

# **Consultation on Standards and Guidance for pharmacist prescribers**

Draft standards, guidance and  
consultation questions

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## **About the Pharmaceutical Society of Northern Ireland**

The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists in Northern Ireland.

Our primary purpose is to ensure that practising pharmacists in Northern Ireland are fit to practise, keep their skills and knowledge up to date and deliver high quality safe care to patients.

It is the organisation's responsibility to protect and maintain public safety in pharmacy by:

- Setting and promoting standards for pharmacists' admission to the register and for remaining on the register;
- Maintaining a publicly accessible register of pharmacists, and pharmacy premises;
- Handling concerns about the Fitness to Practise of registrants, acting as a complaints portal and taking action to protect the public; and
- Ensuring high standards of education and training for pharmacists in Northern Ireland.

The Pharmaceutical Society of Northern Ireland's governing legislation is the Pharmacy (Northern Ireland) Order 1976 which sets out its powers and responsibilities.

On 1 October 2012 the enactment of the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 and its associated regulations, brought additional fitness to practise sanctions, statutory CPD and a new appointed Council with 50% lay and 50% registrant membership.

## **Consultation summary and background**

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The Pharmaceutical Society of Northern Ireland '*Standards and Guidance for Pharmacist Prescribers*' which have been in place since 2009, have now been revised and we are seeking your views on the updated document.

The updated standards and guidance provides more specific information around different areas of practice such as, the new guidance on mixing medicines, and also ensures currency with legislative changes in the UK and Northern Ireland. Changes to the Misuse of Drugs Regulations (Northern Ireland) 2012, now allows pharmacists<sup>1</sup> who have successfully completed a pharmacist independent prescribing course and accredited by the Pharmaceutical Society of Northern Ireland, to prescribe controlled drugs.

This document also 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 imposed by the Pharmaceutical Society of Northern Ireland and its members.

The Code of Ethics of the Pharmaceutical Society of Northern Ireland 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>2</sup> to apply these principles to daily work situations, using his professional judgement.

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).

All pharmacists should be familiar with these standards and understand that they have a professional responsibility to raise concerns if they believe the standards are not being met by an independent prescriber known to them.

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.

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<sup>1</sup> There are currently 136 independent pharmacist prescribers registered with the Pharmaceutical Society of Northern Ireland.

<sup>2</sup> 'Pharmacist' will appear with the male pronoun but should be understood to mean the male/female gender.

## **Legislative context**

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The main legislation that enables pharmacists to prescribe medicinal products for human use is the Prescription Only Medicines (Human Use) Order 1997, as amended and the Medicines (Pharmacy and General Sale – Exemption) Order 1980 as amended in 2005.

Pharmacists gained the right to achieve supplementary prescribing status in 2003 and independent prescribing status in 2006. Legislation allows qualified pharmacist supplementary prescribers to prescribe any medicine, including controlled drugs, for any medical condition within their competence.

The scope of supplementary prescribing is an issue to be agreed in the patient's clinical management plan and will be for the judgement of the independent prescriber.

Legislation also allows qualified pharmacist independent prescribers to prescribe any medicine for any medical condition, within their competence, with the exception of all controlled drugs.

Amendments to the Misuse of Drugs Regulations (Northern Ireland)<sup>3</sup> in May 2012, have introduced a number of changes to the professional use of controlled drugs by pharmacist and nurse independent prescribers.

Pharmacists<sup>4</sup> who have successfully completed a pharmacist independent prescribing course and accredited by the Pharmaceutical Society of Northern Ireland, can now prescribe any licensed medicines for any medical condition including; Schedule 2, 3, 4 and 5 Controlled Drugs, this extends to diamorphine, dipipanone or cocaine for treating organic disease or injury.<sup>5</sup>

For ease of reading, throughout this document; 'his' – masculine pronoun is understood to refer to male/female gender.

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<sup>3</sup> [http://www.dhsspsni.gov.uk/circular\\_the\\_misuse\\_of\\_drugs\\_amendment\\_regulations\\_northern\\_ireland\\_2012.pdf](http://www.dhsspsni.gov.uk/circular_the_misuse_of_drugs_amendment_regulations_northern_ireland_2012.pdf)

<sup>4</sup> There are currently 136 independent pharmacist prescribers registered with the Pharmaceutical Society of Northern Ireland.

<sup>5</sup> Pharmacist Independent prescribers must only ever prescribe within their own sphere of competency.

## **How to respond to this consultation**

We welcome your response to this consultation and have listed some questions to assist you. In order to help us analyse responses, we would strongly encourage you to complete the response template at Appendix A.

The questions are not designed to be exhaustive and we would welcome your views and comments on any part of the document. For ease of reference, the Draft Standards and Guidance and the relevant questions are presented together.

