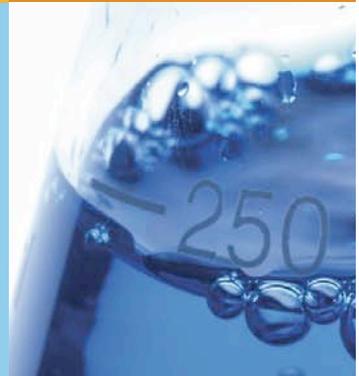


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PROFESSIONAL STANDARDS AND GUIDANCE FOR INTERNET PHARMACY SERVICES



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STATUS OF THIS DOCUMENT

This guidance is addressed to pharmacists but may also help patients and the public understand what is expected of a pharmacist/pharmacy providing internet pharmacy services.

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

This document contains:

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

Serious or persistent failure to follow this guidance will put a pharmacist's registration at risk. The pharmacist must, therefore, be prepared to explain and justify his¹ actions.

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

ABOUT THIS DOCUMENT

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

¹ 'his' – masculine pronoun is understood to refer to male/female gender.

Principle 1 of the Code of Ethics states that you must ***'Make the safety and welfare of patients your prime concern'***. In adhering to this principle, the pharmacist is expected to:

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

This document expands on the principles of the Code of Ethics to explain the pharmacist's professional responsibilities when selling and supplying medicines via the internet. It is designed to meet the Society's obligations and other relevant legislation.

This document *does not* give detailed guidance on legal requirements when selling or supplying medicines via the internet. The pharmacist must comply with relevant legislative and contractual requirements, including Health Service terms of service.

1 BACKGROUND

Pharmaceutical services provided to the public via the internet include amongst other things, the dispensing of prescriptions, the sale of medicines and the provision of information on web site pages. For the purpose of this document, the Society defines internet pharmacy as:

'A registered pharmacy which offers to sell or supply medicines (or other pharmaceutical

products) and/or provides other professional services over the internet, or makes arrangements for the supply of such products or provision of such services over the internet.’

The sale and supply of general sale list, pharmacy and prescription only medicines (POM) for human use via the internet must be made in accordance with the Medicines Act 1968.

This requires that:

- 1.1 the pharmacy premises from where the sale and supply of a pharmacy and prescription-only medicine takes place must be registered with the Society;
- 1.2 the pharmacy must be under the personal control² of a pharmacist and supervision requirements for pharmacy and prescription only medicine sales must be met;
- 1.3 Prescription Only Medicines (POMs) must be supplied only in accordance with:
 - a legally valid prescription,
 - Health Service regulations,
 - Veterinary medicines legislation,
 - a patient group direction (PGD),
 - emergency supply,
 - or
 - by wholesale licence.

2 WEBSITE REQUIREMENTS STANDARDS

Patients must be readily able to identify who is operating an internet site from a registered pharmacy premises. Pharmacy websites must clearly display:

- the name of the owner of the business;
- the address of the pharmacy at which the business is conducted;
- where applicable, the name of the superintendent pharmacist;
- information about how to confirm the registration status of the pharmacy and pharmacist;
- details of how to make a complaint about the ‘on-line’ services provided.

2 Personal accountability in registered pharmacy premises has been governed by the Medicines Act 1968, requiring that a pharmacist be in ‘personal control’: necessitating the physical presence of the pharmacist to ensure safe systems and supervision of work. However following review by government, ‘personal control’ was replaced in the Health Act 2006 with a new requirement that all registered pharmacy premises have a named ‘responsible pharmacist’ accountable for securing the safe and effective running of the pharmacy. The responsible pharmacist regulations will come into force, 1 October 2009.

3 SECURITY AND CONFIDENTIALITY STANDARDS

Patients are entitled to expect pharmacists and pharmacy staff to respect and protect the confidentiality of information acquired in the course of their professional duties. (Refer to *Professional Standards and Guidance on Patient Confidentiality*).

When providing internet pharmacy services the pharmacist must be satisfied that:

- 3.1 the confidentiality and integrity of all patient information is protected to the standard specified by the International Organisation for Standardisation (ISO) in ISO/ IEC 27001:2005: www.bsi-global.com;
- 3.2 all patient data transmissions are encrypted to prevent the possibility of the internet service provider or any other unauthorised party accessing patient information either accidentally or deliberately;
- 3.3 patient information needs to be kept in a secure, fire-proof system and backed up every day. The pharmacist responsible for decision making needs to be clearly identified.

4 PROTECTING PATIENT CHOICE STANDARDS

Co-operation and close working between health professionals are encouraged, but a patient must be free to choose where and how he obtains his pharmaceutical services. When providing internet pharmacy services, the pharmacist must:

- 4.1 avoid participating in any agreement, with a prescriber or other person, that has the effect of limiting patient choice;
- 4.2 ensure that a patient is able to identify which pharmacy is providing pharmaceutical services to him;
- 4.3 be satisfied that the patient has consented to this;
- 4.4 take all reasonable steps to ensure that direction of prescriptions has not occurred.

