Modernising pharmacy regulation:
A consultation on the draft standards for registered pharmacies
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Foreword

Pharmacy makes a significant contribution to the health and wellbeing of the public. Getting the right medicines, at the right time, in the right way, with the right information and advice, means that medicines can be used safely and in a way that works.

The way in which pharmacy care and services are organised is changing. And pharmacy has the potential to make an even greater contribution to health and wellbeing than it has so far. This enhanced role – and the contribution to public health that pharmacy makes – goes far beyond dispensing medicines on prescription. This greater scope brings with it the potential for new risks. Whether medicines or medical devices are directly involved or not, the public is entitled to be properly protected, so that they can safely benefit from pharmacy services in the way everyone wants.

This important consultation sets out our vision for the regulation of registered pharmacies, recognising that while protection of the public must always be paramount, it is also incumbent upon us to ensure that our regulation does not hinder the development of practice by, for example, stifling innovation or the provision of enhanced services, which have the potential to bring significant benefits to patients.

The General Pharmaceutical Council (GPhC) is still a new organisation, with new statutory powers, having taken on regulatory responsibilities for pharmacists, pharmacy technicians and registered pharmacies across Great Britain in September 2010. We believe that the approach set out in the following pages builds on much of what we have done already; placing a focus on standards which describe the outcomes we want for patients and the public, and showing how we will be proportionate in making decisions when our standards are not met.

What we are proposing is a new, modern approach to pharmacy regulation which is designed to make a positive contribution to patient safety. While the document has to cover a good deal of ground, we have tried to use language and to present the information in a way that makes clear our intentions to non professionals as well as registrants. We have included a glossary of terms to help with this. We are keen to hear your feedback on what we are proposing, how you think it can be improved and any further comments or suggestions.

Bob Nicholls CBE
Chair
This document sets out how we intend to modernise pharmacy regulation with the publication of draft standards for registered pharmacies. In developing these proposals we have met with stakeholders, learnt from other regulators, developed a clear understanding of the legal framework and tested our approach against the principles of good regulation\(^1\).

Although the focus of this consultation is the draft standards, there are four parts to this document and each is described in more detail:

1. **Introduction**: An introduction to our overall approach to regulation of registered pharmacies
2. **Registration**: An overview of which premises we intend to register
3. **Standards**: The draft standards we are proposing for registered pharmacies
4. **Compliance and enforcement**: A description of how we plan to secure compliance against the proposed standards and our approach to enforcement activity.

We are seeking views from a wide range of individuals and organisations including patients and the public, pharmacy professionals including owners and superintendents, professional and representative bodies. We also want to hear from other bodies with an interest in our proposed approach to regulating registered pharmacies including other health regulatory bodies and other bodies who inspect pharmacies in England, Scotland or Wales.

We are asking a specific set of questions as well as seeking more general comments. Your answers will help us to develop and finalise our proposals. Of course you do not have to answer all of the questions; we welcome your views on any part of this document.

We intend to make all responses to this consultation public unless you specifically ask for your response to remain confidential to GPhC staff.

There is more information about how to respond to this consultation on page 43. And we have provided a Glossary of terms on page 46 in case you want to clarify what we mean by a word or phrase.

**The deadline for responding to this consultation is 7 May 2012.**

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\(^1\) Better Regulation Executive five principles of good regulation [www.bis.gov.uk](http://www.bis.gov.uk)
Section 1: Introduction
Introduction

As the regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain\(^2\) it is our job to protect, promote and maintain the health, safety and wellbeing of members of the public, and in particular those members of the public who use or need the services of pharmacy professionals or the services provided at a registered pharmacy.

In developing the proposals set out in this consultation document we have relied heavily on ideas and approaches developed by others. These include the five principles of good regulation first set out by the Better Regulation Executive\(^3\) as well as the principles for inspection and enforcement proposed by Sir Philip Hampton\(^4\) and the Council for Healthcare Regulatory Excellence’s document, Right-touch Regulation\(^5\).

Endorsing these principles is the simple part; the challenge for us is to demonstrate through our approach to regulation that what we propose is fair and proportionate – that is, in line with the level of risk posed to health, safety and wellbeing – and not overburdensome. It is also about recognising that sometimes mistakes happen in healthcare which regulation either cannot prevent, or can only do so by taking steps so disproportionate that patients would actually be disadvantaged by, for example, reduced or limited access to services.

In a good regulatory system it is clear to patients and the public who is responsible for upholding standards and other requirements, including relevant law, and that different parts of the regulatory system work together.

We are working closely with registrants and professional bodies to identify any areas of regulatory overlap; and with other regulatory bodies and organisations to reduce or eliminate overlap and identify any regulatory gaps.

Public Protection Triangle

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\(^2\) The Pharmaceutical Society of Northern Ireland is the regulatory and professional representative body for pharmacists in Northern Ireland

\(^3\) [http://www.bis.gov.uk/policies/bre/policy/five-principles-of-good-regulation](http://www.bis.gov.uk/policies/bre/policy/five-principles-of-good-regulation)

\(^4\) [http://www.bis.gov.uk/files/file22988.pdf](http://www.bis.gov.uk/files/file22988.pdf)

Medicines and medical devices themselves need to be safe and effective. The Medicines and Healthcare products Regulatory Agency has the regulatory responsibility here as represented in the first corner of the public protection triangle (Figure 1).

