General Pharmaceutical Council

September 2016

Thinking of reporting a concern to us?

A guide for employers and locum agencies

Contents

Introduction

Who this guide is for

We have written this guide to help employers and locum agencies decide whether to refer concerns to us.
It is important that you contact us if you have a concern about a pharmacy professional which could suggest there is a risk to patient safety or could affect public confidence in pharmacy.

Our role

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales. It is our job to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy. Our main work includes setting fitness to practise requirements, monitoring pharmacy professionals' fitness to practise and dealing fairly and proportionately with concerns and complaints.

An important part of our work is to deal with the small number of pharmacists and pharmacy technicians who fall short of the standards that the public can reasonably expect from healthcare professionals. This means we will investigate information that calls into question a pharmacy professional's fitness to practise. We will refer pharmacy professionals to the fitness to practise committee if we think there is evidence that their fitness to practise is impaired. This can result in restrictions on, or the removal of, a pharmacy professional's ability to practise.

Raising concerns

What is fitness to practise?

A pharmacy professional is 'fit to practise' when they have the skills, knowledge, character, behaviour and health needed to do their job safely and effectively. In practical terms, this means maintaining appropriate standards of competence, demonstrating good character, and keeping to the principles of good practice set out in our various standards, guidance and advice.

An isolated breach of our standards does not necessarily mean that a pharmacy professional's fitness to practise is impaired.

A pharmacy professional's fitness to practise can be impaired for a number of reasons. These include:

- misconduct
- deficient professional performance (DPP)*
- ill-health
- a conviction or caution for a criminal offence

* please see page 16

The aim of managing fitness to practise is to manage risk, maintain patient safety and uphold public confidence in the pharmacy profession. It is not to punish pharmacy professionals or to replace or duplicate your own procedures.

You will find examples of the types of concerns that we do and don't investigate in appendix 1.

We appreciate that it can be difficult to decide whether an issue raises concerns about a pharmacy professional's fitness to practise. If you are not sure about whether to refer a concern to us, you can call us on 020 3713 8000 and ask our concerns team for advice.

If you have a concern

To help us to make sure that all pharmacy professionals are fit to practise, please let us know straight away if you have any concerns that a pharmacy professional's conduct, attitude or behaviour present a risk to patients or the public, or are likely to seriously undermine public confidence in the profession.

You can raise concerns by filling in our online form at
www.pharmacyregulation.org/raising-concerns

We expect referrals to be made in good faith, and that you will have tried to make sure the information provided is fair and accurate.

We will review your concern to decide if we can treat the information you have given as an allegation that a pharmacy professional's fitness to practise is impaired. Therefore it is important to include as much detail as you can about your concern at the outset so that any decision we make is well informed.

If your concern does not call into question a pharmacy professional's fitness to practise, we will write to you explaining why we cannot deal with your concern. We may direct you to another organisation that might be able to help you.

Before telling us about your concern, you may want to see if you have internal processes or policies that could support your decision to refer a concern.

What we investigate

We can only investigate information that calls into question a pharmacy professional's fitness to practise. This means that we can only investigate the most serious concerns about pharmacy professionals.

All pharmacy professionals should keep to the standards of conduct, ethics and performance ('the standards'). These are a range of professional standards that we publish, and you can see them on our website at **www.pharmacyregulation.org/standards/conduct-ethics-and-performance**

A breach of the standards could prompt us to begin an investigation.

Under our standards of conduct, ethics and performance and our standards for registered pharmacies, all pharmacy professionals have a duty to be open and honest with patients when things go wrong. There is also a duty to be open and honest with colleagues, employers and any other relevant organisations – including with us as the regulator – and to raise concerns when appropriate.

What we don't investigate

We are committed to being a 'proportionate' regulator. This means using the right level of regulatory action to make sure that pharmacy professionals are fit to practise. Our investigations are more targeted, efficient and effective if employers investigate concerns effectively and, when appropriate, resolve them locally.

Most concerns we receive about pharmacy professionals come from patients or members of the public. Some of these people are not happy with the way their complaint was managed locally, or they just want an apology for what went wrong. Many of these concerns can be resolved locally. You should have an efficient process in place for resolving concerns locally. This should include making sure you tell the complainant the outcome of your investigation and about any action that you have taken as a result of the complaint. It is important that you encourage an environment and culture where individuals are supported in raising concerns about standards of care and risks to patient safety.

You may also have a concern about a pharmacy professional's conduct as an employee that, while needing action by you, does not call into question their fitness to practise. For example, persistent lateness or a failure to honour locum bookings are unlikely to raise concerns about a pharmacy professional's fitness to practise.