5 SUPPLYING MEDICINES STANDARDS

Patients are entitled to expect the same quality of pharmaceutical care irrespective of whether the service is provided on-line or face-to-face on the pharmacy premises.

5.1 SUPPLY OF NON-PRESCRIPTION MEDICINES AND SUPPLEMENTS STANDARDS

When selling or supplying non-prescription medicines via the internet, the pharmacist must:

- 5.1.1 ensure that advice is available to all prospective purchasers of over-the-counter (OTC) medicines and vitamin and mineral supplements;
- 5.1.2 establish, beyond doubt, that the intended user is the person requesting the product: sufficient information about the patient and the condition(s) being treated must be obtained;
- 5.1.3 assess the suitability of the product for the intended user;
- 5.1.4 provide appropriate counselling or advice on the safe and effective use of the product to be supplied;
- 5.1.5 be aware of the abuse potential of some OTC medicines and other products. The pharmacist must be alert to requests for large quantities of a product, or abnormally frequent requests, and thereupon refuse to make a supply where there are reasonable grounds for suspecting misuse and/or abuse;
- 5.1.6 advise the patient to consult a local pharmacy or other appropriate healthcare professional whenever a request for a medicine or the symptoms described indicate that the patient's best interests would be served by a face-to-face consultation;
- 5.1.7 inform the patient of the identity of the pharmacist assuming professional responsibility for the supply of medicines.

5.2 SUPPLY OF MEDICINES AGAINST PRESCRIPTIONS STANDARDS

Apart from limited exceptions (for example, emergency supplies and patient group directions), POMs must be supplied only in accordance with a legally valid prescription.

When supplying medicines against prescriptions the pharmacist must:

- 5.2.1 ensure that the patient has consented to the pharmacy dispensing his prescription;
- 5.2.2 have systems in place to prevent the unlawful sale or supply of POMs. The pharmacist must be satisfied that the prescriber is '*bona fide*' and that the prescription is genuine;
- 5.2.3 ensure a pharmacist assesses the clinical appropriateness of the prescription for the patient;
- 5.2.4 ensure that the patient, or his/her carer, receives sufficient information

to enable the safe and effective use of the medicine and is aware how further information can be obtained;

5.2.5 advise the patient to consult a local pharmacy whenever a prescription indicates that his interests would be better served by a face-to-face consultation;

5.2.6 verify the authenticity of the prescription;

5.2.7 be aware that all supply of medicines outside the UK must be in compliance with legislation both within the UK and the country to which the medicines are being sent.

GOOD PRACTICE GUIDANCE

- An email of prescription details from the prescriber to the pharmacy does not meet the legal requirements for electronic prescribing. It does not confirm that a legally valid prescription exists and supplies should not be made against information which a prescriber or patient has sent by email until the original prescription has been received.
- The pharmacist should be alert to potential indicators that an adequate clinical assessment of a patient has not been undertaken; for example, where a prescriber is issuing, or counter-signing a high volume of prescriptions for overseas patients, or where a commercial company has employed/contracted a prescriber to issue prescriptions for patients who access its site. In such circumstances, the pharmacist should use his professional judgement to assess the appropriateness of making the supply to the patient.
- The pharmacist should ensure that there is an in-built mechanism or alarm to alert and thereby restrict excessive/multiple orders of medicines.
- It is not recommended to supply Controlled Drugs (CDs) on the internet.

6 INFORMATION AND ADVICE STANDARDS

Patients and public recognise the expertise that pharmacy professionals have in relation to medicines. They expect to be provided with high quality, relevant information in a manner they can easily understand. When providing internet pharmacy services the pharmacist must ensure that:

6.1 generic healthcare advice (i.e. not specific to the patient) provided on pharmacy websites is accurate, up-to-date and presented in a professional manner;

- 6.2 all information relating to specific products complies with the marketing authorisation, the patient information leaflet and relevant legislative requirements;
- 6.3 information relating to medicines includes all relevant details of contraindications and side-effects;
- 6.4 product recommendations are given only in respect of individual patients;
- 6.5 any advertising or publicity complies with relevant legislation. Promotional material the pharmacist authorises, or for which he is responsible, must be accurate and honest and must not abuse the trust, or exploit the lack of knowledge, of the public.

7 POSTING AND DELIVERING MEDICINES STANDARDS

The pharmacist has responsibility for the delivery of medicines to his patients. Medicines must be delivered safely and with appropriate instructions. When delivering medicines to a patient, whether by post or other means, the pharmacist must:

- 7.1 take adequate steps to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely and in a condition appropriate for use;
- 7.2 ensure the integrity of cold chain and safe transportation of liquid or other vulnerable packaging;
- 7.3 ensure medicines are packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. Care must be exercised with thermo-labile products;
- 7.4 ensure that the delivery mechanism used provides a verifiable audit trail for the medicine from the initial request for a medicine through to its delivery to the patient or carer, or its return to the pharmacy in the event of a delivery failure;
- 7.5 ensure that delivery mechanisms safeguard confidential information about the medication a patient is taking.

