equipment etc. would be in breach of Regulation 21 of the Medicines (Advertising) Regulations 1994.
- The Association of the British Pharmaceutical Industry's (ABPI) Code of Practice for the Pharmaceutical Industry sets standards for the advertising and the provision of information to the public about prescription only medicines. Refer to <http://www.pmcpa.org.uk/?q=whatiscodeofpractice>;
- For a pharmacist prescriber, it is good practice to carry out a self-audit of prescribing practice at regular intervals, at least on an annual basis;
- If it is clinically appropriate to alter another prescribed medication, details of the person who made the change should be clearly documented on the patient's record.

## 2.8 PROVIDE A HIGH STANDARD OF PRACTICE AND CARE AT ALL TIMES STANDARDS

- 2.8.1 The pharmacist has a responsibility to communicate effectively with other practitioners involved in the care of the patient, provided patient consent is given.
- 2.8.2 The pharmacist must ensure that the records he makes are accurate, comprehensive and contemporaneous.
- 2.8.3 The pharmacist must ensure that he has professional indemnity arrangements which cover the scope of his prescribing practice regardless of whether he prescribes within, or outside the Health Service.

## GOOD PRACTICE GUIDANCE

- A written agreement outlining the scope of practice, should be in place between the pharmacist prescriber and the employing organisation (e.g. HSC Board and Trust, care home, pharmacy). This ‘*scope of practice agreement*’ should outline the areas in which the pharmacist will prescribe and should determine the methods that are to be used to communicate effectively with other health professionals involved in the patient’s care.

## 3. ADDITIONAL INFORMATION

### 3.1 GUIDANCE ON WRITING PRESCRIPTIONS

Guidance for safe practice in writing prescriptions is outlined in the:

- section on prescription writing in “*Guidance for Non-Medical Prescribing within GP Practices*” (DHSSPS) (November 2008),
- BNF,
- ‘*Use and Control of Medicines*’ (DHSSPS) 2004,
- *PSNI Ethics and Practice Guide (Part 1)*: where the legal requirements are detailed.

- 3.1.1 Prescriptions should never be left blank if signed. Prescriptions should not be signed until they are completed.
- 3.1.2 Computer-generated prescriptions should be used, providing the necessary software and training in its use is available. Handwritten prescriptions should be written legibly.
- 3.1.3 The pharmacist should ensure that his prescriber details are correct on the prescription. The prescription must be annotated with an appropriate strap line (Pharmacist Independent/Supplementary Prescriber) and bear

the unique cipher number of the pharmacist prescriber. (Refer to “*Guidance for Non-Medical Prescribing within GP Practices*” (DHSSPS) (November 2008).

All pharmacist prescribers are recommended to prescribe generically except where this would not be clinically appropriate (in line with local guidance) or where there is no approved generic name. Local formularies should be adhered to where applicable.

For computer generated prescriptions, the pharmacist needs to ensure he is registered with the Business Services Organisation<sup>4</sup> formerly the Central Services Agency (CSA) in order to prescribe from a medical practice’s system. This will prevent incorrect allocation of prescribing budgets and incorrect COMPASS data being generated.

## 3.2 SECURITY AND SAFE HANDLING OF PRESCRIPTION FORMS

3.2.1 The pharmacist is responsible for the safety of the prescription pad and is minded to adhere to the practice’s prescription security protocol. The pharmacist should:

- not leave prescription pads unattended, in full view of patients and/or others within the practice;
- take all reasonable precautions to prevent loss or inappropriate use of the prescription pad;
- use only one prescription pad at a time;
- keep a record of the first and last serial number of prescriptions in pads issued to him.

3.2.2 It is good practice to record the serial number of the first and last remaining prescription form of an in-use pad at the beginning and end of each working day. This would help to identify any forms lost or stolen overnight. If a prescription pad is lost, mislaid or stolen this should be reported immediately to the employing practice or contractor and the local policy should be followed. Refer to the *HSC Board’s Policy on Prescription Security*.

### 3.3 GUIDANCE ON PRESCRIBING CONTROLLED DRUGS (CDS)

A SP may prescribe a CD as part of a CMP. An IP, however, can not prescribe any CD including Schedule 5 CDs.