Whether or not a concern should be dealt with by the employer will depend on the facts of the case. If there is evidence of behaviour which is incompatible with the standards of conduct, ethics and performance, you should refer the concern to us for investigation. If you are not sure whether to refer a concern, you can call our concerns team on **020 3713 8000** for advice.

We will not usually consider an allegation which is more than five years old, unless we need to do this to protect the public or if it is otherwise in the public interest. The following concerns will also not usually be considered, as they are outside our remit:

- employment issues such as hours of work and employment contracts
- contractual issues, for example minor breaches of the pharmaceutical contract
- minor customer service issues such as being rude to a patient or being slow to respond to a customer query

Urgent cases: interim orders

As an employer you have the power to suspend or dismiss a pharmacy professional, but this may not prevent them from working somewhere else.

We have the power to impose an interim order (IO). This is an urgent measure to either suspend a pharmacy professional from being able to practise or restrict their practice in some way. The IO can be kept in place until the fitness to practise process has finished.

Important: if you believe that a pharmacy professional's, or the public's, health and wellbeing is at immediate and serious risk, you should contact us immediately.

You can tell us about any urgent concerns even before you have carried out your own investigation. You may not have a lot of information, but you should tell us as much as you can and send us any supporting documents. If you have already involved the police or another agency, you should let us know.

If you have already referred a matter to us but the situation changes and becomes more urgent, you should let us know immediately. We can impose an IO at any time during an investigation.

See appendix 2 for some examples of urgent concerns we have dealt with.

If you need us to act urgently, call us on 020 3713 8000 to explain that you have completed the online form and that it is an urgent referral.

'Parallel proceedings'

Whether or not you need to tell us about a concern will depend on the circumstances and the seriousness of the concern.

Sometimes we are told about a concern while another agency – such as the police, NHS Protect or the MHRA – is carrying out its own investigation. Similarly, concerns are brought to our attention when an investigation is being carried out by an employer. Unless the pharmacy professional's conduct or behaviour puts patients at risk, we can consider delaying our investigation until the other investigation or employment disciplinary process has finished.

Issues that might cause an employer to take disciplinary action may not be issues that result in us having to restrict a pharmacy professional's practice. Our fitness to practise procedures and an employer's disciplinary or capability processes are different, and can result in different outcomes.

Things to consider before referring a concern

Some issues should be dealt with locally by employers. These cases would include relatively minor incidents where no harm has been caused and no patient safety issues have been raised. In circumstances such as these, it might be more appropriate for any issues to be dealt with locally – for example, by the pharmacy professional receiving further training or support.

Many cases of ill-health can also be managed locally, if:

- the pharmacy professional acknowledges the condition
- the necessary steps have been taken to manage the condition following advice from a doctor or occupational health department, and
- there is no risk to patient safety

Many issues can be resolved quickly and fairly by local procedures. But if a matter does raise issues of fitness to practise or patient safety you should refer it to us. This referral should include any information you gathered as part of your local investigation.

Pharmacy professionals can also tell us about any health issues which may affect their own fitness to practise using our health declaration form, which is online at **www.pharmacyregulation.org/form/health-declarations**

It is your decision as an employer whether or not you refer a case to us. You should therefore record this decision, with appropriate reasons, as part of your local investigation.

Important: you should refer a concern about a pharmacy professional's fitness to practise to the GPhC even if they resign or move somewhere else before a local investigation can be finished. You should also refer concerns that are being dealt with by an employment tribunal.

Threshold criteria

When deciding whether to refer a concern, you may find it helpful to look at the GPhC threshold criteria in appendix 3. The threshold criteria are based on our standards for conduct, ethics and performance.

Making a referral

You can refer a concern to us by filling in our online form at **www.pharmacyregulation.org/raising-concerns**

If you would like to contact us to discuss any aspect of raising a concern, you can email **concerns@pharmacyregulation.org** or phone our concerns team on **020 3713 8000**.

Any concern you refer to us will need to:

- identify the pharmacy professional concerned
- clearly explain the concerns about the pharmacy professional (giving dates, times and locations)
- give details of any witnesses, and
- be supported by appropriate information and evidence

In potentially serious cases, when there may need to be an interim order, you should phone us as soon as possible. We will then review your concern to decide if we need to impose an interim order.

Important: your concern will be disclosed to the pharmacy professional during the investigation.

What might the GPhC expect from me?

We are likely to need your help during the investigation. Depending on the nature of the referral, we might need to interview your staff and ask you either to store items safely (for example, medication boxes), or to send them to us. We will be as flexible as we can when we arrange interviews, to minimise the disruption to your business.

