

Guidance on Raising Concerns

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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 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 pharmacists, 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.**

Section 1 Introduction

1. Speaking up about any concern pharmacists have at work is important to safeguard patients and service users and to identify wrongdoing and risks to public service delivery. When standards of care or behaviour fall below acceptable levels, pharmacists have an ethical duty to speak up.

The purpose of this guidance is to assist pharmacists in meeting their obligations on raising concerns set out in the *Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland (2016)*,¹ (the Code).

The Code sets out the five mandatory principles of professional and ethical practice and provides a framework to aid professional decision-making. It is recognised that pharmacists work in increasingly diverse working environments and, therefore, this guidance is not exhaustive. It is the pharmacist's responsibility to apply the Code principles to their particular circumstances. If a pharmacist is not sure how this guidance applies to their daily work situations, they should seek advice from the individuals and bodies suggested in Section 5 of this Guidance.

Several Principles and Standards in the Code are specifically engaged by the pharmacist's obligations on raising concerns.

Principle 1	Always put the patient first.
Standard 1.2	Uphold the duty of candour and raise concerns.
Standard 1.2.1	Contribute to and foster a culture of openness, honesty and learning.
Standard 1.2.6	If you employ, manage or lead staff, make sure that there is an effective procedure in place that allows staff to raise concerns openly and safely without fear of reprisals.

¹ *Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland* available at <http://www.psni.org.uk/psni/about/code-of-ethics-and-standards/>

Standard 1.2.7

Raise a concern, at an appropriate level, if you become aware of a colleague or other health care professional whose actions, omissions, working practices, professional performance or physical health may compromise patient safety.

Principle 5

Maintain and develop professional knowledge, skills and competence.

In addition, this Guidance aims to:

- reinforce to pharmacists the importance of raising a concern in the appropriate way;
- outline the steps that pharmacists will need to consider taking in order to raise a concern appropriately;
- highlight the importance of keeping up to date with any HSC or employment policies for raising a concern where pharmacists work;
- provide guidance and additional resources available to employers; and
- emphasise to employers and employing organisations that all staff members should be familiar with this guidance and be appropriately trained on how to raise a concern.

1.1 **What is raising a concern or whistleblowing?**

1.1.1 An individual is raising a concern when they bring to the attention of someone in authority a danger, risk, malpractice or wrongdoing within their place of work, which affects others. Those who raise a concern often do so to protect patients, service users, staff and the organisation itself by identifying harm before it's too late. In this Guidance, we use the term raising a concern. Other organisations and the law on occasion refer to this as whistleblowing.

1.2 **Is raising a concern the same as making a complaint or grievance?**

1.2.1 It is important to recognise the difference between raising a concern and making a complaint or grievance.

1.2.2 Raising a concern has a component of others being affected (for example, patients, service users, members of the public or the pharmacist's employer) and the pharmacist raising a concern may not be directly or personally affected by the malpractice or wrongdoing².

1.3 **The importance of raising a concern**

1.3.1 Always remember that patients and the public place significant trust in the knowledge, skills and professional judgement of pharmacists. If a pharmacist is hesitating about reporting a concern, it is important to keep the following foremost.

It is the duty of every pharmacist to:

- put the interests of the patient first;
- act to protect patients; and
- raise a justifiable concern in an appropriate manner, overriding any personal or professional loyalty.

1.3.2 Several well publicised inquiries, such as the Mid-Staffordshire NHS Foundation Trust Public Inquiry and the Inquiry into Hyponatraemia-related deaths, have demonstrated the importance of raising concerns in preventing harm and the potential consequences of failing to speak up.

1.4 **Barriers to raising a concern**

We recognise that barriers to raising a concern can exist in the workplace and that pharmacists may be reluctant to raise a concern for a number of reasons. For instance, pharmacists may be concerned that:

- there may be a negative impact on working relationships;
- there may be a negative impact on their career;
- they may face reprisals or be ostracised by their colleagues or the pharmacy establishment;
- they will cause trouble for their colleagues; and
- nothing will be done as a result of the concern being raised.

² Patients or members of the public who use pharmacy services can make complaints about the service they have received directly to the pharmacy or to the Pharmaceutical Society NI. Information on the complaints procedure of the Pharmaceutical Society NI can be found at: <http://www.psn.org.uk/psni/about/complaints-2/> or by telephoning: 02890 326 927.