Responses should be sent by post, fax or e-mail to:

Standards and Guidance for Pharmacist Prescribers consultation  
Pharmaceutical Society of Northern Ireland  
73 University Street  
Belfast, BT7 1HL

Tel: 028 9026 7933

Fax: 028 9043 9919

E-mail: Michelle McCorry, consultation coordinator [michelle.mccorry@psni.org.uk](mailto:michelle.mccorry@psni.org.uk)

### **Accessibility of information**

If you are having difficulties accessing the documentation or you need us to make adjustments in order to be able to respond to this consultation, please contact us and we will do our best to address the issue.

If you wish your response to remain confidential, the Pharmaceutical Society NI will generally respect that request. However, the information you provide may be subject to disclosure under the Freedom of Information Act 2000 which gives the public a right of access to any information held by a public authority.

### **Consultation period**

The consultation runs for a period of 8 weeks from 23 October 2012 to 18 December 2012. We will analyse the consultation responses and produce a summary report. Decisions on any changes will be announced following decisions by Council, with a view to publishing the final Standards and Guidance in 2013.

## **1. Pharmacist prescribers**

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### **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, practice circumstances and the medicines which they plan to prescribe. The pharmacist may practise solely in one practice mode or move between modes according to patient or practice circumstances.

### **Definitions**

#### **Independent Prescribing**

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

#### **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.

#### **Other methods for supplying and administering medicines**

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 circumstances.

## 1.2 Working within requirements

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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 or the General Pharmaceutical Council (GPhC). His name must be annotated in the Pharmaceutical Society NI'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;
- The pharmacist must only prescribe within their own level of experience and sphere of competence.

### Clinical governance framework<sup>6</sup>

Clinical and social care governance<sup>7</sup> is the system through which the Health and Social Care (HSC) 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 prescribing is included within their overall clinical governance framework to ensure that pharmacists practice safely and competently. Where the independent pharmacist prescriber is self-employed, the clinical governance framework should be reviewed by another independent prescriber from within or out-with the employing organisation. Refer to the HSC Board or Trust for guidance.

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<sup>6</sup> <http://www.nicpld.org/news/prescribing/clincgovframeworkpharm.pdf>

<sup>7</sup> DHSSPS Improving Patients' Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the HPSS in Northern Ireland' (2006) [http://www.dhsspsni.gov.uk/improving\\_patients\\_access\\_to\\_medicines\\_-\\_december\\_2006.pdf](http://www.dhsspsni.gov.uk/improving_patients_access_to_medicines_-_december_2006.pdf) Chapter 6 p22-23



## Competencies

The pharmacist must attain and maintain competencies specific to his role as a prescriber. The main competencies required have been outlined in the National Prescribing Centre (NPC) document – ‘Maintaining Competency in Prescribing: An outline framework to help pharmacist prescribers’<sup>8</sup>.

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.

## Private Practice

All pharmacists who prescribe privately must also follow the standards and guidance outlined in this document as well as Department of Health guidance (Refer to: ‘*The Responsibilities of non medical practitioners intending to prescribe on a private basis*’ (DHSSPS, 16 June 2012)<sup>9</sup>. Pharmacist prescribers should only prescribe within their sphere of competency. It is the responsibility of the pharmacist prescriber to ensure that appropriate arrangements for good governance are in place<sup>10</sup>.

## Liability and indemnity arrangements

The Pharmaceutical Society NI 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 HSC Trust has approved pharmacist prescribing at an appropriate level within the organisation e.g. Trust Board, and that this acquiescence has been recorded in the minutes of that meeting. The job description for a pharmacist should also be amended to describe the scope of his prescribing activities.

## 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 (prescription only medicine – veterinarians) in accordance with the current Veterinary Medicines Regulations.

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<sup>8</sup> [http://www.npc.nhs.uk/non\\_medical/resources/competency\\_framework\\_oct\\_2006.pdf](http://www.npc.nhs.uk/non_medical/resources/competency_framework_oct_2006.pdf) Please note: From 1 April 2011, the National Institute for Health and Clinical Excellence (NICE) took over the function of the National Prescribing Centre.

<sup>9</sup> <http://www.dhsspsni.gov.uk/index/pas/non-medical-prescribing.htm>

<sup>10</sup> [http://www.dhsspsni.gov.uk/improving\\_patients\\_access\\_to\\_medicines\\_-\\_december\\_2006.pdf](http://www.dhsspsni.gov.uk/improving_patients_access_to_medicines_-_december_2006.pdf) page 23

## Pharmacist Prescribers

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1. Are the definitions of the types of pharmacist prescribers sufficient and clearly understood?

Yes

no

not sure

If no, how can we improve the definitions?

2. Do you have any comments on section 1.2 'Working within requirements'?

Yes

no

not sure

Please add further comments

## **2. Standards and guidance for pharmacist prescribers**

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The Code of Ethics of the Pharmaceutical Society NI sets out eight mandatory principles of ethical practice which a pharmacist must follow.