We cannot rely just on the outcome of your own internal disciplinary process, and it is our responsibility to investigate the case fully. We will be grateful for all the relevant documents that you are able to send us. These will help us to work out the scope of our own investigation. We will be able to use any witness statements you obtained as part of your internal investigation as a starting point. But we are likely to need to interview your staff so that we can make sure the evidence is suitable for our own purposes.

Superintendent pharmacist (SI)

In most cases, the SI is responsible for the local investigation and for making the referral to us. As part of our investigation, we are likely to need to prepare a statement for the SI regarding their investigation. This will also involve asking the SI to formally exhibit the key documentary evidence they obtained as part of the investigation. If the SI is not the person who carried out the initial investigation, we are likely to need to approach the most appropriate person best placed to provide the information.

We also receive referrals from organisations that do not have an SI. In these circumstances, we are likely to need to contact the senior manager who carried out, or oversaw, the investigation. In a hospital, this is likely to be the chief pharmacist or head of pharmacy.

Human resources (HR) team's involvement

We realise that investigations can sometimes be challenging for the people involved. Your HR team will probably be involved in giving support and help to members of staff involved in the fitness to practise process. In the first instance, a member of staff should ask the HR team for guidance and support.

We will take all reasonable steps to make sure that you and your staff are involved and supported throughout the fitness to practise process. We will explain how the process works, and provide regular updates about the progress of the case.

The fitness to practise process

After you refer a case to us, we will follow the fitness to practise process shown in the diagram below.

Key

C	Concern received
DR	Direct referral
IO	Interim order
OOJ	Out of jurisdiction
T	Triage

Stage one: concerns received

We will review your concern to decide if we can treat the information you have given as an allegation that a pharmacy professional's fitness to practise is impaired. Therefore it is important to include as much detail about your concern at the outset as you can, so that any decision we make is well informed. If necessary we will get guidance from a GPhC inspector, professionals regulation manager or a senior lawyer to help us decide if a concern calls into question a pharmacy professional's fitness to practise.

If your concern does not call into question a pharmacy professional's fitness to practise, we will write to you to explain why we cannot deal with your concern. We will direct you to any other organisation that might be able to help you.

If your concern is a matter that we can deal with, we will write to you to confirm that we are investigating. We will open a case and assign a case worker or inspector. They will investigate the concern, drawing upon specialist expertise as needed.

We will tell you within three working days of getting your concern whether we will be able to investigate it.

Stage two: investigation

Our investigation process has two stages:

1. Investigation

The concern is opened as a case and given a case reference number. The case is then assigned to either 'stream 1' or 'stream 2'. A case will be assigned to stream 1 if it relates to professional issues or dispensing incidents which are unlikely to meet the threshold criteria. Stream 1 cases are investigated by inspectors. All other cases are assigned to stream 2. Stream 2 cases are investigated by experienced regulatory case workers.

The investigation may involve a range of activities depending on the nature of the case. The case worker or inspector may contact you and make arrangements to discuss the concern fully and get any further information, evidence or witness statements we need. We may make further enquiries with employers or outside agencies such as NHS clinical commissioning groups, Scottish NHS boards, Welsh health boards, the police, the courts and other regulatory bodies.

2.'Sign off'

Once we have finished our investigation we review all the evidence we have and decide on the appropriate action to take. We use the threshold criteria in appendix 3 to decide whether to refer a case to the investigating committee.

The threshold criteria are based on our standards for conduct, ethics and performance.

Cases that meet the threshold criteria are referred to the investigating committee.

We will tell you whether or not your concern is being referred to the investigating committee and we will explain the reasons for this. Please see *Stage three: the investigating committee*.

If the case is not referred to the investigating committee it may be closed with a letter of advice sent to the pharmacy professional or closed with no further action.

How long does the investigation take?

How long it takes to investigate your concern will depend upon how complicated it is, how many witnesses are involved and how quickly we get the evidence we need. In most cases, however, our aim is to have finished the investigation – and to have decided whether the matter will be referred to the investigating committee – within six months of receiving your concern.

We will update you at least every two months on the progress of the investigation. We will also tell you about progress at relevant stages and key decision points.

If your concern is referred to the fitness to practise committee, we will write to you to set out the timescales involved. Please see *Stage five: the fitness to practise committee*.

Stage three: the investigating committee

The investigating committee is an independent panel of people that makes decisions about whether a case should go ahead – and if so, how. The committee will consider a report prepared by us, any evidence (which will include information provided by you), and any submissions made by the pharmacy professional. It meets in private, which means that neither the pharmacy professional nor any witnesses attend.

