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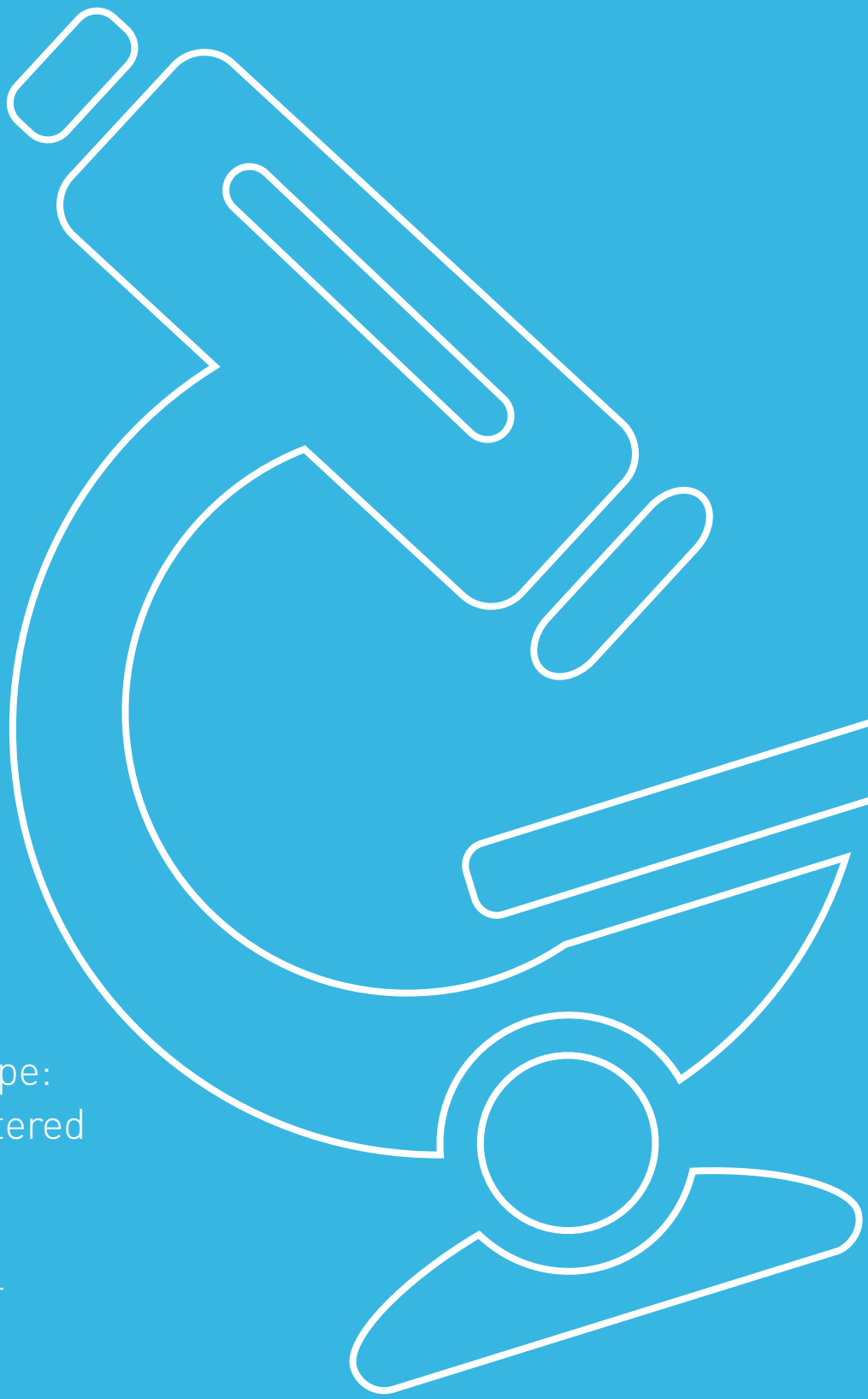
# Regula+e

Upholding standards and public trust in pharmacy

General Pharmaceutical Council



## Inside



www.pharmacyregulation.org

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Regula+e is the registrant bulletin of the General Pharmaceutical Council. It is sent to all registrants and pre-registration trainee pharmacists who are on our database at the time of posting. At times we approach external organisations or individuals to submit articles or opinions on a topical issue. All articles and letters that are commissioned, written or submitted are the subject of editorial scrutiny and may not be printed in full or with reference back to the source.

If you would like to contact the editor, submit a letter or comment on Regula+e, please contact us at:
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# From the chief executive and registrar

We have taken further and significant steps in our plans to modernise the regulation of pharmacy with both a new strategic direction for the organisation and a prototype of our new approach to inspection rolling out from 4 November.

A draft of our new strategic direction was considered by our governing council at its September meeting. This work marks the end of a phase of establishing ourselves as the pharmacy regulator and signals a clear direction of travel for the future of pharmacy regulation.

We have recognised that discharging our statutory functions – like handling fitness to practise cases, registering pharmacists and pharmacy technicians or accrediting pharmacy schools – is only half the job. Performing these statutory functions well is still fundamentally important and the core of our work. But there is another half, and that is about using our regulatory levers strategically to help improve pharmacy practice for the benefit of the public.

What this means, in practice, is still being developed but is likely to include developing new approaches to engaging with people who use pharmacy services as well as analysing and sharing information provided by the public and other bodies for use by us and by those with responsibilities for organising and providing pharmacy care.

The final draft of our Strategic Plan will be laid before the UK and Scottish Parliaments in November. Copies will be available on our website and we will say more on the content of the plan in a future issue of *Regulate*.

The other big development is our governing council agreeing that we are ready to roll out our prototype inspection approach from 4 November to check that the standards for registered pharmacies are being achieved.

There is a guide to the standards in this issue of *Regulate* (see page 11-14) which should help pharmacy owners and superintendents, in particular, and all members of the pharmacy team to better understand the standards and what they are seeking.

The standards are a clear indication of our commitment to improvement in pharmacy practice. Our inspections will be looking to owners and superintendents to provide evidence of how the standards are being achieved every day in pharmacy, not just when an inspector calls. There is more about the prototype approach and what it means for pharmacy on page 15.