### **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.

The 'Standards and Guidance for pharmacist prescribers' elaborates on the principles of the Code of Ethics<sup>11</sup> for the purpose of explaining the pharmacist's responsibilities as a supplementary or independent prescriber.

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<sup>11</sup> Pharmaceutical Society NI 'Code of Ethics' (June 2009):  
<http://www.psnl.org.uk/documents/312/Code+of+Ethics+for+Pharmacists+in+Northern+Ireland.pdf>

## **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. Any equipment used must undergo appropriate regular and appropriate quality assurance checks.
- 2.1.7 The pharmacist must ensure that an adequate risk 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<sup>12</sup>.

The pharmacist 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 prescribing unlicensed medicines patient consent must be obtained (see **section 3.3 and 3.4** of document).

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<sup>12</sup> Further information on 'off label prescribing' is available at the GMC website: [http://www.gmc-uk.org/guidance/ethical\\_guidance/prescriptions\\_faqs.asp#10](http://www.gmc-uk.org/guidance/ethical_guidance/prescriptions_faqs.asp#10)

- 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. These records should be maintained for periods of time as set out in the procedures in operation in your area of practice (e.g. GP surgery/Hospital Trust, registered pharmacy)<sup>13</sup>.
- 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 Use and Control of Medicines<sup>14</sup> and other sources (see Section 3.1).
- 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 clinical guidelines, for example, NICE, GAIN<sup>15</sup> and prescribing guidelines issued by the Department of Health, Social Services and Public Safety/HSC Medicines Management Forum.

#### 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:
  - ✓ medications initiated for a patient;
  - ✓ any other concurrent medication including OTCs; or
  - ✓ medications for conditions within his sphere of competence.

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 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.

<sup>13</sup> General guidance on record keeping can be found in the DHSSPS document, 'Good Management, Good Records'.

<sup>14</sup> [http://www.dhsspsni.gov.uk/pas-use\\_and\\_control\\_of\\_medicines](http://www.dhsspsni.gov.uk/pas-use_and_control_of_medicines)

<sup>15</sup> In August 2007 RMAG, NIRAAC and CREST became the Guidelines and Audit Implementation Network (GAIN) For more information on GAIN see [www.gain-ni.org](http://www.gain-ni.org)

**Make the safety and welfare of patients your prime concern**

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3. Are the standards in section 2.1 easy to read and understand?

Yes  no  not sure

If no, how can we improve them?

3.1 Is the 'Good practice guidance' in section 2.1 (page 13) sufficiently clear?

Very clear  clear  unclear  very unclear

Please state which parts of the guidance are unclear and suggest how they could be made clearer

## 2.2 Respect and protect confidential information

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### Standards

- 2.2.1 The pharmacist must gain a 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 the Pharmaceutical Society of Northern Ireland's *Standards and Guidance for Patient Consent*)<sup>16</sup>
- 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.

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<sup>16</sup> Pharmaceutical Society of Northern Ireland 'Professional Standards And Guidance For Patient Consent'  
<http://www.psni.org.uk/documents/318/Standards+on+Patient+Consent.pdf>

## **Respect and protect confidential information**

4. Are the standards in section 2.2 easy to read and understand?

Yes

no

not sure

If no, how can we improve them?



## 2.3 Show respect for others

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### 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 (See Principle 3 and related obligations in the Code of Ethics<sup>17</sup>)
- 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 the Pharmaceutical Society of Northern Ireland's *Standards and Guidance for Patient Consent*<sup>18</sup>)
- 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 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 and where possible, for the purpose of good record keeping, this should be in written form.

### Please note

A common prescribing record does not communicate prescribing actions from a hospital admission or an out-patient episode. These would ordinarily be communicated on a discharge summary or an outpatient 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 treatment. Always refer to the patient's GP where appropriate.

For more information on consent refer to the Pharmaceutical Society of Northern Ireland's '*Professional Standards and Guidance for Patient Consent*' and refer to the DHSSPS Reference Guide for Consent for examination, treatment or care (2003)  
<http://www.dhsspsni.gov.uk/consent-referenceguide.pdf>

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<sup>17</sup> Pharmaceutical Society of Northern Ireland '*Code of Ethics*' (2009)

<http://www.psni.org.uk/documents/312/Code+of+Ethics+for+Pharmacists+in+Northern+Ireland.pdf>

<sup>18</sup> Pharmaceutical Society of Northern Ireland '*Professional Standards and Guidance for Patient Consent*'

<http://www.psni.org.uk/documents/318/Standards+on+Patient+Consent.pdf>

## **Show respect for others**

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5. Are the standards in section 2.3 easy to read and understand?

Yes

no

not sure

If no, how can we improve them?

## 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 (BNF) and the British National Formulary for Children (BNFC), which contain essential information to help him prescribe, monitor, supply and administer medicines (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 (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 limited.