The investigating committee will decide whether to:

- take no further action
- write a letter of advice to the pharmacy professional
- issue a warning to the pharmacy professional
- agree written undertakings with the pharmacy professional, or
- refer the case to the fitness to practise committee

The investigating committee will only refer a case to the fitness to practise committee if it considers there is a real prospect that the committee will decide that the pharmacy professional's fitness to practise is impaired.

Stage four: preparing for a hearing

If the case is referred to the fitness to practise committee, we will need to prepare the case for the final hearing. This is called the 'principal hearing'. During this stage, we review all the information and evidence we have, to make sure the case is ready for the principal hearing. If anything has changed since the case was referred by the investigating committee, we may need to gather further evidence at this stage.

We also schedule the hearing date at this stage. This will include contacting the witnesses to find out if there are any dates when they cannot attend a hearing. We will also give witnesses more information about what will happen when they come to give evidence at the hearing.

Stage five: the fitness to practise committee

If the case is referred to the fitness to practise committee, a formal hearing will be held. You, and anyone else who has provided a witness statement, may be asked to attend to read out your witness statement and answer questions at the hearing.

The fitness to practise committee is an independent committee that will consider the evidence available, decide whether the facts are proved and decide whether or not the pharmacy professional's fitness to practise is impaired. You can read more information about attending hearings in our guidance for witnesses at **www.pharmacyregulation.org/raising-concerns/hearings/witness-guidance**

The fitness to practise committee may impose the following sanctions:

- take no further action
- issue a warning
- agree undertakings with the pharmacy professional
- impose conditions on the pharmacy professional's practice (often in the form of restrictions on the pharmacy professional's practice)
- suspend the pharmacy professional, or
- remove the pharmacy professional's name from the register

The decisions made by the fitness to practise committee are not intended to punish the individual. They are made to safeguard the

health and wellbeing of pharmacy professionals and members of the public, and to protect the wider public interest.

You can see more about the investigating committee and the fitness to practise committee on our website at **www.pharmacyregulation.org/raising-concerns/hearings/committees**

Fitness to practise committee outcomes

We publish the decision of the fitness to practise committee on any case when a pharmacy professional's fitness to practise is found to be impaired. These decisions remain on our website for 12 months. We do not publish the full decisions of cases that involve a pharmacy professional's health, or if the hearing was in private.

If a committee does not find that the pharmacy professional's fitness to practise is impaired, but considers that it is necessary to issue a warning, the warning will be published on the register and the decision will be published online.

Decisions and rights of appeal

The pharmacy professional concerned has the right to appeal against a decision of the fitness to practise committee to the High Court in England and Wales or to the Court of Session in Scotland. The Professional Standards Authority for Health and Social Care (PSA) also has the power to review certain decisions. It can refer these to the High Court or Court of Session if it considers that the decision is not sufficient for the protection of the public.

How we use information

We keep a record of all concerns, and the outcome of investigations. We may take this information into account when assessing any allegations made against a pharmacy professional in the future.

What you can expect from us

We are committed to investigating concerns efficiently and effectively. We aim to do so proportionately, and to deliver high-quality customer service.

We will keep you up to date during a fitness to practise investigation, and any proceedings before the fitness to practise committee. We will give you relevant updates at least every two months. We will deal with you and any witnesses in a way that is timely and courteous.

If we receive a referral about your employee from someone else we will contact you to let you know, shortly after we receive the referral – unless there are exceptional circumstances.

Each case is allocated to a multidisciplinary regulatory team made up of caseworkers and lawyers, supervised by a senior manager. Each case is the responsibility of a named person within the team. You can contact them for support, information and updates.

Sometimes, for reasons of confidentiality or to keep to the Data Protection Act, we are unable to share specific information with you. If this is so, we will explain why.

Our investigation is independent. The decisions we reach are made impartially, taking into account the GPhC's need to act in the public interest. We understand that you may not agree with the steps we need to take in our investigation, or with the decisions we reach. We will explain our decisions and why we need to take certain investigative steps.

We aim to reassure people raising concerns, witnesses and pharmacy professionals that we are dealing actively with the matter that involves them. We will do this by regular updating, communication and appropriate information sharing.

If you have a concern or complaint about our investigation or our approach, please contact either the professionals regulation manager, the head of professionals regulation (fitness to practise) or go to **www.surveys.pharmacyregulation.org/s/review**

We deal with complaints in line with our complaints process. This can include referring the complaint to the director of inspection and fitness to practise, and to the chief executive.

Appendix 1: More information about concerns

We receive a broad range of different concerns about pharmacy professionals. To help you decide whether you need to refer concerns to us, here is more information about the types of concerns that we do and don't investigate.