We are also preparing three pieces of guidance to accompany the standards for registered pharmacies and there is more news about that work on page 10.

We will need to formally consult on new Rules, which are a form of legislation, to bring our powers to enforce the standards into law. This timing of this work is dependent on the schedule of the UK Parliament so we have not yet been able to set a date for this consultation. This consultation will provide a further opportunity to comment on the standards and individual issues raised by them.

From time to time we invite guest columnists to contribute to *Regulate* on issues that we think you might be interested in. For this issue, we have invited the Chief Pharmaceutical Officer for England, Dr Keith Ridge, to talk about anti-microbial resistance and what role pharmacy can play in tackling this issue.

As always we welcome your feedback, so please do let us know any comments at: **regulate@pharmacyregulation.org**

Duncan Rudkin
Chief executive and registrar

# A new direction for pharmacy regulation

Our new strategic plan 2014–2017 will mark the end of the development phase of the GPhC and signal a clear direction of travel for the future of pharmacy regulation, GPhC chief executive and registrar Duncan Rudkin told the September meeting of our council.

Duncan said: "This plan is informed by a conviction that efficient and effective assurance of core standards is the foundation on which regulation must be built, if it is to protect the public and to have credibility.

"On that secure foundation, we have a duty and an opportunity to play our part in promoting improvement."

Council considered a draft of the plan which outlines a significant change to the way pharmacy regulation is carried out and calls for:

- a completely new form of interaction between the pharmacy regulator and the public who use pharmacy services, including a new approach to the way we use information provided to us by the public and other bodies. Rather than seeing this information as 'complaints' to be processed, looking at it as sources of information that can be used to inform targeted action
- a step change in the way we work in collaboration with other regulators, and the providers and commissioners of pharmacy care and services, and in the effectiveness of this joint working
- a recognition that in performing our statutory functions (handling fitness to practise cases, or accrediting pharmacy schools, for example) we accumulate information and data. This should be analysed and shared, both to help us continuously improve our work, and to provide a unique and valuable resource for those with responsibility for organising and providing pharmacy care and services

The final version of the strategic plan 2014–2017 will be laid before the UK and Scottish parliaments in early November and will be published on our website.

# Understanding pharmacy today: survey update

There is still time to complete our survey and help build a better understanding of what pharmacists and pharmacy technicians are doing in their day-to-day roles and where they are working.

The survey is now well under way. If you have received an invitation and have not yet had time to respond, please take 15 minutes to fill in the questionnaire. The survey will close in early October.

As pharmacists are a large group on our register, we have invited a large random sample of 30,000 to take part.
The size of the sample will allow us to get the information we need and make sure that this information is reliable and representative of the entire group of pharmacists.

As a new and a smaller group, all 22,000 pharmacy technicians have been invited to take part in this survey, which is the first of its kind for pharmacy technicians on the GPhC register.

GPhC chief executive and registrar, Duncan Rudkin, said:

"Thank you to all those who have taken the time to complete the questionnaire.

"We want to encourage as many people as possible to take part. If you haven't yet had the chance to respond, there is still time to contribute and help build a picture of pharmacy as it is practised in Great Britain now.

"We have worked with NatCen Social Research to make sure we collect the information we need in the most cost-effective way, but at the same time ensuring it is reliable.

"The anonymised results will be made public so that the GPhC and organisations representing pharmacists and pharmacy technicians can use this evidence to contribute to discussions about the roles of members of the pharmacy team, and pharmacy as a whole. We would also expect to use this information to inform further research into more detailed aspects of regulation and pharmacy practice."

# Removal from the register for not meeting CPD requirements

We have administratively removed one person from the register for not having submitted their continuing professional development (CPD) record, and are taking action in a further 126 cases where registrants have failed to submit their records on request.

In total, we have issued 127 registrants with notices that we intend to remove them from the register for failing to submit their CPD records. Of these, 15 registrants who have not responded to our initial letter notifying them that they will be removed have subsequently been issued with a notice of removal.

We are continuing to assess cases where registrants have failed to meet CPD requirements during the last call for CPD entries from November 2012 to May 2013.

These cases have arisen since we introduced the CPD framework and rules in July 2011. The registrar can administratively remove someone from the register under these arrangements for failing to submit their CPD record. In the past, this could only be done through fitness to practise (FtP) proceedings.

The registrar also has powers to impose remedial measures. Eight registrants who received a notice that we intend to remove them from the register have written to us outlining why their entry should remain. In five of these cases, we have imposed remedial measures, including one referral to FtP for health concerns, and one request for further evidence.

Remedial measures can also be imposed when submitted entries are evaluated, and do not meet the CPD requirements outlined in the CPD framework. Of the 14,110 registrants who submitted during the last CPD call and review period, 373 of these have had remedial measures imposed.

You can find out more about our requirements for undertaking and recording your CPD, including our CPD standards, framework and rules, at: **www.pharmacyregulation.org/education/continuing-professional-development**

# Progress on renewals

For the majority of registrants and pharmacy premises, the deadline for renewing your registration is 31 October.

If you were planning to pay by direct debit, you will have missed the 24 September cut-off point for making this arrangement. If this is the case, you should have received an email from us explaining that we have suspended your direct debit and that you will need to complete a registration renewal using another form of payment.

To find out how to complete your registration renewal, go to: **www.pharmacyregulation.org/renewal**

# GPhC chair sets out priorities for education and training

The best safeguard for patients is if health professionals behave like professionals, the GPhC's chair, Bob Nicholls, told the Royal Pharmaceutical Society's annual conference in Birmingham on Sunday 8 September.

Mr Nicholls outlined how the GPhC is responding to key developments in pharmacy education and training, highlighting the challenge of embedding professionalism in education and training, as well as influencing changes in the way pharmacy education is structured and delivered in England, Scotland and Wales.

The GPhC is responding to these challenges in a range of ways, including by reviewing the standards for education and training of pharmacists and pharmacy technicians to make sure they reflect changing roles, including greater responsibility for providing clinical services.

Mr Nicholls also raised lessons to be learnt from the Francis report into events at Mid Staffordshire and the Berwick report into patient safety.