In these circumstances there may not be any evidence available for the medicines prescribed and decisions about medicines supplied should be based on authoritative clinical guidance. Good practice is to include clear details of these instances in the CMP/treatment plan as appropriate.

**Exercise your professional judgement in the interests of patients and public**

6. Are the standards in section 2.4 easy to read and understand?

Yes  no  not sure

If no, how can we improve them?

6.1 Is the 'Good practice guidance' in section 2.4 (page 19) sufficiently clear?

Very clear  clear  unclear  very unclear

Please state which parts of the guidance are unclear and suggest how they could be made clearer

## 2.5 Encourage patients (and 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 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 (See Principle 3 of the Code of Ethics<sup>19</sup> and related obligations).

#### Good Practice Guidance

The National Prescribing Centre (NPC) has produced the following document which may be used as a tool for shared decision making with patients: 'A Single Competency Framework for all prescribers'. (May 2012)<sup>20</sup>

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.

<sup>19</sup> Pharmaceutical Society of Northern Ireland 'Code of Ethics' (2009)

<http://www.psnj.org.uk/documents/312/Code+of+Ethics+for+Pharmacists+in+Northern+Ireland.pdf>

<sup>20</sup> [http://www.npc.co.uk/improving\\_safety/improving\\_quality/resources/single\\_comp\\_framework.pdf](http://www.npc.co.uk/improving_safety/improving_quality/resources/single_comp_framework.pdf)

**Encourage patients (and their carers as appropriate) to participate in decisions about their care**

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7. Are the standards and guidance in section 2.5 easy to read and understand?

Yes

no

not sure

If no, how can we improve them?

## **2.6 Maintain and develop professional knowledge and competence**

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### **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. The pharmacist must resist any pressure from patients or other health professionals to do otherwise.
- 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 expertise and competence required for that new role. The pharmacist may require 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 successfully completing the accredited educational course<sup>21</sup> 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 as well as the therapeutic areas in which the pharmacist prescribes.

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<sup>21</sup><http://www.nicpld.org/courses/nonMed/index.asp>

**Maintain and develop professional knowledge and competence**

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8. Are the standards in section 2.6 easy to read and understand?

Yes

no

not sure

If no, how can we improve them?



## 2.7 Act with honesty and integrity

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### 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 must not both prescribe and dispense medicines except in exceptional circumstances e.g. 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 cost effectiveness. A pharmacist prescriber should act solely in the patient's interest, any decision to prescribe must not be based on potentially biased information, fraud or commercial gain.
- 2.7.5 In such circumstances where there may be a perceived conflict of interest the pharmacist must record a declaration of interest, which he must produce on request if required for audit purposes. 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 the Pharmaceutical Society of Northern Ireland's 'Guidance for Pharmacists on Raising Concerns'<sup>22</sup>)

#### 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<sup>23</sup> for the Pharmaceutical Industry sets standards for the advertising and the provision of information to the public about prescription only medicines.
- 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 prescriber's prescription, details of the person who made the change should be clearly documented on the prescription and the change documented on the patient's record.

<sup>22</sup> <http://www.psn.org.uk/documents/314/Guidance+on+Raising+Concerns.pdf>

<sup>23</sup> <http://www.pmcpa.org.uk/?q=getcopiesofcode>

**Act with honesty and integrity**

---

9. Are the standards in section 2.7 easy to read and understand?

Yes

no

not sure

If no, how can we improve them?

9.1 Is the 'Good practice guidance' in section 2.7 (page 26) sufficiently clear?

Very clear

clear

unclear

very unclear

Please state which parts of the guidance are unclear and suggest how they could be made clearer

## **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 full scope of his prescribing practice regardless of whether he prescribes within or outside the Health Service.
- 2.8.4 The pharmacist who works in the NHS and/or private practice must ensure that he is working in accordance with all relevant legislation, professional and regulatory standards and national or local clinical governance frameworks<sup>24</sup>.
- 2.8.5 The pharmacist has a responsibility to prescribe rationally and cost-effectively.<sup>25</sup>

### **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. Health Board, 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.
- Where the pharmacist prescriber is working outside the Health Service he should inform the relevant regulatory and inspection bodies for the independent/private sector in order to enable the monitoring of the clinical governance arrangements undertaken to safeguard patients in his care.

<sup>24</sup> <http://www.dhsspsni.gov.uk/index/pas/non-medical-prescribing.htm>

<sup>25</sup> [http://www.npc.nhs.uk/qipp/resources/Key\\_therapeutic\\_topics\\_Medicines\\_Management\\_for\\_local%20implementation\\_feb%202012\\_final.pdf](http://www.npc.nhs.uk/qipp/resources/Key_therapeutic_topics_Medicines_Management_for_local%20implementation_feb%202012_final.pdf)

**Provide a high standard of practice and care at all times**

---

10. Are the standards in section 2.8 easy to read and understand?

Yes

no

not sure

If no, how can we improve them?