Misconduct

Misconduct is behaviour that falls short of that which can reasonably be expected of a pharmacy professional.

The most common examples of professional misconduct include:

- dispensing errors with 'aggravating features' (see case study one below)
- failure to implement or follow standard operating procedures if this increases the risk of dispensing incidents or patient safety concerns
- fraud
- theft
- significant failure to keep proper records
- physical or verbal abuse of colleagues or members of the public, including bullying and harassment

A pharmacy professional's behaviour outside work may also amount to misconduct if it has the potential to bring the profession into disrepute. If a concern is raised with you about something that happened outside work, and the incident suggests that a pharmacy professional's fitness to practise may be impaired, you should make further enquiries. If appropriate, you should then refer the matter to us.

Case study one

The head office of Healthy Pharmacy Ltd received a complaint from a member of the public on behalf of her elderly mother. The complainant, Mrs B, said that her mother was given the incorrect medication from the Healthy Pharmacy branch near where she lives.

Mrs B's mother, Mrs A, receives a regular repeat prescription for amitriptyline from the pharmacy. On this occasion, Mrs A was given a box labelled as amitriptyline but the medication inside was Gabapentin. Mrs A did not notice and took the medication for several days and noticed that she was feeling sick and drowsy, and that the pain in her back got worse. She went to her GP, where it was discovered that she had been taking the wrong medication. She told her daughter, who complained to head office.

The superintendent pharmacist for Healthy Pharmacy Ltd investigated the matter and confirmed the identity of the responsible pharmacist on the day the incorrect medication was dispensed. During the investigation the superintendent found out that the responsible pharmacist had already discussed the error with the complainant and had asked her not to make a complaint to head office. The pharmacist later admitted that she deliberately did not fill in an incident report (as company procedure required) because she wanted to conceal the error. She was already on a performance improvement plan and was worried that the error would count against her.

Action needed

The superintendent pharmacist should refer the matter to the GPhC. The referral is not necessary just because of the error alone. In this case, there is evidence that the pharmacist tried to conceal the error and prevent its being investigated. This raises concerns about the pharmacist's honesty and integrity which should be investigated by the GPhC.

In deciding how to deal with a case we consider, when appropriate, the level of harm which was caused to a patient by the pharmacy professional's behaviour or error.

The definition of harm is set out under Section 20(7) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The relevant section of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 appear in Appendix 4.

Case study two

Mr Dis the owner of RG Chemists. Mr Dnoticed that there were some irregularities in his till balances. He investigated further and found that on seven occasions over the past three months, his till balance was around £30 less than it should have been.

He checked the staff rota for these dates and several different members of staff worked on most of the days. But one person, a pharmacy technician, was scheduled to work on all the days. Mr D carried out investigatory interviews with all members of staff, including the pharmacy technician Mr C. In the interview, Mr C admitted that he had taken £30 out of the till on a few occasions. He had intended to pay it back but he was in serious financial difficulty due to a lot of personal debt, and he had used the money to pay for his electricity bill and for food for his family. Mr C said he was very sorry but he was ashamed to admit to his problems. The following week, Mr C came in with £210 to repay the money he had taken.

Action needed

Mr D should refer the matter to the GPhC. Theft is an example of misconduct which could mean that Mr C's fitness to practise is impaired because it raises concerns about the pharmacy technician's honesty and integrity. The fact that Mr C admitted the theft immediately and repaid the money would be taken into account when deciding the outcome of the case.

Deficient professional performance

Deficient professional performance (DPP) is a standard of professional performance that is unacceptably low. It generally means there is a pattern of poor performance that has happened over time and which shows that the pharmacy professional is not practising at the standard required of the role. One minor error which does not amount to misconduct is not DPP. But if these errors have happened often or consistently over a length of time, it may be DPP.

DPP issues are usually referred to us after the employer has done all they can to address the problems with a pharmacy professional's practice. Despite ongoing support and training, the pharmacy professional's practice has not improved, and this may often lead to dismissal or a reduction in responsibility. This means that:

- the issue or issues have been identified and discussed with the pharmacy professional
- measures have been put in place to deal with the issue or issues, such as action plans or performance improvement plans setting out objectives and a timeframe for completion
- these measures have been monitored over a period of time to allow the pharmacy professional to demonstrate improvement, and
- there has been no significant improvement as a result of these measures

Although DPP issues are usually referred to us after the employer has been through all their internal procedures, you should contact us **immediately** if you believe that the pharmacy professional's, or the public's, health and wellbeing is at immediate and serious risk. We will then consider whether or not an interim order is needed to restrict the pharmacy professional's practice immediately.