These included the importance of being able to provide assurance to patients and the public that pharmacy professionals on the register are up to date and fit to practise. Bob confirmed that developing plans for revalidation would be a key priority for the GPhC over the coming years.

# Open book reference texts for registration assessment sittings in 2014

If you are planning to sit the registration assessment in 2014, the board of assessors which sets and moderates the assessment has now confirmed the reference texts for the open book paper:

- British National Formulary (BNF) 67 March 2014–September 2014
- 2013–2014 British National Formulary for Children (BNFC)

The board of assessors has agreed that pre-registration trainees should use BNF 66 September 2013–March 2014 for the first part of their training, until BNF 67 is published. Then they should use the new edition.

This is a change from past years where the same edition of the BNF that trainees have used throughout their pre-registration training has been included as an open book reference for the registration assessment.

The reason for the change is that trainees should be using the most up-to-date edition when sitting the registration assessment.

They will only use the one BNFC for the whole of their training year.

You can find out more about the registration assessment in the pre-registration manual at: **www.pharmacyregulation.org/preregmanual**

# Looking back at the June registration assessment

Our governing council has considered for the first time, a breakdown of the registration assessment results by gender, ethnicity, country of training and training sector.

This analysis of the June 2013 assessment was included in a report from the board of assessors, who are an independent body with overall responsibility for setting and moderating the assessment.

Key findings from this analysis include:

- candidates who undertook their pre-registration training in hospitals performed significantly better than candidates from community pharmacies, with 91% of hospital candidates passing on their first attempt compared to 76% of candidates from community pharmacies
- female candidates were 5% more likely to pass on their first attempt compared to male candidates
- White – British and White – Irish candidates were most likely to pass on the first attempt compared to other candidates. The performance of Black – African candidates was significantly lower than for other ethnicities, with a first attempt pass rate of 55%
- candidates from Wales and Scotland performed significantly better than candidates from England, with 93% of candidates from Scotland and 91% of candidates from Wales passing on their first attempt compared to 78% of candidates from England
- there is no appreciable difference between candidates who studied wholly in Great Britain and candidates whose primary pharmacy qualification was gained outside the European Economic Area

We will now undertake a further analysis of these results to gain a greater understanding of the factors that contribute to these differences.

You can read the board of assessor's full report at: **www.pharmacyregulation.org/about-us/who-we-are/gphc-council/council-meetings/12-september-2013**

# Renewal postage

We would like to apologise to the registrants who were sent their *Notice of renewal* letters without any postage having been paid on the envelope.

This batch of *Notice of Renewal* letters was re-issued on Wednesday 28 August.

Some registrants have sought to collect this mail from local post offices and have been asked to pay the outstanding amount.

We have made arrangements with the mailing house to reimburse anyone who has had to pay £1.50 to collect the original *Notice of Renewal* from their post office.

If you are affected and would like to claim back your fee, you can find out how to do this at: **www.pharmacyregulation.org/postage-error-some-notice-renewals**

# Tackling antimicrobial resistance

Dr Keith Ridge, Chief Pharmaceutical Officer for England

**We invite Dr Keith Ridge, Chief Pharmaceutical Officer for England, to explain the significance of the UK government's new strategy to tackle antimicrobial resistance.**

The new UK Antimicrobial Resistance Strategy published on 28 August shows how seriously this government sees the increasing problem of resistance and our lack of new agents to treat it. The harsh reality is that the rapid spread of drug resistance means that we could be close to reaching a point where everyday infections will become untreatable.

The strategy calls all government departments, both human and animal health agencies and other sectors, including industry and academia to work together to solve this pressing national and global problem. There are few public health issues of potentially greater importance than antimicrobial resistance (AMR) in terms of impact for society.

The overarching goal of the strategy is to slow down the development and spread of antimicrobial resistance. To achieve this, work will be carried out simultaneously in the following key areas:

- improving infection prevention and control practices in human and animal health
- optimising prescribing practice
- improving professional education, training and public engagement
- developing new drugs, treatments and diagnostics
- better access to and use of surveillance data
- better identification and prioritisation of AMR research needs
- strengthened international collaboration

The strategy calls on all sectors to make a contribution in the fight against resistance. That includes pharmacists, who have a clear role to play, especially in:

- helping raise awareness and encouraging patients to use community pharmacies for advice
- improving prescribing practice, dispensing and administration
- contributing to the audit of prescribing practice
- providing clinical leadership
- working more collaboratively with managers, and infection prevention and control teams
- prioritising antimicrobial stewardship
- adhering to best practice

I encourage you all to read the strategy and begin to think about the contribution that we can make. We all have a role to play in prescribing and using antibiotics responsibly. If we do not respond to this challenge now, society will face serious problems in the future.

You can download the strategy at: **www.gov.uk/government/uploads/system/uploads/attachment_data/file/238872/20130902_UK_5_year_AMR_strategy_FINAL.pdf**

# Practical progress on Francis report recommendations

We are taking further action to respond to the recommendations of the Francis report into events at Mid Staffordshire NHS Foundation Trust, our governing council heard at its September meeting.

We have already identified six themes which have become part of our existing work programme, rather than a separate workstream. We reported on these in the last issue of *Regula+e* and you can find them at: **www.pharmacyregulation.org/francis-report-position-general-pharmaceutical-council**

We have now considered the report in its entirety and further considered what actions we can take. We plan to focus on achieving the following:

- promoting a culture of openness in pharmacy, by setting clear standards and introducing a more robust process for checking whether concerns are raised and acted on through a new approach to inspections
- improving the way we use information from different sources so that our regulatory interventions can be more effectively targeted. We will be analysing data from our own regulatory functions and from other organisations, in order to target our regulatory interventions effectively based on risk to patients
- providing clear information for patients and the public on the standards they should expect from their pharmacies, including through the publication of inspection reports, and making it easier for people to raise concerns when these standards are not met

You can read more about our response to the Francis report and recommendations at: **www.pharmacyregulation.org/about-us/who-we-are/gphc-council/council-meetings/12-september-2013**

# Pharmaceutical care in Scotland

A new report reviewing pharmacy in Scotland welcomes the approach the GPhC has taken to developing standards for registered pharmacies and considers our emphasis on safeguarding the health, safety and wellbeing of patients and the public, and on supporting professionalism, as consistent with its focus.