Two other key components are:

- competent caring professionals practising to the right standards
- a safe and effective system for managing and delivering services.

We, the GPhC, have regulatory responsibilities in these two areas. Both are essential. On the basis of quality-assured education, training and “fitness to practise” we license people to work as competent caring pharmacy professionals. There are equivalent health professional regulators, such as the General Medical Council and the General Dental Council for doctors and dentists respectively. And secondly, we regulate pharmacies required to register with us. This consultation is about new standards we propose to set for this third important corner of the public protection triangle.

It is important that those responsible for running pharmacy services from the registered pharmacies we regulate know what standards they have to meet. This is in order to ensure there is a safe system for managing and delivering services. And, crucially, the standards need to be set in a way that enables the competent caring professionals on our pharmacy register to practise, as professionals, to the standards we have set for them.

The proposals on which we are consulting take account of all aspects of what is a complex legal framework around medicines and pharmacy, including the legal responsibilities of the “Responsible Pharmacist” defined in the Medicines Act, and Government regulations made under it. This consultation is about a different subject, including the standards we expect the owners and superintendents of registered pharmacies to meet.

In setting the standards that all registered pharmacies must meet it is important that we do not give pharmacy owners and managers a one-size-fits-all blueprint for safe and effective service delivery. This is because:

- what works in one pharmacy may not be as effective in another, because of perfectly legitimate differences
- a regulator like the GPhC cannot and should not take on the responsibilities that rightly sit with owners and managers
• pharmacy is changing quickly and it would not benefit the public if our rules got in the way of safe and responsible innovation

• a one-size-fits-all blueprint would impose restrictions and burdens which might be inadequate in one setting but not nearly stringent enough in another, very different setting.

We recognise that our proposed standards are different from the more detailed standards that pharmacy is used to. The new approach will put more onus on pharmacy owners and superintendent pharmacists to consider and manage the risks in their own pharmacies while setting a clear framework in which they must do so.

It is not enough for us to publish standards for registered pharmacies alone. We must be clear about which premises we believe must be registered with us and must adhere to our standards. We know that patients and the public can get their medicines from other service providers, for example at their doctor’s surgery or while as an inpatient in hospital. We do not have powers to regulate the supply of medicines in these and certain other environments. However we will continue to work with the organisations that do regulate these, as patients and the public would expect the standards to be consistent regardless of who regulates the healthcare setting.

And we will set out the approach we plan to take to securing compliance with the standards and how we will manage non-compliance, including use of our enforcement powers.

This consultation document brings together these three key elements: the registration requirements; the standards; and our approach to compliance and enforcement. We also explain how our approach to regulating the services from registered pharmacies, often referred to as a ‘system regulation’, links to our regulation of individual pharmacists and pharmacy technicians.
Section 2: Registration criteria
Registering a pharmacy with us

In this section we explain our proposed model for registering pharmacies. The model is based on a two stage approach – an eligibility to register test followed by a compliance test.

This section also describes the pharmacy services that the owner must provide for premises to be eligible for registration as a pharmacy.

Our proposals
We intend using a two-stage approach for the registration, renewal or restoration of registered pharmacies.

- **Stage 1:** An eligibility test; and
- **Stage 2:** A compliance test.

The eligibility test is based on our interpretation of medicines legislation¹ (See our Glossary at page 46).

The compliance test is based on the standards for registered pharmacies being met.

Our approach is designed to provide clarity for those considering whether they could, or should, register premises as pharmacies. Where there is a need, or wish, to register, our criteria will provide an indication of whether the application is likely to succeed.

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## The registration model

<table>
<thead>
<tr>
<th>Application made</th>
<th>What does this mean</th>
<th>How is this met?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Has the correct procedure been followed?</td>
<td>Application documentation and fee correctly submitted.</td>
</tr>
<tr>
<td>Stage 1. Eligibility Test</td>
<td>Does the service model fit the definition of a retail pharmacy service?</td>
<td>The service model must include the sale of pharmacy-only medicines or the supply of medicines against prescriptions for human use.</td>
</tr>
<tr>
<td>Stage 2. Compliance Test</td>
<td>Will the owners meet the standards for registered pharmacies on day 1?</td>
<td>Successful inspection of premises prior to registration. Conditional registration may be applied to seek compliance with the standards.</td>
</tr>
</tbody>
</table>
Applying the Eligibility Test

Our primary concern is the safe and effective delivery of pharmacy practice. We know that various service models exist within pharmacy. The section below sets out some of these and explains how the eligibility test would apply.

We have based the eligibility test on the legal definition of a retail pharmacy business\(^7\) and the legal requirements for the sale or supply of pharmacy and prescription only medicines\(^8\). Therefore to decide if the application would pass the eligibility test, we will ask ourselves the following question:

‘Will the pharmacy services include the sale of pharmacy medicines for human use and/or the supply of prescription only medicines for human use against a prescription?’