- 1.4.1 However, the adoption of good work practices, based on pharmacists' ethical obligation to speak openly and freely about their concerns, underpinned by supportive workplace policies (Section 5 below) and the legislative protection available, should ensure that pharmacists suffer no detriment for raising a concern and will help ensure the continued protection of patients and the public.
- 1.4.2 The *Public Interest Disclosure (Northern Ireland) Order 1998*³ and the *Employment Rights (Northern Ireland) Order 1996*⁴ set out a step-by-step approach to raising and escalating pharmacists' concerns within their organisation. They also provide protection to employees within the workplace and pharmacists⁵ who raise genuine concerns about malpractice in the workplace.
- 1.4.3 This legislation aims to protect pharmacists from unfair treatment or victimisation if they raise a concern about:
- a danger to the health or safety of an individual (for example, irresponsible or illegal prescribing, patient abuse or a professional whose health or fitness to practise may be impaired);
 - a crime;
 - a civil offence or legal obligation (for example, fraud, theft or the illegal diversion of drugs);
 - a miscarriage of justice;
 - damage to the environment;
 - a cover-up of information about any of the above.
- 1.4.4 Protection is also available for disclosures to regulatory bodies and, in exceptional circumstances, wider disclosures (for example to an MLA or the media) may also be protected.
- 1.4.5 If pharmacists are unsure how this guidance applies to their situation or if they want some confidential advice before they proceed or at any stage during the process, the Pharmaceutical Society NI recommends

³ Available at <http://www.legislation.gov.uk/nisi/1998/1763/contents/made>

⁴ Available at <https://www.legislation.gov.uk/nisi/1996/1919/contents>

⁵ Guidance on employment status and your rights in relation Raising Concerns/Whistleblowing is available on the Government website for Northern Ireland see: <https://www.nidirect.gov.uk/articles/employment-status>

that they seek advice from the independent raising concerns charity, Protect (formally Public Concern at Work. See Section 6 for details).

- 1.4.6 Failure by pharmacists to report their concerns, in circumstances where they are aware of malpractice or behaviour which may cause a patient and/or the public harm, may constitute a breach of the Code and may form the basis of a complaint to the Pharmaceutical Society NI of professional misconduct and a pharmacist's fitness to practise may be brought into question.

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Section 2 When should a pharmacist raise a concern?

Pharmacists must exercise their professional judgement in the best interests of the patient or the public and must always be able to justify their actions.

Principle 1

Always put the patient first.

The care of the patient must come before all other considerations.

All pharmacists registered with the Pharmaceutical Society NI have a professional and ethical duty to raise any concerns in their place of work which puts the safety of patients or the public at risk.

Standard 1.2

Uphold the duty of candour and raise concerns.

Standard 1.2.7

Raise a concern, at an appropriate level, if you become aware of a colleague or other health care professional whose actions, omissions, working practices, professional performance or physical health may compromise patient safety.

Pharmacists must be open and honest with patients and service users when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.

Pharmacists must also be open and honest with their regulators, raising concerns where appropriate. They must support and encourage each other to be open and honest and not stop someone from raising a concern.⁶

Pharmacists have this responsibility whether they are an employer, employee, a locum or a temporary member of staff. Failing to raise a concern and doing nothing is unacceptable and may bring a pharmacist's fitness to practise into question.

⁶ Joint statement by Chief Executives of statutory regulators of healthcare professional 13 October 2014. Available at https://www.professionalstandards.org.uk/docs/default-source/publications/advice-to-ministers/progress-on-strengthening-approach-to-candour-november-2014.pdf?sfvrsn=fdda7e20_8

Pharmacists have a duty to report to an appropriate person or authority:

- any practices that are blatantly illegal or unprofessional and pose an immediate threat to public safety;
- any genuine concerns about the behaviour of a colleague including: pharmacists, pharmacy technicians, pharmacy owners, managers and employers, other healthcare professionals or people providing care and treatment for others, or anyone else with whom they come into contact during the course of their work;
- issues related to the broad care environment which may impact upon others, such as: resources, people, products, staffing or organisational issues;
- issues related to the health of a colleague or anyone else pharmacists come into contact with during their work which may affect their ability to practise safely and care for patients and service users appropriately; and
- financial malpractice including criminal acts and fraud, misuse or unavailability of clinical equipment, including lack of appropriate training.