3.3.1 The pharmacist may prescribe CDs only where he is legally entitled to do so.

3.3.2 It is strongly recommended, as good practice, that the quantity of any CDs prescribed, excluding those in Schedule 5, should not exceed 30 days of clinical need per prescription. If more than 30 days supply is made, the reason for this should be noted in the patient's notes.

3.3.3 The pharmacist may use computer-generated prescriptions for all CDs, providing the necessary software is in place and there is an audit trail of his prescribing practice.

Please note: All CD prescriptions for Schedule 2, 3 and 4 CDs are only valid for 28 days from the date of signing or appropriate start date specified on the prescription.

The Department of Health website has the most up to date information on the management and use of controlled drugs and it can be accessed at:

<http://www.dhsspsni.gov.uk/index/pas/pas-controlled-drugs>.

Please refer to the most up to date guidance to keep abreast of all the relevant legislative requirements at: <http://www.opsi.gov.uk/legislation>.

### 3.4 GUIDANCE ON PRESCRIBING UNLICENSED MEDICINES

Unlicensed medicines are those medicines without a current UK marketing authorisation. **Independent pharmacist prescribers are not legally permitted to prescribe unlicensed medicines.**

The pharmacist may prescribe an unlicensed medicine as a supplementary prescriber as part of a CMP providing:

- the doctor or dentist and the pharmacist prescriber, acting as a supplementary prescriber, have agreed the plan with the patient in a voluntary relationship;
- the pharmacist is satisfied an alternative licensed medicine would not meet the patient's needs;
- the pharmacist is satisfied there is a sufficient evidence base and/or experience to demonstrate the medicine's safety and efficacy for that particular patient;

- the doctor/dentist and the pharmacist are prepared to take the responsibility for prescribing the unlicensed medicine and have agreed the patient's CMP to that effect;
- the patient agrees to a prescription in the knowledge that the medicine is unlicensed and understands the implications of this;
- the medication chosen and the reason for choosing it, is documented in the CMP/clinical records.

### 3.5 GUIDANCE ON PRESCRIBING MEDICINES FOR USE OUTSIDE THE TERMS OF THEIR LICENCE ('OFF-LABEL')

'Off-label' prescribing is where a licensed medicine is prescribed outside the terms of its license. (See paragraph 2.1.8).

It is possible, under current legislation, for pharmacist prescribers (both independent and supplementary) to prescribe '*off-label*'. However, in order to do so the pharmacist should ensure that the following conditions are met:

- the pharmacist is satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy in these circumstances. Where the manufacturer's information is of limited help, the necessary information should be sought from another source;
- the pharmacist has explained to the patient or parent or carer in broad terms, the reasons why medicines are not licensed for their proposed use;
- the pharmacist makes a clear, accurate and legible record of all medicines prescribed for the patient and the reasons for prescribing a medicine '*off-label*';
- the pharmacist may also, as a supplementary prescriber, prescribe a medicine for use outside the terms of its license providing:
  - \* there is a CMP in place, written in conjunction with a doctor or dentist and in voluntary partnership with the patient or parent or carer;
  - \* a doctor or dentist and the pharmacist prescriber take responsibility for prescribing the medicine and jointly oversee the patient's care, monitor the situation or outcome and ensure any follow up treatment is given as required.

Any verbal information given to a patient or his/her representative should be supported by written information provided by the pharmacist prescriber.

## 3.6 GUIDANCE ON REPEAT DISPENSING (RD)

### DEFINITIONS

**REPEAT PRESCRIBING** is a partnership between patient and prescriber that allows the prescriber to authorise a prescription so it can be repeatedly issued at agreed intervals, without the patient having to consult the prescriber each time<sup>5</sup>.

**REPEAT DISPENSING (RD)** is the process by which patients with long-term medical conditions can obtain repeat supplies of their medicines over a defined period of time from a pharmacy of their choice, without the need to contact their prescriber on each occasion a new supply is needed<sup>6</sup>.