If the answer to this question is no, we will not register the premises as a registered pharmacy.

On this basis, in the future we will not register premises where the service consists solely of:

1. the sale or supply of medicines for animal use
2. the sale or supply of herbal or homeopathic medicines that are available on general sale
3. the wholesale of medicines for human use
4. the supply of medicines in a hospital made in the course of the business of that hospital
5. providing healthcare advice and information
6. the sale of medicines available on general sale, or
7. the manufacture and wholesale of medicines.

Further information about these definitions can be read in the Glossary of terms on page 46.

\(^7\) Section 132 of the Medicines Act 1968
\(^8\) Section 52 of the Medicines Act 1968
Modernising pharmacy regulation: A consultation on the draft standards for registered pharmacies
Compliance through conditional registration

We have legal powers\(^8\) to impose and/or change conditions on premises applying to be registered as a pharmacy, applying for renewal or restoration to the register. These powers are to be used ‘for the purpose of securing the safe and effective practice of pharmacy at those premises’.

We have reflected on the range of applications we have received in the past and have identified a number of situations where we think it will be appropriate to impose conditions on registered pharmacies.

These are:

1. **Initial application to register a pharmacy**
   
   If an application meets both stage 1 and stage 2 of an application process, we may impose a condition that registration will be subject to the registered pharmacy being open, operating and trading by a certain date.

2. **Temporary premises**
   
   On occasion, we receive applications for temporary pharmacies to be registered. This may be because of an exhibition, for example at the Birmingham NEC, a festival, such as Glastonbury or sporting or leisure activity like Wimbledon. We will impose a condition that the pharmacy will only be registered for a short time before, during and after the event.

3. **Closed premises**
   
   We receive applications for registration of pharmacies that do not have premises that are open for patients and the public to visit in person. These are referred to as ‘closed premises’ and will often be mail order or internet pharmacies. We will impose a condition that the premises cannot open for patients and the public to visit in person unless we are notified so that we can decide if our standards continue to be met.

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**Q1** Do the proposals provide sufficient clarity about the premises that need to be registered with us as a pharmacy?

**Q2** Do you have any comments or observations about the proposed two stage test for registration or renewal of registered pharmacies?

**Q3** The document sets out three situations where we think it may be appropriate to impose conditions on registered pharmacies. In what, if any, other situations should conditions be applied?

**Q4** Do you have any other comments or observations to make with regard to these specific proposals?

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\(^8\) Section 74D of the Medicines Act 1968
Section 3: Standards for registered pharmacies
Section 3: Standards for registered pharmacies

Introduction

The purpose of these standards is to create and maintain the right environment, both organisational and physical, for the safe and effective practice of pharmacy.

We recognise that for anyone operating a registered pharmacy, in the NHS or in the independent sector, there will always be competing demands. These may be professional, managerial, legal or commercial. However, medicines are not ordinary items of commerce. Along with the associated pharmacy services, medicines are fundamental healthcare services and this must be taken into account when applying these standards.

Responsibility for meeting the standards lies with the pharmacy owner. If the registered pharmacy is owned by a ‘body corporate’ (for example a company) the superintendent pharmacist also carries responsibility along with the company. Whoever is responsible, they need to take into account the nature of the pharmacy and the services provided and, most importantly, the needs of patients and members of the public. We also expect them to be familiar with all associated guidance, including our compliance guidance.

As well as meeting our standards, the pharmacy owner and superintendent pharmacist must make sure they comply with all relevant legislation, regulatory standards and legal requirements – for example, medicines legislation, the NHS terms of service, the Equalities Act 2010 and health and safety legislation.

All pharmacists and pharmacy technicians should also become familiar with these standards, and understand that they have a professional responsibility to raise concerns if they believe the standards are not being met.

Patients and the public can read the standards to understand what they should expect from registered pharmacies.

Throughout this document we use the term ‘pharmacy services’. This includes all pharmacy-related services provided by a registered pharmacy – for example, the supply of medicines, advice, and services such as smoking cessation and prescription collection and delivery services. These services would also, for example, include a registered pharmacy providing pharmacy services to a care home.
Introduction

Throughout this document we use the term ‘staff’. This includes agency and contract workers, as well as employees and other people who are involved in the provision of pharmacy services by a registered pharmacy.

Throughout this document we use the term ‘you’. This means:

- the pharmacist who owns a pharmacy as a sole trader, or
- the pharmacist who owns a pharmacy as a partner in a partnership, or
- the body corporate and
- the pharmacist who is the appointed superintendent pharmacist for a body corporate.

In some limited circumstances (for example following death or bankruptcy), a representative can take the role of the pharmacy owner. In these cases, the appointed representative will be responsible for making sure these standards are met.
The structure of this standards document
We have grouped the standards under five principles. Under each principle there are three sections:

- the principle itself
- the standards for that principle
- examples of how you would show compliance with those standards.

The principles
The principles are the backbone of our regulatory approach. They are all equally important and must be met.