The review of NHS Pharmaceutical Care of Patients in the Community in Scotland by Dr Hamish Wilson and Professor Nick Barber was published on 14 August 2013.

Professionalism, autonomy and the role of effective professional relationships in realising the full benefits of pharmaceutical care are some of the key themes of the review.

These themes link to our belief that encouraging professional decision making and supporting pharmacy professionals to embrace and demonstrate professionalism in their work, are the most effective ways to protect patients and ensure the safe and effective provision of pharmacy services.

The review also makes recommendations that are relevant to a number of areas of GPhC work, including future arrangements for pharmaceutical care, performers lists and pharmacy workforce and education requirements.

The Scottish Government has published its vision and action plan in response to the review, setting out the next steps for NHS pharmaceutical care in Scotland. We look forward to working with them to ensure that our regulatory approach continues to reflect and respond to developments and innovations in pharmacy practice in Scotland.

You can read the report at:
**www.scotland.gov.uk/Publications/2013/08/4406**
and the vision and action plan at:
**www.scotland.gov.uk/Publications/2013/09/3025**

# Joint working with Healthcare Inspectorate Wales

We will be setting out how we work with Healthcare Inspectorate Wales (HIW ) in our contribution to a short inquiry into HIW's work, which is being carried out by the National Assembly for Wales' Health and Social Care Committee.

The inquiry will look at the investigative and inspection functions of HIW and will consider how HIW collaborates and shares information with other regulatory bodies to fulfil its responsibility to make sure patients have access to safe and effective services, and in its responses to systematic failures and incidences of serious concern.

We will make sure that the committee are aware of our progress towards creating a memorandum of understanding with HIW, and our joint roles and responsibilities in ensuring safe and effective pharmacy practice in communities across Wales.

# Standards for registered pharmacies update

## Quick facts

- standards for registered pharmacies launched in September 2012. Read our short guide to the standards on pages 11-14
- owners and superintendents of company-owned pharmacies who are renewing premises registration must make a declaration that they have read and will meet those standards
- a prototype of our approach to inspecting against the standards is rolling out from 4 November, which will include live inspections
- we will not release public reports of inspections in the initial prototype phase
- pharmacies who are inspected during the prototype phase will be judged against a new set of criteria
- we will not issue statutory improvement notices during the prototype phase
- we are working on three pieces of guidance related to the standards – preparation of unlicensed medicines; distance selling; and safe supply of Pharmacy medicines

You can find a copy of the standards at:
**www.pharmacyregulation.org/sites/default/files/Standards%20for%20registered%20pharmacies%20September%202012.pdf**

# Guidance update

We will be publishing guidance on three topics to enhance understanding of the standards for registered pharmacies:

- the preparation of unlicensed medicines from a registered pharmacy
- distance selling by pharmacies (including internet supply)
- supply of Pharmacy medicines

### On the preparation of unlicensed medicines:

Our primary concern is keeping patients safe. We are preparing new guidance to explain how pharmacies preparing medicines, including the preparation of extemporaneously prepared methadone, must mitigate risks to patients and meet our standards for registered pharmacies. Our new approach to inspection will check this activity, when appropriate.

### On distance selling:

We are widening the scope of this guidance to cover not only the internet but also those pharmacies carrying out other forms of distance selling, such as mail order. There are a number of complex legal issues, including cross-border retail and European Union (EU) legislation, which need to be considered before finalising this guidance.

We plan to conduct further research and to engage with pharmacy over the rest of September and October this year.

### On the safe supply of Pharmacy medicines:

There is an ongoing debate in pharmacy about how medicines can be supplied safely. The recent Which? report about the quality of over the counter consultations has been part of that debate. Earlier this year we worked with the Royal Pharmaceutical Society (RPS) to bring the pharmacy community together to discuss how to improve care for patients in this area.

We are keen to continue to be part of this debate and will be releasing a background paper on the safe supply of Pharmacy medicines shortly. And there will be further opportunities to comment in the upcoming consultation on rules that will bring into law our powers to enforce the standards for registered pharmacies.

We do not plan to publish the finalised guidance until much closer to the introduction of the rules.

# Standards for registered pharmacies: a short guide


One of the ways we protect the public is by setting standards. These describe what safe and effective pharmacy care looks like.

We have asked patients and members of the public, and the pharmacy profession, what these arrangements should look like, whether someone uses a pharmacy close to home, in a supermarket or online. We recognise that there are different ways that pharmacies and pharmacy services are arranged and delivered. Using all that information, we have developed the standards for registered pharmacies.

Pharmacies can only register with us and remain on that register if they are eligible and meet these standards.

Everyone who works in a pharmacy should make themselves aware of these standards. All staff are responsible for keeping patients safe and helping to improve their health and wellbeing.

When we come to check how well the standards are being achieved, it is pharmacy owners and superintendents of company-owned pharmacies who we will be holding to account.

**We want to use the standards to:**

- improve the quality of pharmacy practice
- share examples of good practice, as well as highlight poor practice, when necessary

## Five principles

The standards are set out under five principles which describe arrangements for safe and effective pharmacy practice.

**principle 1** – looks at how you identify and manage risks in your pharmacy

**principle 2** – looks at staffing issues

**principle 3** – is about your pharmacy premises

**principle 4** – is about how you deliver pharmacy services

**principle 5** – is about equipment and facilities

When we talk about pharmacy services we mean: all pharmacy-related services provided by a registered pharmacy including the management of medicines, advice and referral services, clinical services such as vaccinations, and services provided to care homes.

All the principles are important. You might notice that there are a number of themes that run across more than one principle, like confidentiality and managing risk.

Under each principle there is a list of standards which must be achieved if a pharmacy is to continue to be registered.

## What is different?

It will be up to owners and superintendents to provide us with evidence about how well the standards are being achieved. A pharmacy can demonstrate that they are achieving the standards any way they like.