Repeat dispensing (RD) should only be offered to patients for whom it is appropriate, such as those with chronic conditions who are likely to remain stable for the duration of the dispensing period and who take stable, long term medication. Patients on a large number of medicines or who are likely to be hospitalised may be less suited to inclusion in a repeat dispensing scheme. Following a review of the patient's medication, the pharmacist prescriber issues the patient with a Repeatable Prescription (RA) and an accompanying set of Batch Issues (RD) on standard HS21 prescription forms for the patient's repeat medicines.

([http://www.centuralservicesagency.com/files/rd\\_sheme\\_information/file/Repeat%20Dispensing%20Guidance%202008.pdf](http://www.centuralservicesagency.com/files/rd_sheme_information/file/Repeat%20Dispensing%20Guidance%202008.pdf).)

3.6.1 A pharmacist prescriber may issue a repeat dispensing prescription.

3.6.2 Patients must give consent to be included in a repeat dispensing scheme.

The pharmacist prescriber should be satisfied that patients understand the implications for confidentiality as well as the clinical and practical effects of inclusion.

3.6.3 Before signing a repeat dispensing prescription the pharmacist needs to be satisfied that it is safe and appropriate to do so and that secure procedures are in place to ensure that:

- the patient is issued with the correct prescription;
- each prescription is regularly reviewed and is re-issued only to meet clinical need;

<sup>5</sup> Saving time, helping patients: A good practice guide to quality repeat prescribing, Repeat Prescribing Service Improvement Guide, and Dispensing with Repeats. The National Prescribing Centre for England.

<sup>6</sup> Northern Ireland Repeat Dispensing Guidance. DHSSPSNI July 2008.

- a medication review takes place sometime within 12 months of the repeat prescription being issued, in keeping with the practice's repeat prescribing protocol: provided the prescriber is satisfied the patient's condition is stable and that he/she is knowledgeable about his/her condition;
- the correct dose and quantity is prescribed;
- the patient's condition is monitored; and
- further examination or assessment of the patient takes place as necessary.

### 3.7 GUIDANCE ON REMOTE PRESCRIBING VIA TELEPHONE, EMAIL, FAX, VIDEO-LINK OR WEBSITE

In certain circumstances, it may be necessary to use a telephone or other non face-to-face medium to prescribe medicines and treatments for patients.

Remote prescribing presents particular risks in ensuring that the prescription is:

- transferred accurately;
- understood by the person receiving the prescription remotely; and
- that checks are conducted to confirm the identity of the patient.

Where prescribing is by telephone, for example, to inform a patient of a dose change, a 'read-back' mechanism should be employed to ensure the information has been understood. Remote prescribing should only be used where necessary in exceptional circumstances and not for convenience.

Appendix 2 of this document is taken from the distance learning material entitled, "*Medicines Governance: Improving Patient Safety*". This distance learning material is available from [www.nicpld.org](http://www.nicpld.org) and details protocols for secondary care on:

- good practice in the transfer of information about a patient's existing prescribed medication by telephone; and
- good practice in giving patients and carers information, by telephone, about a change in the dose of prescribed medication.

There are no similar protocols available for primary care at time of print.

Such situations may occur where the pharmacist:

- has responsibility for the care of the patient;
- is providing out-of-hours or urgent care services;
- is working in remote and/or rural areas;

- has prior knowledge and understanding of the patient's condition and medical history;
- has authority to access the patient's records and he is working as a supplementary prescriber, but the doctor or dentist required to authorise the CMP works at a distance.

The pharmacist should carry out an adequate risk assessment for each individual case of remote prescribing. Records of remote prescribing, including the reasons for prescribing in this manner, should be made.

If remote prescribing is necessary, clear protocols for operating remote prescribing must be agreed with employers.

The pharmacist must not give directions verbally to other professionals to administer medicines. All directions to administer medicines must be in writing and in line with the Nursing and Midwifery Council Standards for Medicines Management (November 2008).