Principle 1: The governance arrangements safeguard the health, safety and wellbeing of patients, the public and members of staff.

Principle 2: Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.

Principle 3: The premises where pharmacy services are provided, and any associated premises, are safe and suitable.

Principle 4: The management of medicines and medical devices safeguards the health, safety and wellbeing of patients and the public.

Principle 5: The equipment and facilities that are available are safe and suitable.
The standards
The standards are requirements that must be met when you operate a registered pharmacy. Responsibility for meeting the standards lies with the pharmacy owner. If the registered pharmacy is owned by a body corporate (for example a company) the superintendent pharmacist also carries responsibility, along with the company.

Compliance indicators
This section gives examples of how you can show that you have met the standards we have set. This is not a complete list. For some of our standards, the compliance indicators we have set out may be the only way that you can demonstrate you have met our standards. In other cases, the compliance indicator may be one of a number of ways that you can demonstrate you have met our standards.

Whether you use these indicators or a different approach, you must be able to demonstrate that our standards have been met. Documents serve essential governance, management and legal purposes. But our fundamental concern is with what you do, rather than what you write.

Applying the standards
The principles for registered pharmacies, and the standards that must be met, are all equally important. You therefore need to read them in their entirety.

We know that a pharmacy owner, and/or superintendent pharmacist, may be accountable for one, a few or a large number of registered pharmacies. We expect the pharmacy owner and/or superintendent pharmacist to make sure that these standards are met whatever the number of pharmacies they are accountable for.

If you are accountable for more than one pharmacy, we recognise that you may need to have management structures in place to make sure that our standards are met.
Principle 1

The governance arrangements safeguard the health, safety and wellbeing of patients, the public and members of staff.

Appropriate governance arrangements include having clear definitions of the roles and accountabilities of the people involved in providing and managing pharmacy services. It also includes the arrangements for managing risks, and the way the registered pharmacy is managed and operated.

Standards

1.1 The safety and quality of pharmacy services are regularly reviewed and monitored

1.2 The risks associated with providing pharmacy services are identified and managed

1.3 All activities and services are carried out in a safe and effective way

1.4 There are clear lines of accountability for all the services provided

1.5 The roles of individuals involved in providing and managing pharmacy services are clearly defined

1.6 Patients and the public can raise concerns about the registered pharmacy, the pharmacy services and the staff and these are dealt with appropriately

1.7 Reports from the GPhC and any other organisations with whom you have statutory obligations, are taken into account and action is taken where appropriate
1.8 There are appropriate professional indemnity arrangements in place for services provided by the registered pharmacy, and suitable public liability and other relevant insurance arrangements in place for the premises themselves.

1.9 All necessary records for the safe and effective running of the registered pharmacy are kept and maintained appropriately.

1.10 The confidentiality of patient and public information is properly managed.

1.11 Children and vulnerable adults are appropriately safeguarded.

Compliance indicators
The following are examples of how you can demonstrate that you have taken steps to meet the standards:

- you consider what products are and are not appropriate to sell from the registered pharmacy
- you consider which services are appropriate to offer from the registered pharmacy
- records are clear, legible, accurate, up to date and available at the registered pharmacy
- you record and regularly review incidents and take action where appropriate
- you record near misses, dispensing errors and accidents in the registered pharmacy, and any action taken as a result of these
- an effective risk-management policy and procedure is in place, for example using a risk register
- a complaints procedure is in place which is openly available to patients and the public
- there is an audit trail of complaints received and how these have been considered and responded to in a timely manner
- you consider feedback and guidance from us, other appropriate bodies, patients and members of the public, and you respond accordingly
- you listen to feedback from staff, and the patients and public who use your pharmacy
- there is evidence that you have appropriate indemnity arrangements for the registered pharmacy and all the services provided
- you have plans in place for the continuing provision of pharmacy services in case service provision is disrupted
- staff have undergone appropriate child protection training.
Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.

The staff you employ and the people you work with are key to the safe and effective practice of pharmacy. Staff members, and anyone involved in providing pharmacy services, must be competent and empowered to safeguard the health, safety and wellbeing of patients and the public in all that they do.

Standards

2.1 Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training

2.2 Staff can meet their own professional and legal obligations and are empowered to exercise their professional judgement in the best interests of patients and the public

2.3 Staff are empowered to raise concerns about meeting these standards, and other aspects of pharmacy services if they think that patient safety is or may be compromised

2.4 Incentives or targets do not compromise patient safety or the professional judgement of staff

2.5 There are enough suitably qualified, skilled staff for the safe and effective provision of the pharmacy services provided

2.6 There is a culture of openness, honesty and learning,
Compliance indicators

The following are examples of how you can demonstrate that you have taken steps to meet the standards:

- you verify the qualifications of, and carry out relevant checks on, all staff you employ
- staff understand their individual roles and responsibilities, and those of the other members of their team, as well as the limits on these
- staff have access to the training they need and have any approved training their duties require
- you identify the essential elements of training for each role and have evidence that staff have done the training
- you review the progress and performance of staff, particularly trainees, for example through appraisal, and give honest and constructive feedback
- employment policies and contracts make it clear that staff are empowered to exercise their professional judgement in the interests of patients, the public and other staff members
- staff with management and control responsibilities have the genuine authority they need to live up to their legal and professional duties
- all staff understand that healthcare professionals who provide services for the pharmacy have their own legal and professional obligations
- you consider the number of staff and the skill mix that are needed for the safe and effective provision of pharmacy services, communicate this to staff and take reasonable steps to deal with any of their concerns
- you encourage and consider the feedback or views of staff about the provision of pharmacy services
- staff report and record mistakes and near misses and learn from them
- you have a procedure for staff to raise concerns about poor practice or if they feel that the actions of others are putting patients or the public at risk, for example a whistle-blowing policy
- policies and practice clearly show that staff who raise concerns about patient safety will be supported
- targets and incentives for staff have no adverse effect on the safety and quality of services.
Principle 3

The premises where pharmacy services are provided, and any associated premises, are safe and suitable.

It is important that patients and the public receive pharmacy services from premises that are suitable for the pharmacy services and which protect and maintain their health, safety and wellbeing. To achieve this you must make sure that all premises where pharmacy services are provided are safe and suitable. Any associated premises, for example non-registered premises used to store medicines, must also comply with these standards where applicable.

Standards

3.1 The premises that pharmacy services are provided from are safe and properly maintained
3.2 The size, design and layout of the premises are suitable for the pharmacy services provided
3.3 The design and layout of the premises protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services
3.4 The premises are maintained to an appropriate level of cleanliness and hygiene
3.5 The pharmacy services are accessible to people who want to use them
3.6 The premises are secure and safeguarded from unauthorised access
3.7 Pharmacy services are provided in an environment that is appropriate for the provision of healthcare.
Compliance indicators
The following are examples of how you can demonstrate that you have taken steps to meet the standards:

• you consider the volume of work and work flow through the dispensary and develop procedures to reduce risks
• you consider how to provide services in a professional and safe manner
• there is sufficient and appropriate storage space in the premises
• there are procedures in place to keep the premises hygienic and clean
• show how and where private and confidential discussions and consultations are carried out with patients and members of the public
• you consider the needs of all patients and members of the public who come into the premises and use pharmacy services, and make reasonable adjustments or make alternative arrangements for service provision

• you identify and manage any risks that are specific to the premises
• the security systems you have in place are specific to your registered pharmacy to prevent unauthorised access and safeguard your staff, patients and the public, and the medicines, medical devices and other substances kept on the premises
• patients and the public, staff and others, are safeguarded from any repairs or maintenance work that may affect their safety.
The management of medicines and medical devices safeguards the health, safety and wellbeing of patients and the public.

Standards
4.1 Medicines and medical devices are obtained from a reputable source
4.2 Medicines and medical devices that are sold or supplied are fit for purpose, of an appropriate quality and safeguard the health, safety and wellbeing of patients and the public
4.3 The environment that medicines and medical devices are stored in takes account of the requirements for the individual products
4.4 Medicines and medical devices are stored securely and are safeguarded from unauthorised access
4.5 Concerns are raised when it is suspected that medicines or medical devices are not fit for purpose
4.6 Medicines and medical devices are disposed of safely and securely.
Compliance indicators

The following are examples of how you can demonstrate that you have taken steps to meet the standards:

- the source of your medicines and medical devices is reputable
- medicines and medical devices are stored appropriately and securely, according to their stability, use, legal category and the level of risk associated with them
- you consider where medicines are displayed, including whether medicines should be available for self selection or not
- you have a procedure in place to notify the relevant authority if you suspect medicines are counterfeit or not fit for purpose
- there is sufficient and appropriate storage space for medicines and medical devices
- stock which is safe and appropriate to sell or supply is clearly segregated from that which is not
- you make sure that medicines and medical devices are routinely disposed of, in a way that safeguards patients and the public
- you make sure that medicines and medical devices are disposed of in line with product and environmental guidelines
- you have a procedure in place to manage alerts for medicines and medical devices.
Principle 5

The equipment and facilities that are available are safe and suitable.

The availability of safe and suitable equipment and facilities is fundamental to the provision of pharmacy services and is essential for staff to safeguard the health, safety and wellbeing of patients and the public when providing effective pharmacy services.

Standards

5.1 All equipment and facilities that are needed for the services provided are readily available at the registered pharmacy

5.2 The equipment and facilities at the registered pharmacy are:
   • obtained from a reputable source
   • safe to use
   • stored securely
   • appropriately maintained
   • suitable for the intended purpose.

5.3 The equipment and facilities are used in a way that protects the privacy and dignity of the patients and the public who receive pharmacy services

5.4 There are systems in place to reduce the impact on patients and the public if any of the equipment or facilities fail
Compliance indicators
The following are examples of how you can demonstrate that you have taken steps to meet the standards:

- you identify the equipment and facilities needed to provide safe and effective services, taking into account for example:
  - the services provided
  - the presence of a pre-registration trainee pharmacist
- reliable, up-to-date pharmacy reference sources are available
- the source of your equipment is reputable
- the equipment and facilities are properly installed and maintained to make sure they are in proper working order
- you listen and respond to feedback from your staff, and the patients and public who use your pharmacy, on the availability and usefulness of equipment and facilities
- there are adequate back-ups for all the systems you use and a procedure in place if there is a loss of utility services to minimise risks to patient safety and disruption of patient care
- you consider how and where equipment and facilities are placed and used in the pharmacy.
Q5 Is it clear where the responsibility for meeting the standards lie?