Standard 1.2.1

Contribute to and foster a culture of openness, honesty and learning.

Pharmacists must also be open and honest with their colleagues, employers and relevant organisations, and take part in reviews and investigations when requested.

Section 3 How to raise a concern

- 3.1 Pharmacists raising a concern openly, as part of day to day practice, is an important part of improving quality of service and providing assurance of patient safety. When a concern is raised and dealt with appropriately, at an early stage, corrective action can be put in place to ensure the continued delivery of high quality and compassionate care.⁷
- 3.2 When raising a concern, pharmacists should be objective, honest and clear about the reason for their concern. It is important to let the facts speak for themselves.
- 3.3 Pharmacists should acknowledge any personal grievance that may arise from the situation but focus on the issue of patient safety and/or public interest.
- 3.4 Pharmacists must be familiar with any HSC or employment policies for raising a concern where they work and be appropriately trained on how to raise a concern.
- 3.5 If pharmacists wish to raise or escalate a concern, they should pursue the following steps:

⁷ Review of the Operation of Health and Social Care Whistleblowing Arrangements Regulation and Quality Improvement Authority (2016) available at <https://www.rqia.org.uk/RQIA/files/71/714c4651-e428-4f85-8142-4f88e81ba0ac.pdf>

Stage 1: Check the workplace policy

The workplace policy will tell pharmacists how to raise a concern and will give details of the contact person for raising concerns within the organisation. If the policy cannot be found, or it is not clear, pharmacists should seek advice from some of the sources listed in Section 5. Pharmacists may wish to reference the HSC Framework model policy – Your right to raise a concern (Whistleblowing) 2017, for additional guidance on what a policy should contain.⁸

Stage 2: Raise the concern internally

Pharmacists should follow their organisation's Raising Concerns or Whistleblowing policy and the steps set out within it to raise their concern. Raising the concern internally, at a local level, is usually the most appropriate first response. Pharmacists should keep an accurate record of their concerns and action taken. Pharmacists' employers should inform them how they intend to handle their complaint and set a timeline for feedback. This may vary depending on the seriousness or complexity of the concern.

Stage 3: Escalating the concern internally

In some cases, it may not be appropriate to raise the concern directly with an employer or manager, particularly if they are the source of the concern or if a pharmacist is not satisfied with their response. Pharmacists can escalate their concern to a higher level of management within their organisation, for example, the superintendent pharmacist or chief pharmacist.

Stage 4: Escalating the concern to a regulator or investigative body

If pharmacists have used all the options for raising their concerns internally and are not satisfied with the response, they may wish to escalate their concern to an external organisation with authority to investigate the issue, for example, the HSC Board, the Trust, the Pharmaceutical Society NI or the relevant professional regulator. A list of these regulatory organisations can be found in Section 6 of this guidance.

Stage 5: Raising or escalating the concern externally – going public

In very serious circumstances, pharmacists may consider going public with a concern. In this situation, we recommend they seek advice from an organisation listed in Section 5 before taking action.

⁸ <https://www.health-ni.gov.uk/sites/default/files/publications/health/hsc-whistleblowing.PDF>

- 3.6 During the course of professional practice, pharmacists may have concerns about a specific person, for example, a colleague or a vulnerable person. Pharmacists should, where possible, maintain confidentiality and not disclose information without consent unless disclosure is legally required or permitted. Good practice recommends that a timely record be made of any referral(s) / interventions.

Further Standards and Guidance on service user confidentiality are provided in *Standards and Guidance on Patient Confidentiality*⁹ and the *Code of Practice on Protecting Confidentiality of Service User Information*¹⁰

3.7 Maintaining knowledge of best practice

Principle 5	Maintain and develop professional knowledge, skills and competence.
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In compliance with Code Principle 5, keeping pharmacists' knowledge, skills and competence up to date throughout their working life is essential. Pharmacists must be aware of the most recent guidelines and advice on raising a concern, issued by the regulator, their professional associations¹¹ and any HSC or employment policies for raising a concern where they work. Such awareness will help ensure that openly raising a concern is part of their day to day practice with a view to improving quality of service and providing assurance of patient safety.