10.1 Is the 'Good practice guidance' in section 2.8 (page 28) clear?

Very clear

Clear

Unclear

Very unclear

Please state which parts of the guidance are unclear and suggest how they could be made clearer

### **3. Additional information**

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Section 3 of this document contains information and guidance.

#### **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)<sup>26</sup>
- BNF
- '*Use and Control of Medicines*' (DHSSPS) 2004<sup>27</sup>
- Pharmaceutical Society of Northern Ireland Guide to General Legal Requirements<sup>28</sup>

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 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).<sup>29</sup>)

All pharmacist prescribers are recommended to prescribe generically, whether a product is available generically or not, except where this would not be clinically appropriate (in line with local guidance). 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 in order to prescribe from a medical practice's prescribing budget. This will prevent incorrect allocation of prescribing budgets and incorrect COMPASS data being generated.

Pharmacists working in secondary care should ensure they are registered on the Trust NMP register and adhere to local Trust policy for prescription writing.

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<sup>26</sup> <http://www.dhsspsni.gov.uk/non-medical-prescribing>

<sup>27</sup> [http://www.dhsspsni.gov.uk/pas-use\\_and\\_control\\_of\\_medicines](http://www.dhsspsni.gov.uk/pas-use_and_control_of_medicines)

<sup>28</sup> <http://www.psni.org.uk/documents/597/GuideLegalRequirementsFull+July2010.pdf> (see page 25)

<sup>29</sup> <http://www.dhsspsni.gov.uk/non-medical-prescribing>

## Guidance on writing prescriptions

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11. Does the guidance in section 3.1 contain the right level of detail?

Too detailed                       about right                       not detailed enough

Please indicate the issues on which you think more detail is required

## **3.2 Security and safe handling of prescription forms**

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- 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 local policy should be followed.

Refer to NHS Guidance on security of prescription forms available on DHSSPS website:

<http://www.dhsspsni.gov.uk/pas-security-prescription-forms-guidance-feb08.pdf>



## **Security and safe handling of prescription forms**

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12. Does the guidance in section 3.2 contain the right level of detail?

Too detailed

about right

not detailed enough

**Please indicate the issues on which you think more detail is required**

### **3.3 Guidance on prescribing Controlled Drugs (CDs)**

---

Amendments to the Misuse of Drugs Regulations (Northern Ireland)<sup>30</sup> in May 2012, have introduced a number of changes to the professional use of controlled drugs by pharmacist and nurse independent prescribers. Before the change, pharmacist independent prescribers could not prescribe any controlled drugs under their own authority.

#### **The legislative changes permit:**

- Pharmacist Independent Prescribers (PIPs) and Nurse Independent Prescribers (NIPs) to prescribe, administer and give directions for the administration of Schedule 2, 3, 4 and 5 Controlled Drugs (CDs). This extends to diamorphine, dipipanone or cocaine for treating organic disease or injury, **but not the treatment of addiction**.
- PIPs and NIPs to produce written directions that will allow any person, acting in accordance with those directions to compound or mix Schedule 2, 3, 4 or 5 Controlled Drugs.
- The supplementary prescribing pharmacist may prescribe CDs only where he is legally entitled to do so, as part of a clinical management plan.

3.3.1 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.

3.3.2 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.

3.3.3 All pharmacist independent prescribers may prescribe Schedule 2, 3, 4 or 5 CDs privately and should use a PCD1 form which is available to order from BSO at: <http://www.hscbusiness.hscni.net/pdf/PCD1.doc>

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<sup>30</sup>[http://www.dhsspsni.gov.uk/letter\\_amendments\\_to\\_misuse\\_of\\_drugs\\_regulations\\_cd\\_prescribing\\_by\\_nurse\\_and\\_pharmacist\\_independent\\_prescribers.pdf](http://www.dhsspsni.gov.uk/letter_amendments_to_misuse_of_drugs_regulations_cd_prescribing_by_nurse_and_pharmacist_independent_prescribers.pdf)

**Please note:**

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

The website of the Department of Health, Social Services and Public Safety (DHSSPS) has a range of up to date information on the management and use of controlled drugs. It can be accessed at: <http://www.dhsspsni.gov.uk/index/pas/pas-lie/pas-controlled-drug-licensing.htm>

The DHSSPS website also contains comprehensive guidance documents on the management of Controlled Drugs in the primary and secondary care sectors:

- **Primary Care:**

<http://www.dhsspsni.gov.uk/safer-management-of-controlled-drugs-2010.pdf>

- **Secondary Care:**

<http://www.dhsspsni.gov.uk/safer-management-cda-2009.pdf>

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

## **Guidance on prescribing Controlled Drugs (CDs)**

13. Is the guidance in section 3.3 sufficiently clear?

Very clear

clear

unclear

very unclear

Please say which parts of the guidance are unclear and suggest how they could be made clearer

### **3.4 Guidance on prescribing unlicensed medicines**

Unlicensed medicines are those medicines without a current marketing authorisation.