Q6 What is unclear?

Q7 The introduction to the standards should set the context and clarify and explain how the standards are relevant to different audiences. What else, if anything, should be added in the introduction?

Q8 The standards are grouped under five main principles. Under each principle there are three sections – the principle itself, the standards that relate to that principle and examples of how compliance would be shown. Does the structure work well?

Q9 How could it be improved?

Q10 Are the standards under each principle clear?

Q11 What is unclear?

Q12 Is anything missing from the standards under each principle?

Q13 What standards should be added?

Q14 Are the compliance indicators clear?

Q15 What is unclear?

Q16 The indicators are examples only and do not represent a complete list of everything that might indicate compliance with the standards. What if any additional or alternative indicators would it be helpful for us to include here?

Q17 To what extent do you agree or disagree that the standards and compliance indicators provide pharmacies with a clear and usable framework?

Q18 What, if any, further support tools or information would pharmacy owners or superintendent pharmacists need to be able to meet these standards?

Q19 What if any concerns do you have about the practical implications of implementing these standards in registered pharmacies?
Section 4: Securing compliance and our approach to enforcement
Our focus on compliance

We know that the current inspection model will need to change. To sit alongside the new inspection model, a new framework will be used to make decisions about whether the standards we are proposing have been met and how to secure compliance if there have been failures to meet the standards. Before developing and testing this new model, we want to hear the feedback from the consultation on the proposed standards.

This section sets out our current thinking and the proposed direction of travel. It is intentionally more discursive than the rest of the consultation but we would welcome feedback on this section as we continue to explore how best to inspect and regulate registered pharmacies in a way that is proportionate and based on risk. It is right that we are able to use powers to take urgent action against registered pharmacies where there is an immediate threat to patient safety.

However we believe that in the vast majority of cases, it is going to be in patients’ best interest for us as the regulator to work with pharmacy owners and superintendent pharmacists to secure compliance with our standards rather than moving to a more adversarial and expensive legal enforcement approach.
Compliance guidance

We recognise that pharmacy owners, superintendents and registrants may require additional information about how best to achieve and to demonstrate compliance, particularly as what we are proposing is to move away from a prescriptive rules based approach to outcome-focused standards. For this reason, under each standard we have included a section called ‘showing compliance’.

These are examples of how you can show you have met the standards. This is not an exhaustive list and these examples are indicative only – they are not mandatory, although achieving the standard is. We recognise that the standards can sometimes be met in more than one way and showing compliance will often differ depending on the activities being undertaken in a registered pharmacy. Whether owners and superintendents use these examples or a different approach, you must be able to demonstrate that our standards have been met.

We are exploring as part of this consultation, what additional information is needed for owners and superintendents to support them in meeting our standards. Recognising our desire to avoid an overly prescriptive ‘one-size-fits-all’ approach, it is not currently our intention to provide a comprehensive guidance document covering all the standards. We do not feel that this would be proportionate and could lead to a check box approach to compliance. However, we do believe that there may be a need for additional guidance on compliance for certain specific areas either because of the complexity of process or where the model of service may be new or technology based. Potential topics may include:

- Compliance guidance for pharmacy owners operating an internet pharmacy
- Compliance guidance for registered pharmacies working under an exemption from MHRA licensing requirements.
Introduction

In this section we describe the work we are doing to develop our approach to decision-making and enforcement action. We have included this section to provide information to inform responses to the consultation questions on the registration criteria and draft standards.

Decision making and enforcement

The GPhC’s focus will be on supporting people to meet the standards.

In addition to providing compliance indicators to sit alongside the standards and further compliance guidance for a limited number of situations, we propose to support compliance by visiting and inspecting registered pharmacies. We understand that every time an inspection is carried out at a registered pharmacy, it puts pressures on the time of the staff working in the pharmacy and draws time away from operation of services and direct patient care. However, we believe a robust inspection model is needed to protect patients, support compliance with the standards we are proposing to set and enable us to make a decision about any risks based on what we see during the inspection and evidence presented to us by the owner or superintendent.

How our current model of inspection works

We have a team of about 30 inspectors who currently visit registered pharmacies approximately every three years.

Our inspectors examine how the pharmacy operates and provide advice to pharmacy staff about what we believe needs to happen to ensure services are safe and effective.

They also look at specific services such as the management of controlled drugs to ensure legal requirements are being met and support our investigations team where there are concerns about a registrant’s fitness to practise.
In parallel with this consultation, we will also explore opportunities to use information from existing sources, such as primary care organisations or through existing NHS complaints mechanisms, as well as information from our own regulatory systems. This will assist the development of a genuinely risk-based approach to regulation focusing our attention on where the risks are higher and reducing burdens for those registered pharmacies which are safe and consistently complying with the required standards.