⁹ Pharmaceutical Society of NI (2016) *Standards and Guidance on Patient Confidentiality* available at <http://www.psn.org.uk/wp-content/uploads/2012/09/StandardsonPatientConfidentialityrevised24feb2016.pdf>

¹⁰ Code of Practice on Protecting the Confidentiality of Service User Information January 2012. Available at <https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/confidentiality-code-of-practice0109.pdf>

¹¹ Raising a Concern Professional Guidance February 2016. Pharmacy Forum NI available at <http://forum.psn.org.uk/wp-content/uploads/2016/12/Raising-a-Concern-PDF.pdf>

Section 4 Extra Guidance for employers (or those with management responsibility)

Standard 1.2.6

If you employ, manage or lead staff, make sure that there is an effective procedure in place that allows staff to raise concerns openly and safely without fear of reprisals.

- 4.1 Government inquiries into unsafe health practices, for example the Gosport Independent Panel Report,¹² have highlighted the importance of robust systems for raising concerns in the prevention of harm. If pharmacists employ, manage or lead staff, it is their professional responsibility to ensure that there is an effective procedure in place that allows staff to raise a concern openly and safely without fear of reprisals. (Code Standard 1.2.6).
- 4.1.1 If a pharmacist employs, manages or leads staff, they should encourage and support a culture in which their staff:
- can speak openly and freely about a concern;
 - can be reassured that whatever they say will be treated with appropriate confidence and sensitivity; and
 - will be treated courteously and sympathetically and, where possible, will be involved in decisions about how a concern is handled and considered.
- 4.1.2 If a pharmacist employs, manages or leads staff, they must make sure that:
- there are written policies and procedures to manage concerns that are raised and that these are accessible to all staff;
 - all staff, including temporary staff, are encouraged to raise a concern about the safety of patients including risks posed by colleagues;
 - all concerns are taken seriously and properly investigated and that all appropriate staff, including temporary staff and locums, are kept informed of progress;

¹² Learning from Gosport is available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/758062/government-response-to-gosport-independent-panel-report.pdf

- any staff who raise a concern are protected from unfair criticism or reprisals including any detriment or dismissal;
- systems are in place to support pharmacy professionals who are the subject of a concern whether it is due to their poor performance, health or behaviour;
- they do not stop anyone from raising a concern;
- an appropriate manager is appointed to take responsibility for ensuring implementation of the raising concerns / whistleblowing policy; and
- staff named on any policy to receive and deal with a concern raised by a member of staff are appropriately trained in the policy and the importance of an open and honest culture within the organisation.

4.1.3 Working in partnership with trade unions, staff associations and employee representatives is an important part of ensuring fairness and promoting awareness of the policies, procedures and support mechanisms which a good employer will have in place.¹³

4.1.4 A policy should include:

- the seriousness with which your organisation treats raising concerns claims and the efforts you will go to when you investigate any potential wrongdoing;
- the procedure to be followed when it comes to making a disclosure. Staff should be able to inform their line managers or a designated person of any issues in confidence. In the event the wrongdoing concerns their line manager, the policy should make clear that staff can bypass them and talk directly to senior management or a designated person;
- that any disclosures are made in strict confidence;
- how disclosures are investigated and concluded;
- that staff won't be penalised or suffer detriment as a result of making disclosures; and
- that all concerns raised should be treated with equal importance regardless of how they are submitted.

¹³ Raising Concerns at Work: Whistleblowing Guidance for Workers and Employers in Health & Social Care (NHS, 2014) Available at <https://www.norfolkscb.org/wp-content/uploads/2016/11/Raising-Concerns-at-Work.pdf>

4.1.5. Records and Monitoring

- If a pharmacist employs, manages or leads staff, they should keep appropriate records of all concerns raised and the action taken to deal with them. Concerns raised by staff are an important source of information for an organisation. It is important that key aspects are captured so that the value of whistleblowing arrangements can be determined, and lessons learned, where appropriate.
- It is good practice for all employers, in addition to maintaining individual case files, to have a central register of all concerns raised in a readily accessible format for audits. Any system for recording concerns should be proportionate, secure and accessible by the minimum necessary number of staff.¹⁴

4.1.6 Review and Refresh

- An employer's Raising Concerns policy and procedure should be audited, reviewed and refreshed periodically, taking into consideration any changes to any external best practice guidance and/or the law.
- Where possible, employers should consult staff and representatives when reviewing and revising their Raising Concerns policy and procedures.