Pharmacist independent prescribers may prescribe unlicensed medicines to their patients, on the same basis as doctors and dentists, and provided that they are competent and take responsibility for doing so.

Pharmacist Supplementary Prescribers may prescribe an unlicensed medicine as part of a Clinical Management Plan providing the doctor or dentist and the pharmacist prescriber, acting as a supplementary prescriber, have agreed the plan with the patient in a voluntary partnership.

Pharmacists should usually prescribe licensed medicines for their licensed uses.

Pharmacists may prescribe an unlicensed medicine where:

- 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.

## Guidance on prescribing unlicensed medicines

14. Is the guidance in section 3.4 sufficiently clear?

Very clear

clear

unclear

very unclear

Please say which parts of the guidance are unclear and suggest how they could be made clearer

### **3.5 Guidance on mixing medicines**

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Changes to medicines regulations which came into effect from December 2009,<sup>31</sup> enable Pharmacist Independent Prescribers to mix medicines prior to administration to patients, and to direct others to mix.

The legal changes also define mixing as ‘the combination of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient.’

These changes apply to all clinical areas, including palliative care, where the mixing of medicines prior to administration is accepted practice and supported by the employer’s policies for the delivery of healthcare.

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<sup>31</sup> [http://www.dhsspsni.gov.uk/mixing\\_medicines.pdf](http://www.dhsspsni.gov.uk/mixing_medicines.pdf)

## Guidance on mixing medicines

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15. Is the guidance in section 3.5 sufficiently clear?

Very clear

clear

unclear

very unclear

Please say which parts of the guidance are unclear and suggest how they could be made clearer



### **3.6 Guidance on prescribing medicines for use outside the terms of their licence ('off-label')**

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'Off-label' prescribing is where a licensed medicine is prescribed outside the terms of its licence.

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 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 licence 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.

## Guidance on prescribing medicines for use outside the terms of their licence ('off-label')

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16. Do you agree with the recommended steps to be taken when informing the patient of the decision to prescribe 'off-label' outlined in the guidance?

Yes  No  not sure

17. Is the guidance in section 3.6 sufficiently clear?

Very clear  clear  unclear  very unclear

Please say which parts of the guidance are unclear and suggest how they could be made clearer

### 3.7 Guidance on repeat prescribing

#### 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.

**Repeat dispensing** 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>32</sup>.

Repeat dispensing 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 medication review, the pharmacist prescriber issues the patient with a Repeatable Prescription and an accompanying set of Batch Issues on standard HS21 prescription forms for the patient's repeat medicines<sup>33</sup>.

- 3.7.1 A pharmacist prescriber may issue a repeat dispensing prescription in line with procedures agreed with his employing organisation.
- 3.7.2 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.
- 3.7.3 Before signing a repeat 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;
  - 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 own 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.

<sup>32</sup> See DHSSPS repeat dispensing guidance [http://www.dhsspsni.gov.uk/pas-repeat\\_dispensing\\_2](http://www.dhsspsni.gov.uk/pas-repeat_dispensing_2)

<sup>33</sup> <http://www.hscbusiness.hscni.net/services/Family%20Practitioner%20Services/General%20Pharmaceutical%20Services/Pharmacists/NI%20Repeat%20Dispensing%20Scheme/Repeat%20Dispensing.html>

## Guidance on repeat prescribing

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18. Is the guidance in section 3.7 sufficiently clear?

Very clear

clear

unclear

very unclear

Please say which parts of the guidance are unclear and suggest how they could be made clearer

### 3.8 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 remote form of communication to prescribe medicines and treatments for patients.

Remote prescribing presents particular risks in ensuring 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<sup>34</sup>. 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 need to be agreed with employers.

The pharmacist should 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 (April 2010) <http://www.nmcuk.org/Documents/Standards/nmcStandardsForMedicinesManagementBooklet.pdf>