**Developing our inspection model**

We are proposing to move away from a ‘one-size-fits-all’ inspection model, where all registered pharmacies are inspected at regular intervals of approximately every three years, to a model where we prioritise inspections for those registered pharmacies where we believe there is a higher risk to patients and the public, either because of the nature of the services they provide, or because we have concerns.

We intend to develop and publish risk indicators using evidence from a range of sources, including the inspections we conduct, when the new standards come into force. The indicators are likely to develop further on the basis of feedback from pharmacy staff, employers and patients and the public and also, as more data is collected to inform our decisions about when and who to inspect. It is also likely to develop as we consider how new models of pharmacy service delivery emerge.

All registered pharmacies will be required to provide some core information as part of the application or renewals process. This information is likely to include information covering basic facts about the registered pharmacy such as the services it provides, for example whether it offers an internet service.

**Risk based regulation**

The proposed model for regulating pharmacy is intended to enable a more ‘risk-based’ approach to inspecting and enforcing our standards. As a concept risk-based regulation acknowledges that not all risk can be removed and to do so would be disproportionate. A risk-based approach to regulation targets resources at those areas where risk is deemed to be higher in relative terms, and resources and burden is reduced where there is evidence of lower risk.
Notice of an inspection
In most cases notice of an inspection will be issued to the registered pharmacy owner or superintendent in advance, consistent with current practice. However, we intend to carry out a small number of unannounced inspections, to enable us to compare whether there is any difference in the outcome between pre-notified inspections and unannounced inspections and assess whether our inspection model is robust. We also believe we may need to carry out a small number of unannounced inspections at short notice where concerns have been raised and where we believe there may be a serious risk to patient safety.

The nature of an inspection
We recognise that there will need to be significant changes to the current inspection model to take into account new standards once they are approved. We will develop the new model once the standards are approved. As part of this, we will be considering what evidence we need to collect to confirm that the standards are being met, with particular regard to the outcomes for patients and the public and in a way that keeps burdens on the registered pharmacy to a minimum.

Some of the evidence might be gathered by reviewing information supplied at registration, renewal of registration (updated to reflect key changes), or in advance of an inspection.

The inspection team will review systems and processes, observe the delivery of services to patients, and speak with staff. Wherever possible, inspectors will also speak with patients visiting the pharmacy during the inspection. Decisions as to whether standards have been met will only be made following a physical inspection of the registered pharmacy and services provided. We want the inspection model to be flexible. It is likely to vary depending on a number of factors including, but not limited to, the types of services provided by the registered pharmacy as well as any recent changes that have taken place to, for example, the range of services or the skills mix in the pharmacy.

Criteria for decision-making
Decisions on the extent to which standards have been met will be based on an assessment of risk to patient safety. We will develop and publish decision-making criteria, using evidence from inspections of registered pharmacies conducted prior to the standards coming into force.

The criteria will take into account:-

• the nature of the risk
• the impact of the risk on patient and public safety if not effectively mitigated, and
• the likelihood of the risk occurring.
Clearly, the greater the impact and likelihood of the risk occurring, the higher priority must be given to mitigating the risks, through improvement action.

Our decision framework is likely to propose that an inspection will result in one of three outcomes:

- **full compliance**: there is evidence that all of the standards are being met
- **substantial compliance**: there is evidence that most of the standards are being met. The risks to patient or public safety are not high (less likely to occur and/or relatively low impact), or
- **major non-compliance**: there is evidence either that many of the standards are not being met or of a major breach of one or more of the standards. The risks to patient and public safety are high (likely to occur and/or with significant impact).

We believe that it is in the best interests of patients and the public for decisions about compliance to be published and intend to do so once new standards for registered pharmacies are in place. As part of this process of publication we expect to issue the inspection report to the owner in advance, detailing the outcome and the evidence found to support that outcome. Where appropriate, the report will also identify post-inspection requirements.

The report would be published on the online extract of the register relating to the registered pharmacy.

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10 These are working titles only at this stage.
**Enforcement**

The main focus of an inspection will be to support achievement of compliance.

However, where the inspection team identifies major non-compliance with the standards or a failure to remedy weaknesses as previously agreed, we would use the powers\(^{11}\) we have to issue an improvement notice, requiring the owner(s) to take specified measures to address those areas of non-compliance, and the timescale within which improvements must be made\(^{12}\).

If on further inspection, at the expiration of the period set out in the improvement notice, the inspector remains of the view that the standards have not been met, the GPhC then has powers\(^{13}\) to:

- remove the premises’ entry from the register; or
- suspend the entry until such time as the owner has complied with the improvement notice and impose such other requirements or conditions as the registrar considers it necessary to impose.

The GPhC can also consider prosecution for failure to comply with the terms of an improvement notice if we think that this would be necessary to protect the public.

**Disqualification of a body corporate**

In addition to specific powers of enforcement as set out above, we also have the ability, following proper process\(^{14}\), to disqualify a corporate body and direct removal of the registered pharmacy in limited circumstances, one of which is failure to make sure that our standards are met. The relevant legislation also sets out detail in relation to the grounds for disqualification\(^{15}\).