[http://www.nmc-uk.org/aFrameDisplay.aspx? DocumentID=221](http://www.nmc-uk.org/aFrameDisplay.aspx?DocumentID=221)

### 3.8 GUIDANCE ON REPORTING ADVERSE REACTIONS

The same guidance on reporting adverse reactions applies to pharmacist prescribers as to pharmacists generally. **Remember, if in doubt, report adverse drug reactions.**

- Where appropriate, if a patient experiences an adverse reaction to a medication he/she has been prescribed the pharmacist should record this in the patient's notes, notify the prescriber if he did not prescribe the medicine and notify the Medicines and Healthcare products Regulatory Agency (MHRA) and Commission on Human Medicines (CHM) via the Yellow Card Scheme<sup>7</sup> immediately. Yellow cards are found in the back of the British National Formulary or online at: [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) or alternatively free-phone 0800 7316789.
- In addition, the pharmacist has a duty to inform the patient that he/she may also report an adverse reaction independently under the Yellow Card Scheme.
- Any untoward incidents should be reported to the National Reporting and Learning System which is the reporting system of the National Patient Safety Agency (NPSA) directly at: <http://npsa.nhs.uk/health/reporting>.

<sup>7</sup> The Yellow Card Scheme is run by the MHRA and CHM. The scheme is used to collect information from health professionals and patients on suspected adverse drug reactions (ADRs).

- Local reporting schemes may be in place: either via the HSC Trust, HSC Board, head office of a multiple or pharmacy company etc.

### 3.9 GUIDANCE ON REPORTING MEDICATION INCIDENTS

A medication incident is a preventable medication-related or undesirable unintended event that led or could have led to patient harm, loss or damage. This definition encompasses 'near-misses', that is, those medication-related occurrences where the patient did not suffer harm, but there was the potential for harm, loss or damage.

Medication incidents can occur in any step of the medicines use process, including prescribing, dispensing and administration of medicines as well as in the transfer of medicines related information.

Following an incident the focus is on 'what went wrong' rather than 'who went wrong'. This does not mean staff are not accountable for their actions but it is recognised that individuals can and do make mistakes.

If a medication incident has occurred:

- a) look after the patient and ensure that they receive appropriate treatment (if required);
- b) analyse what was the root cause of the error/incident;
- c) report the incident so that others can learn;
- d) incidents should be documented and learning points should be taken and implemented.

Procedures for medication incident reporting are well established within the secondary care setting. Refer to the HSC Trust's 'Incident reporting policy' and 'Procedures for the Investigation and Root Cause Analysis of Incidents, Complaints and Claims.' Similar procedures will be developed for primary care in future.

However, disciplinary action may be required in certain circumstances, for example, where the intention was to cause harm or where there are repeated, unreported errors or violations.

Serious adverse incidents within the HPSS should be reported to the Department in line with the procedure outlined in the circular, <http://www.dhsspsni.gov.uk/hsspmm05-05.pdf>.

## GUIDANCE THAT SUPPORTS THIS DOCUMENT

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

- Code of Ethics for pharmacists,
- Professional Standards and Guidance for the Sale and Supply of medicines,
- Guidance for Pharmacists on Raising Concerns
- Professional Standards and Guidance for Patient Consent,
- Professional Standards and Guidance for Patient Confidentiality,
- Pharmacist Prescribers pack,
- Clinical governance framework for pharmacist prescribers and organisations commissioning or participating in pharmacist prescribing.

These documents can be downloaded as well as more copies of this guidance from the Society's website ([www.psni.org.uk](http://www.psni.org.uk)) or telephone on 02890 326 927 for a hard copy(ies).

## ACKNOWLEDGEMENT

RPSGB

Department of Health, Social Services and Public Safety

## ADDITIONAL RESOURCES

- Improving Patients' Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the HPSS in Northern Ireland (December 2006). <http://www.dhsspsni.gov.uk>
- Department of Health information on non-medical prescribing <http://www.dh.gov.uk>
- Department of Health, Social Services and Public Safety: 'The Use and Control of Medicines' (April 2004)
- Drugs and Therapeutics Bulletin on non-medical prescribing [www.npc.co.uk](http://www.npc.co.uk)
- Maintaining competency in prescribing: an outline framework for pharmacist prescribers [http://www.npc.co.uk/pdf/pharmacist\\_comp\\_framework\\_Oct06.pdf](http://www.npc.co.uk/pdf/pharmacist_comp_framework_Oct06.pdf)
- Medicines Matters DOH July 06 – A guide to mechanisms for the prescribing, supply and administration of medicines [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_064325](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064325)
- National Prescribing Centre: A guide to good practice in the management of controlled drugs in primary care (England) – Second Edition