Our inspectors will gather and record evidence in a number of ways, including:

- looking at written or documentary evidence
- observing what is going on
- posing scenarios to staff
- by testing systems

To illustrate further, it will not be enough to point us to standard operating procedures (SOPs). Owners and superintendents will need to provide evidence that staff are aware of the SOPs in use in the pharmacy and that those SOPs reflect how the pharmacy operates.

## The principles

We have set out what we think each principle means, including some questions which you might find helpful to consider.

This is not an exhaustive list and neither do these questions replace the standards themselves. We encourage all members of the pharmacy team to read and become familiar with the standards, which can be found at:
**www.pharmacyregulation.org/sites/default/files/Standards%20for%20registered%20pharmacies%20September%202012.pdf**

## Principle 1: How you identify and manage risks in your pharmacy

When we talk about risk we mean managing risks to patient safety. This principle is about having the right governance systems and processes in place to keep patients safe. Not all pharmacies provide the same services. They need to be able to demonstrate that services are delivered safely, and can be done safely every day.

### Questions to consider:

- have I got systems and processes in place to manage risks associated with the services I am providing?
- have I got arrangements in place to regularly review my systems and processes to make sure they remain safe and fit for purpose, and reflect current practice? And how can I demonstrate this?
- how have I made sure that staff are clear about what they can and cannot do within their roles?
- do I keep records of near misses, errors and incidents and have any changes been made to how the pharmacy operates following an incident or near miss?
- are patients asked for feedback?
- how can I demonstrate that staff are acting on concerns/complaints/feedback from patients? And can I show what has improved as a result?
- have I got appropriate and up-to-date insurance?
- are my records up to date and legally compliant? Can I assure myself that confidential information is not shared intentionally or unintentionally without patient consent?
- do my team know what to do to safeguard potentially vulnerable children and adults?
- when I have locums working for me, if asked, are they clear about the skills and qualifications of other members of the pharmacy team? Are there clear lines of accountability written down and signed? Have they received training?

It might also help to have information about what services you provide and whether you conducted a risk assessment before you started a new service.

## Principle 2: Empowered and competent staff

In this principle, the bottom line is that all members of the pharmacy team are able to meet their professional and legal obligations to put the interests of patients first, and without being hindered by improper influences or targets.

Each member of the pharmacy team needs to be trained to the appropriate level for their role, and the right mix of skills should be in place to deliver the range and volume of services the pharmacy offers.

A culture of openness and honesty should be encouraged and fostered. This means encouraging staff to report and record errors and incidents, and to learn from them. Staff should feel able to make suggestions about how to improve services and expect those suggestions to be listened to and acted on.

### Questions to consider:

- can I demonstrate that there are enough suitably qualified/trained pharmacy staff to deliver the range and volume of services I am providing?
- have I changed staff numbers or the mix of skills when a new service has been introduced?
- do staff have 1-2-1s/team meetings/ appraisals?
- how can I demonstrate that staff are appropriately supervised, particularly trainees?
- how can I demonstrate that staff are encouraged and required to report and record errors/incidents/near misses, and learn from them?
- how can I demonstrate that staff views/feedback have been used to improve services for patients?
- do I set targets or offer incentives for staff and can I assure myself that they don't impact on patient care?
- do staff know what to do should they have concerns about the poor professional practice of others or if the standards are not being achieved?

## Principle 3: How you manage the pharmacy premises

This is about the management of the actual premises – being able to show that the space we register as the pharmacy is clean, hygienic, secure and properly maintained, and appropriate for providing the services on offer, including the protection of privacy, dignity and confidentiality of patients.

### Questions to consider:

- how do I use the workspace? Can I demonstrate that the size, design and layout of the pharmacy supports safe practice?
- do I have a consultation room or can I demonstrate that there is a quiet area where patients can have confidential conversations with pharmacy staff?
- can I demonstrate that the pharmacy has appropriate heating, lighting and ventilation controls?
- can the pharmacy be closed when the rest of the store is open? Who holds the keys?
- where do I store excess stock?

## Principle 4: How you deliver pharmacy services

This is about managing the services offered by the pharmacy - and we don't just mean supplying medicines. It is also about making sure the pharmacy is accessible, including making information available about the services on offer, and in formats and languages that meet the needs of the local community.

### Questions to consider:

- how can I demonstrate that the services I offer are accessible and that I have made reasonable efforts to make them accessible?
- do I signpost patients to other service providers?
- do I tailor services to the local population?
- how can I demonstrate that patients are given the right advice about how to take their medicines?
- can I demonstrate that I have robust stock management arrangements – including for ordering, storing, date checking and rotating stock?
- do I have a dispensing audit trail?
- what do I do with patient returns?
- do I provide a delivery service and if so, do I have an audit trail for deliveries?
- if providing internet services - how do I manage the sale of OTC medicines?

## Principle 5: Equipment and facilities you have and use to deliver pharmacy services

This is about having the right equipment and facilities for the services the pharmacy provides.

### Questions to consider:

- do I have all the equipment I need to provide the services I offer?
- how can I demonstrate that the equipment is clean, working and properly calibrated?
- how can I demonstrate that the pharmacy has up-to-date reference sources?
- can I assure myself that equipment is stored safely and securely?
- how do I store paper records? Are PMR passwords protected?

# Implementation update

### Consultation on rules

The GPhC was set up and operates under a piece of legislation called the Pharmacy Order. This requires that the standards for registered pharmacies are put into rules, which are a form of secondary legislation called a statutory instrument. We must formally consult on new rules, so plan to run a consultation in due course.

The consultation will provide a further opportunity to provide feedback on individual issues raised by the standards.

### Inspection prototype starts 4 November

We will be rolling out a prototype of our approach to inspecting pharmacies from 4 November 2013, which will include live inspections across England, Scotland and Wales.

The prototype is the result of 18 months of work and testing with pharmacists, pharmacies and their teams, patients and the public, our professional sounding boards, and a range of organisations and stakeholder representing the interests of all parts of pharmacy.

We have not yet set a date for when the prototype phase will be completed – we will let you know once we are in a position to do so.