4.1.7 The inappropriate handling of a genuine concern could place patients and the public at risk, be detrimental to the person raising the concern and undermine the public's confidence in the pharmacy profession. Instances where a pharmacist who employs, manages or leads staff deliberately ignores, stymies or disciplines a member of staff who has raised a genuine concern in the public interest, may form the basis of a fitness to practise investigation and may bring their fitness to practise into question.

¹⁴ See Your Right to raise a concern (whistleblowing) HSC framework and model policy 2/11/2017 available at <https://www.health-ni.gov.uk/sites/default/files/publications/health/hsc-whistleblowing.PDF> for further information

Section 5 Help and advice

5.1 Additional advice and information on any aspect of raising a concern may be obtained from the following sources:

- senior members of staff in your organisation;
- the accountable officer, if the concern is about controlled drugs;
- Protect formally Public Concern at Work¹⁵;
- Health and Social Care Board;
- Health and Social Care Trust;
- indemnity insurance provider/defence organisation;
- a professional association (such as the Pharmacy Forum NI, the Ulster Chemists' Association (UCA), National Pharmacy Association (NPA), the Guild of Healthcare Pharmacists);
- the Regulation and Quality Improvement Agency (RQIA);
- the charity, Pharmacy Advice and Support Service (PASS);
- an independent legal advisor;
- your union;
- the Pharmaceutical Society NI or, if your concern is about a colleague in another healthcare profession, the appropriate regulatory body.

¹⁵ Protect formally Public Concern at Work, is an independent authority who provides free confidential advice to people who are unsure of whether, or how, to raise a concern about practices that they have witnessed at work. The helpline can be contacted on 020 3117 2520 or by emailing whistle@protect-advice.org.uk

Section 6 Useful contacts

Advice and help

Protect formally Public Concern at Work

CAN Mezzanine

7 - 14 Great Dover Street

London SE1 4YR

Website: www.pcaw.co.uk

Help E-mail address: whistle@protect-advice.org.uk

Phone: 020 3117 2520

Guild of Healthcare Pharmacists

Health Sector,

Unite the Union,

Unite House, 126 Theobald's Road,

London, WC1X 8TN

Website: www.ghp.org.uk

Phone: 020 3371 2009

National Pharmacy Association

Mallinson House, 38-42 St Peter's Street,

St Albans AL1 3NP

Website: www.npa.co.uk

Phone: 0172 785 8687

NHS National Helpline

Provided by Speak Up

Website: <https://www.speakup.direct/>

Phone: 0800 0724 725

Pharmacist Advice and Support Service (PASS)

Website: <http://forum.psni.org.uk/pass/>

Phone: 028 9032 6927

Professional regulatory bodies

Pharmaceutical Society NI

Website: www.psni.org.uk

Phone: 028 9032 6927

General Chiropractic Council

Website: www.gcc-uk.org

Phone: 0207 713 5155

General Dental Council
Website: www.gdc-uk.org
Phone: 0207 167 6000

General Medical Council
Website: www.gmc-uk.org
Phone: 0161 923 6602

General Optical Council
Website: www.optical.org
Phone: 0207 580 3898

General Osteopathic Council
Website: www.osteopathy.org.uk
Phone: 0207 357 6655

General Pharmaceutical Council
Website: www.pharmacyregulation.org
Phone: 0203 365 3400

Health Professions Council
Website: www.hpc-uk.org
Phone: 0207 582 0866

Nursing and Midwifery Council
Website: www.nmc-uk.org
Phone: 0207 637 7181

Other regulatory and investigatory bodies

Professional Standards Authority
Website: <https://www.professionalstandards.org.uk/>
Phone: 0207 389 8030

Northern Ireland
Regulation and Quality Improvement Authority (RQIA) in Northern Ireland
Website: www.rqia.org.uk
Phone: 0289 536 1111