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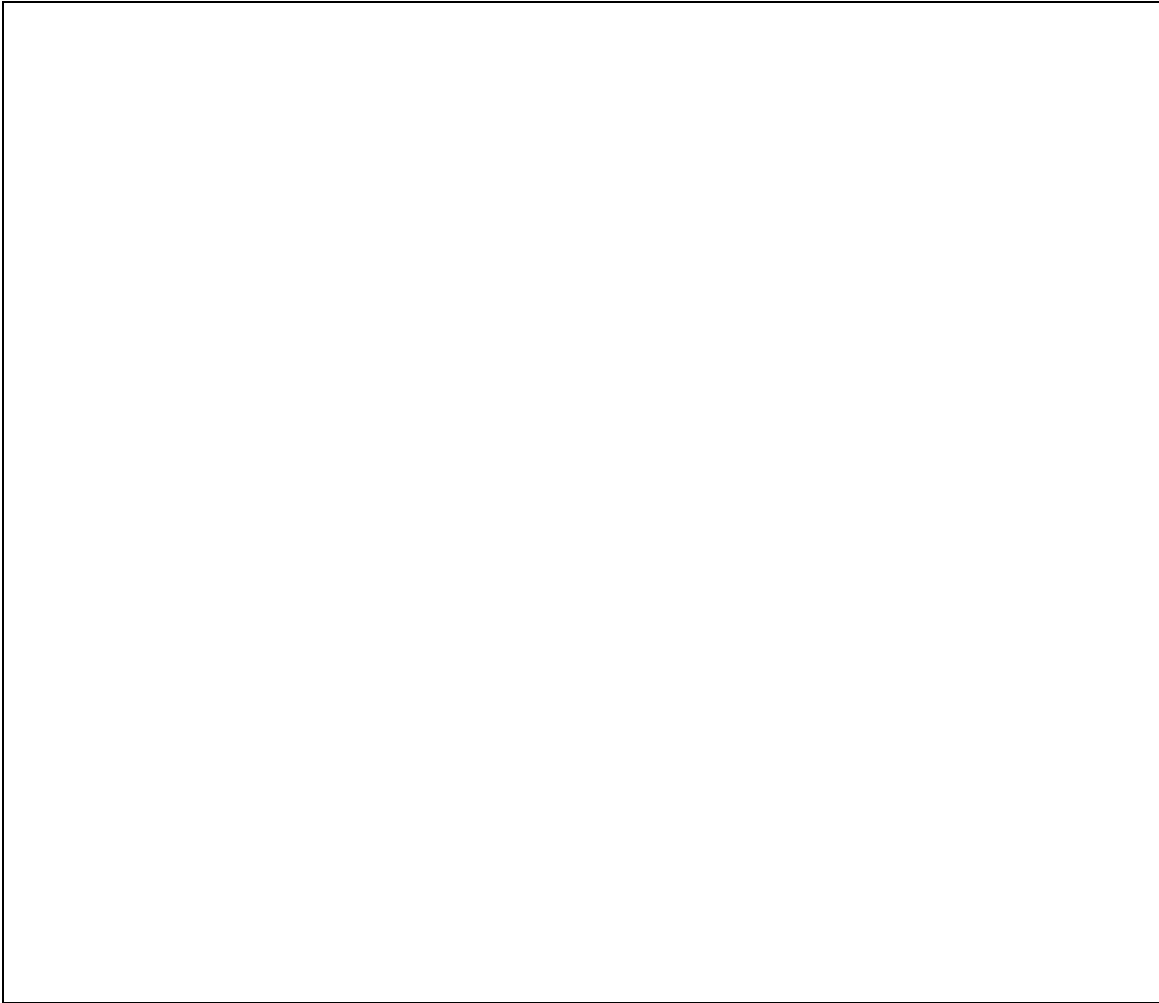
<sup>34</sup> Further Guidance on Medicines Governance in Primary Care available here: [http://www.dhsspsni.gov.uk/pas-medicines\\_governance\\_in\\_primary\\_care](http://www.dhsspsni.gov.uk/pas-medicines_governance_in_primary_care)

**Guidance on remote prescribing via telephone, email, fax, video- link or website**

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- 19. Do you think the guidance on remote prescribing achieves the right balance between patients' autonomy and safety?**

**20. Do you have any other comments on the 'Guidance on remote prescribing via telephone, email, fax, video- link or website' section?**

A large, empty rectangular box with a thin black border, intended for the user to provide their comments on the specified section of the guidance.

### **3.9 Guidance on reporting adverse drug reactions (ADRs)**

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

- i. 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>35</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 freephone 0800 7316789.
- ii. 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.

### **3.10 Guidance on Reporting Medication Incidents**

---

A medication incident is a preventable medication-related or undesirable unintended event the 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 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. 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.

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<sup>36</sup>;
- d) Incidents should be documented and learning points should be taken and implemented.
- e) The patient's primary prescriber should be informed

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<sup>35</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).

<sup>36</sup> Any untoward incidents should be reported to the National Reporting and Learning System which is the reporting system of the National Patient Safety Agency <http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident>. Local reporting schemes may be in place: either via the HSC Trust, HSC Board, head office of a multiple or Pharmacy Company etc.



## Medication incident reporting

Any untoward incidents should be reported to the National Reporting and Learning System which is the reporting system of the National Patient Safety Agency

<http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident>

Local reporting schemes may be in place, either via the HSC Trust or Board, head office of a multiple, or, Pharmacy Company etc.

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*'..

In primary care the 'Adverse Incident Form (AIF1)' has been developed and must be completed and forwarded to the General Medical Services department at the HSC Board where it will be dealt with appropriately.