We recognise that we would benefit from having the flexibility to amend and improve arrangements in the light of early feedback and experience.

Pharmacies which are inspected over the prototype period will be given a judgement on how well they have performed against the standards.

Through the process of developing our new three-year Strategic Plan, the GPhC has considered what it wants to achieve against a backdrop of changes to the role of regulation and the focus in health and social care on improving quality.

As part of our new Strategic Plan 2014 – 17, we have made a commitment to do what we can, as the pharmacy regulator, to encourage improvement in the quality of pharmacy practice.

We are proposing to use the following provisional judgements during the prototype phase:

- a poor pharmacy – has failed to achieve the premises standards overall. It is likely to have major non-compliances against standards which indicate a moderate to high risk to patient safety
- a satisfactory pharmacy – achieves the majority of standards. Where there are minor non compliances, these present a low risk to patient safety
- a good pharmacy – achieves all standards consistently well and can demonstrate positive outcomes
- an excellent pharmacy – achieves all standards consistently well and can demonstrate innovation in the delivery of pharmacy services.

We will use feedback to inform and finalise our approach to these judgements.

### Public reporting

We will not be publishing reports of inspections in the initial prototype phase. Work is continuing on developing our approach to public reporting – we will be holding an event with patients and members of the public in late September, as well as discussing this further with our professional sounding board members, and stakeholders, in early October.

### More information for owners and superintendents

We are launching a new online publication for owners and superintendents, called *Pharmacy Standards Update*, which will include the latest news and view on our standards. The first issue will be sent via email shortly to owners and superintendents of pharmacies registered with the GPhC.

Dear Editor,

The Trustees and staff at Pharmacist Support would like to congratulate all the newly registered pharmacists joining the profession this year. We appreciate the dedication, focus and hard work required in successfully training to be a pharmacist.

Pharmacist Support is the profession's independent charity. We support pharmacists, pre-registration trainees, students of pharmacy, former pharmacists and dependants of pharmacists. As the profession's independent charity we currently assist around 5% of the pre-registration trainee population each year, as well as many pharmacists. Whether it's a simple enquiry or request for information, support from a fellow professional, financial assistance, or simply a need to talk something through in confidence, the charity can help. If we cannot assist directly, we will aim to find you someone who can. There are numerous ways to contact us including telephone, email, online via our new live chat function, website or social media.

We would encourage readers to have a look at our website (**www.pharmacistsupport.org**) and see what we have to offer. Someone may not need assistance at the present time, but if they do at some point in the future, they will be better prepared to know where to seek help.

The charity is funded by pharmacists and their families, and works closely with pharmacy bodies. This makes us uniquely placed both to understand and assist with the pressures faced by those in the profession – something we do with integrity, empathy and pride. The charity also introduces and frequently pilots new services that may not be publicised. Therefore we encourage people to speak to us directly, as we may be able to provide assistance that isn't yet advertised.

The charity will also be seeking to recruit two new trustees shortly, to join the board at the beginning of 2014. If you are interested in volunteering for a vibrant, evolving charity that supports your profession, please take a look at our vacancies page at: **www.pharmacistsupport.org**

With warm regards

Diane Leicester
Charity Manager

# Fitness to practise: determinations

If a fitness to practise committee determines that a registrant's fitness to practise is impaired, the committee may impose a sanction that is proportionate to the conduct that has been found proven. This may include, for example, issuing a warning, placing conditions on the individual's registration, suspension of registration or, in the most serious cases, erasing the individual from the register so that they can no longer practise.

The matters listed here include the registrant's registration number, date of determination and the sanction.

Determinations of the facts and additional information about the hearings can be found on our website at: **www.pharmacyregulation.org/search/search_decisions**

## Fitness to Practise Committee determinations

**Smith, Christopher Adrian, 2074490**
Determination date 10 June 2013
Review hearing: suspension for a further six months

**Morales Santander, Isabel, 2057378**
Determination date 29 July 2013
Suspension for two months

**Khan, Habib, 2054174**
Determination date 27 June 2013
Removal from the register. This has been appealed at High Court

**Kaufman, Jacob Alan, 5005632**
Determination date 27 June 2013
Suspension for three months with immediate measures

**Hewitt, Eleanor Faith, 5032575**
Determination date 28 June 2013
Suspension for twelve months with immediate measures

**Thomas, Vivian Melando, 2056768**
Determination date 2 July 2013
Conditions imposed on registration for 18 months, with a review before expiry

**Asif, Mohammed, 2028721**
Determination date 4 July 2013
Removal from the register with immediate measures

**Baxi, Rajnish Singh, 2049754**
Determination date 8 July 2013
Suspension for 12 months with immediate measures, with a review before the end of that period

**Sharma, Neelu, 2047478**
Determination date 11 July 2013
Removal from the register with immediate measures

**Sewell, Leanne Alexandra, 2067576**
Determination date 12 July 2013
Review hearing: removal from the register with immediate measures

**Majchrowicz, Piotr Mikolaj, 2069549**
Determination date 18 July 2013
Conditions imposed on registration for three years, with a review after two years

**Gordon, Sasha, 5003904**
Determination date 25 July 2013
Review hearing: removal from the register

**Gokaraju, Satya Narayana, 2035334**
Determination date 30 July 2013
Review hearing: suspension from the register for twelve months

**Yousaf, Mohammad Atif, 2048146**
Determination date 1 August 2013
Review hearing: conditions continue

**Johnson, Folsade Anne, 2046550**
Determination date 6 August 2013
Removal from the register with immediate measures

**Hoyle (nee Briggs), Vanessa Jane, 2042904**
Determination date 14 August 2013
Review hearing: conditions on registration varied and continued for 12 months

**Mabbott, Fraser Adam, 2076546**
Determination date 22 August 2013
Private hearing: suspension for 12 months

**Mehta, Shailen Kiran, 2057184**
Determination date 23 August 2013
Suspension for four months

**Symonds, Kevin Gerald Reginald, 5007070**
Determination date 27 August 2013
Suspension for twelve months

## Interim orders:

**Tran, Thang, 2071818**
Determination date 6 June 2013
Review hearing: interim suspension order to remain in force

**Cheema, Jaspal Singh, 2038866**
Determination date 7 June 2013
Review hearing: interim suspension order to remain in force