GOOD PRACTICE GUIDANCE

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

8 OVERSEAS PRESCRIPTIONS STANDARDS

Supplying medicines to patients overseas carries particular risk. There may be differences in a product's licensed name, indications for use or the recommended dosage regimen. A pharmacist must exercise his professional judgement and due diligence in deciding whether to dispense a prescription or not. Prior to supplying a prescription-only medicine to a patient overseas, the pharmacist must ensure that:

- 8.1 the prescription is not fraudulent, that is, is legally valid and is clinically appropriate for the patient;
- 8.2 due consideration is given to any differences in the licensed indications, marketing authorisations and/or legal classification of the prescribed medicine in the UK and the patient's country of residence and that, when necessary, these are explained to the patient;
- 8.5 appropriate information and advice is provided to the patient;
- 8.6 legal requirements for export are met;
- 8.7 medicines will be delivered safely, securely and in accordance with Standard 7 (*Posting and delivering medicines*);
- 8.8 professional indemnity insurance arrangements adequately cover the supply of medicines and provision of other pharmaceutical services to patients overseas;
- 8.9 appropriate prescription records are made.

GOOD PRACTICE GUIDANCE

- While a prescription issued, or countersigned, by a UK registered prescriber for a patient overseas may be legally valid, the General Medical Council advises that doctors prescribe drugs or treatment (including repeat prescriptions) only when they have adequate knowledge of a patient's health and medical needs. Because of this, the pharmacist also needs to be satisfied of the appropriateness of dispensing such a prescription. The pharmacist should consider contacting the prescriber to ascertain his reasons for prescribing for a patient abroad and satisfy himself that there has been an appropriate clinical assessment of the patient.
- The Misuse of Drugs Regulations prohibits a prescription for a Schedule 2 or 3 Controlled Drug from being signed by a prescriber whose address is not within the UK.
- Refer to Regulatory Guidance on EEA and Swiss prescriptions (November 2008)³.

9 RECORD KEEPING STANDARDS

The pharmacist must maintain records about on-line consultations and medicines supplied which are sufficient to guard against risks of abuse or misuse. A verifiable audit trail from the initial request for a medicine through to its delivery to the patient must exist. If the pharmacist provides internet pharmacy services he must maintain records of:

- 9.1 the identity of customers who have been supplied with medicines via the internet;
- 9.2 details of the medicines requested and supplied;
- 9.3 the information upon which decisions to supply were made;
- 9.4 the identity of the pharmacist who has assumed professional responsibility for supply of a medicine following an email/on-line request to purchase.

GUIDANCE THAT SUPPORTS THIS DOCUMENT

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

- Code of Ethics for pharmacists
- Professional Standards and Guidance for the Sale and Supply of Medicines
- Professional Standards and Guidance on Patient Consent
- Professional Standards and Guidance for Patient Confidentiality
- Guidance for Pharmacists on Raising Concerns.

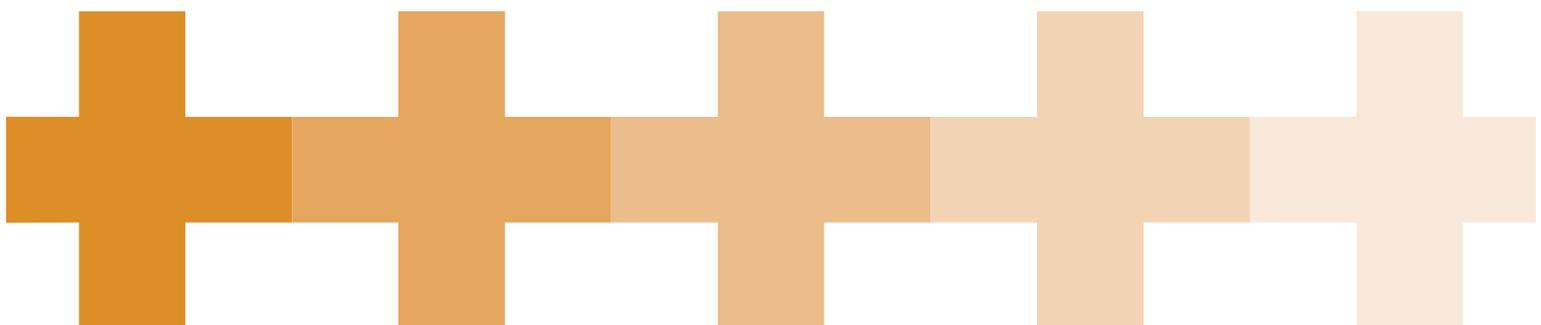
These documents are available to download from the Society's website (www.psni.org.uk) or telephone on 02890 326 927 for a hard copy (ies).

Also available to download from the Royal Pharmaceutical Society website:

- Guidance on the sale and supply of veterinary medicines
www.rpsgb.org/guidance
- Practice Guidance for Community Pharmacists on the Veterinary Medicines Regulations 2005.
www.pharmj.com/pdf/society/pj20051105-veterinary.pdf

ACKNOWLEDGEMENT

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