- [http://www.npc.co.uk/controlled\\_drugs/cdpublications.htm](http://www.npc.co.uk/controlled_drugs/cdpublications.htm)
- NHS Scotland National Education Scotland: Supplementary prescribing for pharmacists in Scotland <http://www.nes.scot.nhs.uk/pharmacy/prescribing/>
- Nursing and Midwifery Council Standards for Medicines Management <http://www.nmcuk.org/aFrameDisplay.aspx?DocumentID=221>
- Nursing and Midwifery Council prescribing standards <http://www.nmcuk.org/aFrameDisplay.aspx?DocumentID=1645>
- Patient Group Directions: A guide to good practice <http://www.npc.co.uk/publications/pgd/pgd.htm>
- Saving time, helping patients: a good practice guide to quality repeat prescribing [http://www.npc.co.uk/repeat\\_prescribing/repeat\\_presc.htm](http://www.npc.co.uk/repeat_prescribing/repeat_presc.htm)
- Scottish Executive Health Department HDL 2004 35: Implementation of supplementary prescribing for pharmacists <http://www.scotland.gov.uk/Publications/2004/06/19514/39164>

#### USEFUL WEBSITES:

- The Department of Health Social Services and Public Services [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)
- Central Service Agency (replaced by Business Services Organisation in April 2009) [www.centralserviceagency.com](http://www.centralserviceagency.com)
- The Department of Health [www.dh.gov.uk](http://www.dh.gov.uk)
- The National Prescribing Centre [www.npc.co.uk](http://www.npc.co.uk)
- The Medicines and Healthcare products Regulatory Agency [www.mhra.gov.uk](http://www.mhra.gov.uk)
- The National Patient Safety Agency [www.npsa.nhs.uk](http://www.npsa.nhs.uk)
- The Royal Pharmaceutical Society of Great Britain [www.rpsgb.org.uk](http://www.rpsgb.org.uk)
- Northern Ireland Centre for Pharmacy Learning and Development [www.nicpld.org](http://www.nicpld.org)
- Queens University Belfast [www.qub.ac.uk](http://www.qub.ac.uk)
- University of Ulster [www.ulster.ac.uk](http://www.ulster.ac.uk)
- Office of Public Sector Information (Part of National Archives) [www.opsi.gov.uk/legislation/](http://www.opsi.gov.uk/legislation/)

## APPENDIX 1

### PRESCRIBING MEDICINES FOR USE OUTSIDE THE TERMS OF THEIR LICENSE ('OFF-LABEL')

Although there are a number of circumstances in which this may arise, it is most likely to occur in prescribing for children. Currently pharmaceutical companies do not usually test their medicines on children and as a consequence, cannot apply to license their medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary in paediatric practice.

When prescribing a medicine for use outside the terms of its license the prescriber must:

- be satisfied that it would better serve the patient's needs than an appropriately licensed alternative;
- be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy. The manufacturer's information may be of limited help in which case the necessary information must be sought from other sources;
- take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or arrange for another independent prescriber to do so;
- make a clear, accurate and legible record of all medicines prescribed and, where not following common practice, reasons for prescribing the medicine.

## APPENDIX 2

### MEDICINES GOVERNANCE TEAM: PROTOCOL FOR GOOD PRACTICE IN THE TRANSFER OF INFORMATION ABOUT A PATIENT'S EXISTING PRESCRIBED MEDICATION BY TELEPHONE (HOSPITAL-BASED).

#### INTRODUCTION

There is significant risk to patients from poor verbal communication of medicines information where it relates to a patient's existing prescribed medication, particularly where this occurs by telephone. While every effort should be made to ensure this information is transferred safely in a written format, there may be circumstances where verbal transfer by telephone is

unavoidable or necessary to clarify written information. The verbal transfer may occur between different staff groups, staff and patients, within and between HPSS organisations.