This form can only be accessed via the intranet in the GP practice. Serious adverse incidents within the HSPSS should be reported to the Department of Health, Social Services and Public Safety (DHSSPS) in line with the procedure outlined in the circular,

<http://www.dhsspsni.gov.uk/hssppm05-05.pdf>

Adverse incidents involving medical devices should be reported to the Northern Ireland Adverse Incident Centre (NIAIC) at: [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic).

## Reporting adverse drug reactions and medication incidents

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21. Is the guidance outlined in sections 3.9 and 3.10 sufficiently clear?

Very clear

clear

unclear

very unclear

Please say which parts of the guidance are unclear and suggest how they could be made clearer

## **General**

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22. Do you have any additional comments, recommendations or suggestions you would like to make in relation to the Draft Standards and Guidance for pharmacist prescribers in Northern Ireland?

Please add any further comments

## **Equality issues**

The Pharmaceutical Society of Northern Ireland in reviewing these standards and guidance considered the nine equality strands: religious belief; political opinion; racial or ethnic group; men and women; marital status; age; person with a disability and sexual orientation.

23. Do you think that applying these standards and guidance will have an adverse impact on any of the aforementioned categories that should be considered before further development?

If so, please identify which groups could potentially be affected and how this might be addressed.

## **Economic impact**

24. Do you think that applying these standards and guidance will have any potential economic impact that should be considered before further development?

If so, please identify any potential economic impacts for further consideration.

## **Guidance that supports this document**

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The Pharmaceutical Society NI 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
- Professional standards and guidance for Patient Consent
- Professional standards and guidance for Patient Confidentiality
- Professional Guidance on Maintaining Clear Professional Boundaries
- Professional Guidance on raising concerns

These documents can be downloaded and more copies of this guidance from the Pharmaceutical Society NI website ([www.psni.org.uk](http://www.psni.org.uk)) or telephone on 028 9032 6927 for a hard copy.

### **Acknowledgement**

General Medical Council (GMC)

Royal Pharmaceutical Society (RPS)

Department of Health, Social Services and Public Safety (DHSSPS)

## Additional Resources

- General Medical Council: 'Good Medical Practice' (updated March 2009)  
[http://www.gmc-uk.org/guidance/good\\_medical\\_practice.asp](http://www.gmc-uk.org/guidance/good_medical_practice.asp)
- 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/improving\\_patients\\_access\\_to\\_medicines\\_-\\_december\\_2006.pdf](http://www.dhsspsni.gov.uk/improving_patients_access_to_medicines_-_december_2006.pdf)
- Department of Health website: 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)  
[http://www.dhsspsni.gov.uk/pas-use\\_and\\_control\\_of\\_medicines](http://www.dhsspsni.gov.uk/pas-use_and_control_of_medicines)
- 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.nhs.uk/non\\_medical/resources/competency\\_framework\\_oct\\_2006.pdf](http://www.npc.nhs.uk/non_medical/resources/competency_framework_oct_2006.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) – Third Edition  
<http://www.npc.nhs.uk/guidance.php/>
- 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/Documents/Standards/nmcStandardsForMedicinesManagementBooklet.pdf>
- Nursing and Midwifery Council prescribing standards  
<http://www.nmc-uk.org/Educators/Standards-for-education/Standards-of-proficiency-for-nurse-and-midwife-prescribers/>
- Patient Group Directions: A guide to good practice  
[http://www.npc.nhs.uk/non\\_medical/resources/patient\\_group\\_directions.pdf](http://www.npc.nhs.uk/non_medical/resources/patient_group_directions.pdf)
- Scottish Executive Health Department HDL 2004 35: Implementation of supplementary prescribing for pharmacists  
[http://www.sehd.scot.nhs.uk/mels/HDL2004\\_35.pdf](http://www.sehd.scot.nhs.uk/mels/HDL2004_35.pdf)

## Useful websites

- The Department of Health Social Services and Public Safety, Northern Ireland  
[www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)
- Business Services Organisation  
[www.hscbusiness.hscni.net](http://www.hscbusiness.hscni.net)
- The Department of Health (England)  
[www.dh.gov.uk](http://www.dh.gov.uk)
- The National Prescribing Centre<sup>37</sup>  
[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<sup>38</sup>  
[www.npsa.nhs.uk](http://www.npsa.nhs.uk)
- The Royal Pharmaceutical Society  
[www.rpharms.com](http://www.rpharms.com)
- The General Pharmaceutical Council  
[www.pharmacyregulation.org](http://www.pharmacyregulation.org)
- Northern Ireland Centre for Pharmacy Learning and Development  
[www.nicpld.org](http://www.nicpld.org)
- National Institute for Health and Clinical Excellence  
[www.nice.org.uk/](http://www.nice.org.uk/)
- 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/)

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<sup>37</sup> The NPC became part of NICE in April 2011.

<sup>38</sup> On 1 June 2012 the key functions and expertise for patient safety developed by the National Patient Safety Agency (NPSA) transferred to the NHS Commissioning Board Special Health Authority.