Case study

A pharmacy technician worked in the pharmacy department of a hospital. Between January and June 2012, they made four errors which included dispensing the wrong medication and providing incorrect instructions on the label. The pharmacy manager, Ms E, met with the pharmacy professional after each of the errors was discovered and discussed with him what may have been the cause.

Following the fourth error, Ms E decided that she would monitor the pharmacy professional's performance and would meet with him fortnightly to check on his progress. Once a fortnight, Ms E would ask the pharmacy professional to check and dispense 50 items which she would then review herself for any errors. Between June and September 2012, no errors were made.

Between September and December 2012, the pharmacy professional made a further six errors, some of which made it on to the ward and were only picked up by the nursing staff. Ms E decided to put in place a more formal performance management process, so that the right level of support could be offered to the pharmacy professional.

In January 2013, the pharmacy professional was given a performance improvement plan (PIP). The PIP set out five objectives which the pharmacy professional had to achieve within 12 weeks. Ms E also arranged to meet with the pharmacy professional every week to give him support and to discuss any concerns he had. Also, the pharmacy professional was sent on training courses and given a mentor to whom he could go with any concerns.

Between January and March 2013, a further four errors were made by the pharmacy professional. Again, the errors were about the incorrect medication, or the wrong instructions, being provided. A formal meeting was held after each error was discovered, and the reasons for the error were discussed with the pharmacy professional. The pharmacy professional was asked to provide a 'reflective piece' following each error, explaining what steps he would take to prevent such errors happening again.

A formal review meeting was held at the end of March 2013. Ms E explained that the pharmacy professional had not met the PIP objectives in the time allowed. It was decided that a further 6 weeks would be given to allow the pharmacy professional time to show that he could achieve the objectives and work at the standard required of his role.

In early April 2013, the pharmacy professional dispensed medication at three times the amount prescribed. Following this incident, the pharmacy professional went on sick leave, which was followed by planned annual leave.

The pharmacy professional returned to work in June 2013. He completed a phased return to work, building up his hours over four weeks. It was decided that, given his absence from work, the objectives would be set again and he would be given a further 12 weeks to achieve them.

Between June and August 2013, the pharmacy professional made a further seven errors. At this point he was suspended from work pending further investigation.

Ms E produced a capability review report and submitted it to senior management for review. A capability hearing was arranged for October 2013. At the hearing, the panel took into account the support, training and development opportunities provided by the hospital to the pharmacy professional. It was considered that the hospital had exhausted all options in terms of supporting the pharmacy professional. The panel decided that the pharmacy professional had not shown that he was able to practise at the standard required of him, despite ongoing support over a prolonged period of time.

Action needed

Ms E should refer the matter to the GPhC. There is evidence that the pharmacy technician's fitness to practise may be impaired by reason of deficient professional performance. The employer tried to manage the concerns locally by putting in place an appropriate support plan, and the pharmacy technician's performance was measured against this for a significant amount of time. However, the pharmacy professional's performance did not improve and the capability hearing concluded that the pharmacy professional was not able to practise at the required standard. This raises concerns about risks to patient safety.

Cautions and convictions

One of the most common types of cases investigated by the GPhC is when a pharmacy professional has received a caution or a conviction. All criminal convictions and cautions should be declared by the pharmacy professional to the GPhC within seven days. Not doing so may also lead to fitness to practise proceedings.

Fixed-penalty traffic offences, such as a speeding fine or parking ticket, do not need to be disclosed to us.

If you are unsure whether to make a referral, please contact us for advice.

Case study

Ms F is a pharmacist at Bigstore Pharmacy. In a recent meeting with her line manager, Ms F mentioned that she had recently received a court conviction for speeding and had been fined.

Her line manager asked if she had told the GPhC, and she replied that she had not because she didn't think she had to for traffic offences.

Action needed

Ms F's line manager advised Ms F to call the GPhC to check. The customer service representative told Ms F that because she had received a court conviction, she should report it. Ms F then filled in the online fitness to practise declarations form and told her line manager that she had done this.

Ms F was right to tell the GPhC about her conviction. Although certain traffic-related offences which result in a fixed penalty notice do not need to be declared, police cautions and any court conviction should be declared within seven days.

Ill-health

Many pharmacy professionals with health conditions or disabilities are able to practise safely, with or without adjustments to help and support them. However, there are health issues which could have an effect on a pharmacy professional's ability to practise.

Issues that should be referred us are long-term, untreated or unacknowledged health conditions, both mental and physical, which might impair a pharmacy professional's ability to practise safely without supervision. This includes harmful use of, or dependence on, alcohol or drugs.