This protocol is designed to outline good practice for all HSC Trust staff involved in the transfer of verbal information by telephone about a patient's existing prescribed medication.

This protocol is not designed to cover verbal prescriptions or verbal amendments to prescriptions, for which Trusts should provide clear protocols for staff based on the guidelines outlined in *'The Use and Control of Medicines'* (April 2004).

Every attempt must have been made to safely transfer information about a patient's existing prescribed medicines in a written format according to HPSS protocols, before attempting verbal transfer of information by telephone.

### **REQUESTING INFORMATION**

On contacting another staff member to request verbal information by telephone about a patient's existing medicines:

- ensure that in the process of requesting information, you do not reveal any other information about the patient or their condition to the other member of staff that is not necessary for the purposes of the information request,
- inform the other staff member of your name, designation and reason for calling,
- confirm that the person you are speaking to is authorised to provide or receive the information and document their name and designation,
- confirm the patient's identity by giving the other staff member the patient's full name and details but ensuring that you retain one piece of information that you will ask them to provide as full confirmation of the patient's identity, for example, date of birth, address or hospital number,
- request the information about the patient's existing prescribed medication and where required, ensure that the full medicine name, strength, form, dose, directions, quantity supplied, date of last issue and allergy history is specified,
- ensure that the information about the patient's existing prescribed medicines is current and up to date,

- if you are unsure of the medicine name, ask for it to be spelt out in full,
- read back this information to the other member of staff to confirm accuracy, ensuring that any abbreviations are spoken in full, for example, repeat 'tid' as 'three times daily',
- document this information and any other relevant information in the patient's case notes,
- document the date and time of the telephone call,
- take time to question whether the information received makes sense for the patient,
- ensure that the information received is brought to the attention of all relevant staff,
- the verbal transfer of information should be followed within 24 hours with written information where possible. You must take steps to ensure this is reviewed to confirm that the verbal transfer has taken place correctly.

### PROVIDING INFORMATION

If you are providing information about a patient's existing medication by telephone to another member of staff:

- expect to follow the steps in this protocol,
- document the information you have given and who you have given the information to.

## MEDICINES GOVERNANCE TEAM: PROTOCOL FOR GOOD PRACTICE IN GIVING PATIENTS OR CARERS INFORMATION, BY TELEPHONE, ABOUT A CHANGE IN THE DOSE OF PRESCRIBED MEDICATION.

### INTRODUCTION

This protocol is designed to outline good practice for all HSC Trust staff involved in transfer of verbal information by telephone to a patient or carer about dose changes to a patient's prescribed medication.

This is an important area of risk, where patients receive medicines with individualised doses that are subject to change. This can be for medicines such as warfarin or ciclosporin where the dose is dependent on the patient's therapeutic response or drug monitoring.

Every effort should be made to transfer information about the dose safely using a written format, before attempting to transfer the information verbally.

On contacting the patient or carer about a patient's dose:

- ensure that in the process of providing information, you do not reveal any other information about the patient or their condition that is not necessary for the purposes of the providing the information,
- inform the patient or carer of your name, designation, location and reason for calling,
- confirm that the person you are speaking to is authorised to receive the information, either the patient or a nominated carer,
- document the name of the person receiving the information and whether they are the patient or carer,
- confirm the patient's identity by giving the other person the patient's full name and details but ensuring that you retain at least one piece of information that you will ask them to provide as full confirmation of the patient's identity, for example date of birth, address or hospital number,
- confirm the strength(s) of medicine supplies available to the patient,
- provide the dose information using simple language, avoiding the use of jargon or abbreviations and taking account of the strengths of medicine that the patient has available,
- where liquid medicines are involved, particular care should be taken to avoid confusion between different dose units, for example 'mg' and 'ml',
- encourage the patient/carer to document the dose, for example, in their anticoagulant therapy record,
- ask the patient/carer to repeat the dose back to you as confirmation of the dose that will be taken or administered,
- document this information and any other relevant information in the patient's case notes,
- document the date and time of the telephone call.