**Faizollahi, Bita, 2047300**
Determination date 10 June 2013
Application hearing: suspension imposed for twelve months

**Hirani, Ghanshyam Kanji, 2026341**
Determination date 14 June 2013
Application hearing: suspension imposed for twelve months

**Simpson, Jacqueline Elizabeth, 2036106**
Determination date 14 June 2013
Application hearing: suspension imposed for eighteen months

**McDougall, Alan, 2026449**
Determination date 14 June 2013
Review hearing: interim suspension order to remain in force

**Rasool, Hussain Jamal, 2068258**
Determination date 20 June 2013
Review hearing: interim suspension order to remain in force

**Iftikhar, Arif, 2054938**
Determination date 24 June 2013
Review hearing: interim order currently imposed to remain in force

**Wood, Janice, 5000692**
Determination date 24 June 2013
Review hearing: interim conditions order currently imposed to remain in force

**Gulamhusein, Murtaza Noorali Mohamedali, 2029954**
Determination date 25 June 2013
Review hearing: interim suspension order to remain in force

**Estafanos, Younan, 2081159**
Determination date 25 June 2013
Review hearing: interim suspension order to remain in force

**Numan, Mohammed, 2072381**
Determination date 25 June 2013
Review hearing: interim conditions order to remain in force

**Dwyer, Gloria, 5022643**
Determination date 25 June 2013
Review hearing: interim suspension order to remain in force

**Chawan, Shaida, 2051633**
Determination date 26 June 2013
Review hearing: interim suspension order to remain in force

**Thakrar, Upesh, 2038583**
Determination date 3 July 2013
Review hearing: interim suspension order to remain in force

**Quill, Emmett, 2064586**
Determination date 8 July 2013
Review hearing: interim conditions order to remain in force

**Miles, Carla Louise, 5029710**
Determination date 25 July 2013
Interim suspension for 18 months with immediate measures

**Attard, Azizah, 2053509**
Determination date 29 July 2013
Application hearing: suspension imposed for eighteen months

**Issop, Mohsin, 2080138**
Determination date 1 August 2013
Review hearing: interim suspension order to remain in force

**Logan, Chris, 2054337**
Determination date 6 August 2013
Review hearing: interim suspension order revoked

**Kirby-Smith, Alex, 2066259**
Determination date 7 August 2013
Review hearing: interim suspension order to remain in force

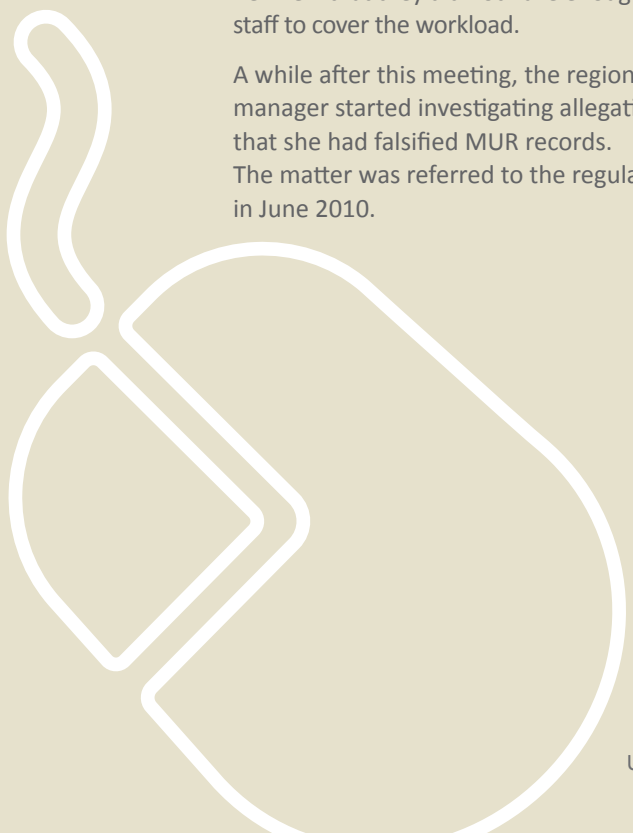
**Patel, Manhar Prabhubhai, 2018623**
Determination date 15 August 2013
Review hearing: interim suspension order to remain in force

**Rahman, Abdul, 2047456**
Determination date 19 August 2013
Review hearing: interim conditions order to remain in force

Please check the GPhC register for warnings for individual registrants by going to:
**www.pharmacyregulation.org/registers**

# Fitness to practise: learning

We receive concerns about pharmacy professionals from a wide variety of sources. Some of the concerns fall below our threshold criteria and so do not get referred to our investigating committee or fitness to practise committee. Cases are only referred to these committees where there is reason to believe that the registrant's fitness to practise may be impaired.



## Managing Medicines Use Reviews (MURs)

Overclaiming for Medicines Use Reviews (MURs) was, in all probability, the result of errors and a systems failure in a busy pharmacy branch where the manager was under stress and this was known by her employers, the fitness to practise committee found.

The regional manager of the branch had approached the management of MURs inappropriately, showing "a concentration on profit for the company to the exclusion of patient benefit", and had demonstrated a lack of understanding of the clinical importance of MURs.

There was no impairment found in the case of the pharmacy manager.

The committee said it hoped the owners of the pharmacy chain would "consider our comments with care".

The pharmacy manager looked after a busy pharmacy dispensing approximately 8000 items a month. The workload was heavy and she had been struggling to cope. She had met with the regional manager to discuss these issues and raise her view that they did not have enough staff to cover the workload.

A while after this meeting, the regional manager started investigating allegations that she had falsified MUR records. The matter was referred to the regulator in June 2010.

The pharmacy manager resigned before a disciplinary hearing could take place and the pharmacy repaid £1568 that had been claimed for MURs that had not been completed.

All parties agreed that the pharmacy manager stood to gain nothing financially.

The committee noted that the company which owned the pharmacy had circulated guidelines to pharmacy managers which referred to the clinical purpose of MURs, and those guidelines included the passage:

"Our goal is to achieve the contractually agreed 400 MURs per year in England and Wales which will generate £8.2 million for the business.