The matter can probably be managed or resolved locally if:

- the type and severity of the health problem is unlikely to pose a risk to patients, either now or in the future
- there is no evidence that the pharmacy professional's health has had a significant effect on their clinical competence or conduct so far
- there is evidence that the pharmacy professional has insight into the issue and is receiving appropriate treatment or support
- the pharmacy professional is in stable, long-term employment
- there is independent medical opinion to support the pharmacy professional's insight and cooperation with treatment, and
- the pharmacy professional is covered by an effective, locally managed support plan

The matter should be referred to us if:

- the type and severity of the health problem mean it is more likely to pose a risk to patients now or in the future. For example, the condition might have high rates of relapse or may be more likely to result in a lack of insight or cooperation on the part of the pharmacy professional
- the condition has been present for some time and you have only just been made aware of it, or you have been unable to put in place an adequate support plan
- the pharmacy professional is not in stable employment
- independent medical opinion raises concern, or is conflicting, about the pharmacy professional's level of insight or cooperation, or
- the pharmacy professional is (or was) part of a locally managed action plan but is intending to leave (or has left) employment, and you believe there is still a risk to patient safety or the pharmacy professional's welfare

You **must** refer the matter to us if:

- there is a clear risk to patients
- there is a clear risk to the pharmacy professional
- the pharmacy professional is or has recently been compulsorily detained under The Mental Health Act 1983
- there are performance or conduct concerns

- the pharmacy professional's health has led to alcohol abuse, or involvement in criminal activity such as drug abuse or violence, or
- the pharmacy professional lacks insight, has not tried to get appropriate treatment, or has stopped using support

Case study one

Mr H, a pharmacist, was diagnosed with depression and anxiety by his GP. He was signed off work for three months. Three weeks before Mr H was due to return to work, Mr H's line manager, Ms G, arranged a meeting with Mr H. He brought a letter from his GP which said that he was taking medication to manage his condition and was about to begin a course of cognitive behavioural therapy. The GP also said that he felt that Mr H could benefit from a phased return to work, but that he was otherwise fit to return to his duties as a pharmacist.

In the meeting, Mr H said that he felt far better and was keen to get back to work. Ms G agreed that Mr H should come back to work part time to begin with and work up to a full working week over the next two months. She also appointed a workplace mentor who would have regular meetings with Mr H during his phased return to make sure that he was ready. The mentor would monitor his work over the first few weeks.

Ms G felt that the matter was resolved and decided not to tell the GPhC.

Action needed

Ms G was right not to tell the GPhC about Mr H's health issue because:

- any risk to Mr H or the public was low
- Mr H's GP felt that he was fit to practise, and
- appropriate support was available to Mr H at work

However, Ms G should continue to monitor the situation. If she feels that Mr H's situation deteriorates, or if she has any concerns about his practice once he returns to work, she should refer the matter to the GPhC.

Case study two

Miss J is the regional manager for Greenblue Pharmacy. Miss J got a call from a dispenser in the Downtown branch of Greenblue. The dispenser said that she had some concerns about the locum pharmacist who had been in the store that day. She said that he was acting a bit strangely in the afternoon and she thought that he might have gone to the pub for lunch.

Miss J visited the store the next day and spoke to the locum. He said that he had gone to the pub but had only stopped in for a sandwich and had not had a drink. He told Miss J that the dispenser, who was not at work that day, had not been happy with

some of the tasks he'd asked her to do the day before. Miss J did not see any other problems in the pharmacy so she did not pursue the matter.

Several weeks later, Miss J got another call from the dispenser from the Downtown branch. The dispenser said that the pharmacist had been to the pub for lunch again and seemed to be drunk. He smelled of alcohol and had fallen asleep in the dispensary. Miss L immediately went to the branch and asked to speak to the pharmacist. Miss L could not smell alcohol on him but he appeared unsteady on his feet, he was slurring his words slightly and his appearance was unkempt.

Miss L arranged for a different pharmacist to come to the pharmacy and sent the locum home. She interviewed the dispenser and the counter assistant on duty, who said she had seen the locum coming out of the pub round the corner when she went outside to put something in the bins, and he seemed to be stumbling. The counter assistant also said that she had seen the locum in the park a few times on weekends drinking cans of strong lager on his own and that he often seemed 'out of it'. Miss L cancelled all future appointments with the locum pharmacist and informed his locum agency and the GPhC immediately.

Action needed

Miss L was right to refer the matter to the GPhC as a matter of urgency because the locum pharmacist may have been under the influence of alcohol while at work. This could have had serious implications for the safety of both the pharmacist himself and patients of the pharmacy. It is possible that the pharmacist has a health problem which involves alcohol abuse. An interim order might be appropriate in this case – see *Urgent cases: interim orders* for more information.

Appendix 2: Urgent concerns

The following are examples of the types of urgent concerns we have received.

Case study one

A pharmacy professional, Mrs K , was working as a locum pharmacist at AM Pharmacy. Mrs K was seen by a colleague on 8 August putting a bottle of Oramorph into her handbag. The following day, the same colleague saw Mrs K drinking directly from a bottle of Oramorph while in the dispensary.

The matter was reported and Mrs K 's handbag was searched. Two bottles of Oramorph, a box of Subutex tablets and a box of temazepam tablets were found in her bag. Although the police were called, Mrs K had left the pharmacy by this time and could not be found at her home address. The pharmacy manager recalled that Mrs K had said she was working as a locum at a number of pharmacies.

Action needed

The pharmacy manager should tell the GPhC about this matter immediately. There is a potential risk to the safety of both Mrs K and any patients for whom she might be dispensing as a locum.

Case study two

Miss L was off sick from work. In a call to her manager to explain why, she said that she couldn't work with the pharmacist, Mr S, anymore.

At first she didn't want to explain what she meant, but eventually she said that Mr S had been sending her flirty text messages for several weeks and trying to get her to go out with him. A few days ago he tried to kiss her. On her last shift, he called her into the consultation room, pushed her up against the wall and tried to grope her. She ran off in tears but felt too ashamed to tell anyone. Miss L said that a few of the other women who worked there have had the same thing happen to them but were too scared to say anything in case they lost their jobs.

Action needed

Miss L's manager should report the matter to the GPhC urgently because the allegations against Mr S are very serious and sexual in nature. Mr S's colleagues are potentially at risk and it would be in the public interest to deal with this risk as soon as possible.

For specific examples of all types of cases that we have investigated, take a look at the fitness to practise section of our website. Here you will find information on the latest cases that have reached the fitness to practise committee, including details of the allegations and the decisions made by the committee.

Appendix 3: GPhC threshold criteria

Cases are not to be referred to the investigating committee unless one of the following statements is true:

Principle 1: Make patients your first concern

- There is evidence that the pharmacy professional's conduct or performance caused moderate or severe harm or death, which could and should have been avoided.
- There is evidence that the pharmacy professional deliberately attempted to cause harm to patients, and the public or others.
- There is evidence that the pharmacy professional was reckless with the safety and wellbeing of others.

Principle 2: Use your professional judgement in the interests of patients and the public

- There is evidence that the pharmacy professional put their own interests, or those of a third party, before those of their patients.
- There is evidence that the pharmacy professional culpably failed to act, when necessary, in order to protect the safety of patients.

Principle 3: Show respect for others

- There is evidence that the pharmacy professional failed to respect the human rights of patients, or demonstrated in their behaviour attitudes which are incompatible with registration as a pharmacy professional.
- There is evidence that the pharmacy professional failed to maintain appropriate professional boundaries in their relationship with patients and/or others.

Principle 4: Encourage patients and the public to participate in decisions about their care

- There is evidence that the pharmacy professional damaged, or put at significant risk, the best interests of patients by failing to communicate appropriately with patients or others.

Principle 5: Develop your professional knowledge and competence

- There is evidence that the pharmacy professional practised outside of their current competence.
- There is evidence that the pharmacy professional failed to maintain their knowledge and skills in a field relevant to their practice.
- There is evidence of a course of conduct which is likely to undermine public confidence in the profession generally, or

put patient safety at risk, if not challenged by the regulatory body.

Principle 6: Be honest and trustworthy

- There is evidence that the pharmacy professional behaved dishonestly.
- There is evidence of behaviour on the part of the pharmacy professional which is likely to undermine public confidence in the profession generally, if not challenged by the regulatory body.

Principle 7: Take responsibility for your working practices

- There is evidence that the pharmacy professional has practised in a way that was systemically unsafe, or has allowed or encouraged others to do so, when he or she has responsibilities for ensuring a safe system of working.
- There is evidence of adverse physical or mental health which impairs the pharmacy professional's ability to practise safely or effectively.

If the Registrar is in doubt as to whether the above criteria have been met he shall refer the case to the investigating committee.

Appendix 4: Definition of harm

The definition of harm under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Section 20(7):

"moderate harm" means—

a) harm that requires a moderate increase in treatment, and

b) significant, but not permanent, harm;

"moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

"notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or

b) severe harm, moderate harm or prolonged psychological harm to the service user;

"prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf—

a) on the death of the service user,

b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or

c) where the service user is 16 or over and lacks capacity (as determined in accordance with sections 2 and 3 of the 2005 Act) in relation to the matter;

"severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

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