"To help our pharmacists and their teams achieve this, we suggest that you aim to undertake two MURs a day. We also expect the locums we employ to support branch teams in the achievement of this goal."

However, an email sent by the regional manager had been much more explicit. "The tone of it was exclusively concentrated on profit, and not on patient care," the committee said.

The committee found that the way the regional manager dealt with the problems raised by the manager had been inappropriate.

"It was a situation in which the likelihood of errors was increased, and patient safety could have been compromised," they said.

The committee found they could not establish the allegations of deliberate dishonesty made against the pharmacy manager. There was no evidence of dishonesty or fraud.

Rather, in all probability, "there were errors and a systems failure in a busy branch where the manager was under stress, and known by the management to be under stress, and having difficulty in coping."

The committee noted some discrepancies between the evidence given by several witnesses, and their witness statements. They said that where an allegation of dishonesty was made against a professional, evidence had to be fairly and rigorously analysed and the preparation of accurate witness statements had to be completed with "conspicuous fairness and attention to detail".

**Learning points**

- do not claim payment for professional services that you have not carried out – be honest and trustworthy
- you have a professional responsibility to raise concerns about circumstances that you feel could compromise patient safety
- your professional judgement must not be affected by incentives or targets given to you by your employer
- only carry out professional services where appropriate, considering the patient's best interests at all times.

## Imposing beliefs on patients

During the supply of emergency hormonal contraception (EHC) a pharmacist told the patient concerned that it amounted to a chemical abortion, was ending a life, and that this would be on her conscience. The fitness to practise committee imposed conditions on a pharmacist's practice for three years following a hearing into this matter.

The patient said she had been shocked and taken aback by what the pharmacist had said. The pharmacist did not give the patient the option of going to another pharmacy and had handed her the drug, saying again that it was a chemical abortion.

The patient said she had been made to feel "rotten and horrible".

Upon the matter being investigated, the pharmacist had eventually admitted that he may have used terms like "chemical abortion" and "ending a life" when speaking to the patient.

The committee found that the pharmacist's actions amounted to serious misconduct and that his fitness to practise was impaired. He was in breach of the standards of conduct, ethics and performance in several respects, and they were not technical or trivial breaches.

The pharmacist's conduct had presented an actual or potential risk to patients or to the public, in that patients might be deterred from seeking EHC for fear of being the subject of "an embarrassing or distressing lecture". Having received EHC, they might decide against taking it, possibly resulting in unwanted pregnancies.

He had clearly breached fundamental principles of the profession of pharmacy, including the requirement on a pharmacist to recognise a patient's right to their own personal values and beliefs, and the requirement on a pharmacist to ensure that their views did not affect how he or she provided professional services.

The committee said that the pharmacist "fails to understand that the regulator recognises and makes allowance for the inability of pharmacists with certain religious beliefs to supply certain medicines or provide certain services as to do so would be in conflict with their religious beliefs. The proper course, the regulator says, in these circumstances is to refer the patient to another pharmacy or pharmacist.

"What a pharmacist must not do is endeavour to impose his own beliefs and moral code upon the patient by condemning the medicine or treatment, by the use of words obviously calculated to upset the patient and discourage the patient from using the medicine or treatment. This is not permitted, and the registrant does not seem to comprehend this restriction," the committee said.

The pharmacist had agreed that he would not provide EHC in the future.

However, there appeared to be little recognition that his actions had been wrong and contrary to "essential principles of pharmaceutical practice". For instance, he had stressed that he had routinely provided EHC to patients before in the same manner. As far as he was aware, no one had complained "and I believe that I complied with my obligations under the relevant professional standards."

The committee concluded that although the pharmacist had apologised if his actions had caused offence, it was difficult to avoid the conclusion that he was wholly unrepentant about the conduct that had led to the hearing. The committee was far from assured that the distressing messages about EHC would not be repeated.

**Learning points**

- you should not seek to impose your views and beliefs on patients
- you must not deter patients from getting, or taking, their treatment or medicine when it is safely and appropriately prescribed, or requested
- you should ensure that when you provide information you are impartial
- make sure that you treat patients politely and considerately, maintaining their dignity
- you must ensure that your professional judgement is not affected by your personal interests.

The committee imposed conditions on the pharmacist's practice for three years, saying that the conduct which had given rise to impairment could not only be controlled, but probably eliminated, by imposing three conditions:

1: To notify in writing all employers or prospective employers, and all agents acting on behalf of employers and locum agencies, in relation to any work, whether paid or unpaid, for which registration with the General Pharmaceutical Council is required, of the allegations found proved in these proceedings, and the restrictions imposed on your pharmacy practice.

2: To notify the General Pharmaceutical Council before undertaking any position for which registration with the General Pharmaceutical Council is required, and which requires you to act as a responsible pharmacist, superintendent pharmacist, or pharmacist owner, in the course of your duties, and to provide the General Pharmaceutical Council with the contact details of your employer, superintendent pharmacist, or pharmacist owner.

3: To consent to the General Pharmaceutical Council exchanging information with your employer, or any locum agency, or any other person or organisation for whom you provide services which require registration with the General Pharmaceutical Council.

The committee also imposed two practice restrictions: Not to engage in the provision of emergency hormonal contraception (EHC), and a further practice restriction that the pharmacist must refrain from providing advice or information to patients based on his personal, moral or religious beliefs.

You can find out more about the role of the investigating committee at:
**www.pharmacyregulation.org/raising-concerns/hearings/committees/investigating-committee**

And about the fitness to practise committee at:
**www.pharmacyregulation.org/raising-concerns/hearings/committees/fitness-practise-committee**

Our threshold criteria can be found at:
**www.pharmacyregulation.org/sites/default/files/The%20threshold%20criteria.pdf**

Check that a pharmacy professional is registered:
**www.pharmacyregulation.org/registers**

**Copies of Regula+e are available to download from our website www.pharmacyregulation.org/publications**

**We welcome feedback and comments on this publication which can be sent to regulate@pharmacyregulation.org**

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