**Inspections and fitness to practise**

We know that we need to be clear and open about how we will manage our work including the regulation of the ‘system’ or services provided by registered pharmacies and our regulation of individuals, ‘professional regulation’ where our interest is in the fitness to practise of the individual pharmacist or pharmacy technician.

We use our fitness to practise procedures to manage concerns raised about pharmacist or pharmacy technician registrants. They serve an important purpose but they are not the enforcement mechanism for making sure that our standards for registered pharmacies are met.

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\(^{11}\) Article 13, Pharmacy Order 2010

\(^{12}\) If the Registrar considers it necessary, he may also impose immediate conditions on the premises, under s74(D)(2) of the Medicines Act 1968.

\(^{13}\) Article 14, Pharmacy Order 2010

\(^{14}\) s80 Medicines Act 1968 as amended

\(^{15}\) s81 Medicines Act 1968 as amended
Inevitably, in the course of our work to ensure appropriate standards are maintained for registered pharmacies, it is possible that fitness to practise concerns may emerge in respect of individual registrants which may need to be considered through our fitness to practise procedures. These concerns may relate to an individual pharmacy professional working within the pharmacy, or may relate to the pharmacy owner, where they are a pharmacist or a superintendent pharmacist. For example, fulfilling the superintendent’s responsibilities is an important part of their professional practice; therefore major non-compliance with these standards may raise a question about their fitness to practise, although consideration of this would form part of a separate decision-making process.

It is our view that high quality provision of healthcare is most likely when all parts of the ‘health system’ are working well together: professionals, colleagues in teams, employers and national bodies and regulators. Conversely serious problems happen when these individuals or groups do not work well together or when there is no effective link between available information. This information could include data from our inspection model or information available from other sources such as primary care organisations or concerns raised by either professionals, patients or others such as regulators. We believe our proposed model can help to mitigate these risks, helping to maintain high quality care from registered pharmacies through modern pharmacy regulation.

Q20 Our current view is that there will be a need for additional guidance on compliance for certain specific areas either because of the complexity of process or where the model of service may be new or technology based. Potential guidance includes:
- Compliance guidance for pharmacy owners operating an internet pharmacy
- Compliance guidance for registered pharmacies working under an exemption from MHRA licensing requirements.

To what extent do you agree or disagree with our assessment that compliance guidance will be needed in these areas?

Q21 Are there any other areas where you believe compliance guidance will be required?

Q22 We cannot fully develop our approach to compliance until the standards have been finalised; therefore this section of the document broadly sets out current thinking. Do you have any comments or observations about the broad approach described?

Q23 We recognise that everyone, in particular pharmacy owners and superintendent pharmacists, will need support to familiarise themselves with the new standards and get ready for the new approach to regulating registered pharmacies in the transition phase. What can we do to make sure the transition is as straightforward as possible?

Q24 Do you have any further comments to make about the proposals in this consultation?
How to give us your comments
How to give us your comments
We are asking a series of questions about our proposals and would welcome your responses.

The easiest way to let us know your views is to go to our dedicated consultation website www.registeredpharmacies.org

You can download copies of the consultation document and the questionnaire, or fill in our questionnaire or just the questions you are interested in, online.

If you want to produce your own response, you can email that to: consultations@pharmacyregulation.org

If you would like a hard copy of the consultation document and/or questionnaire, you can:

phone: 020 3365 3506
email: consultations@pharmacyregulation.org

write to:
Registered Pharmacy Consultation
c/o Communications Department
General Pharmaceutical Council
129 Lambeth Road
London SE1 7BT

Other formats
There is a Welsh Language version of this consultation document available at www.registeredpharmacies.org

You can request an alternative format by emailing us at consultations@pharmacyregulation.org or calling us on 020 3365 3506.

We will be publishing more information about the consultation on our dedicated consultation website www.registeredpharmacies.org, and in our registrant bulletin, Regula+e, and stakeholder e-bulletin, Upda+e. You can also follow the progress of the consultation on social media sites like Twitter, LinkedIn and Facebook.

All information in responses, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (primarily the Freedom of Information Act 2000, the Data Protection Act 1998 and the Environmental Information Regulations 2004).

If you want your response to remain confidential, you should explain why you regard the information you have provided as confidential. However, we cannot give an assurance that confidentiality can be maintained in all circumstances.

Your response to this consultation may be published in full or in a summary of responses. Responses to the consultation will be anonymised if they are quoted. Individual contributions will not be acknowledged unless specifically requested.
Next steps
We have planned a range of activities and events to support this consultation. Once the formal period for feedback has concluded, we will consider all the responses and produce a report summarising what you said. This report on feedback will be available on our website and we will make available copies to those who participated in the consultation.

Outlined below is a flowchart which summarises the key stages which need to take place. This includes a significant period of time set aside for those who will be accountable for upholding the standards to familiarise themselves with both the final set of agreed standards, as well as subsequent guidance and policies from the GPhC.

We will be hosting a number of meetings and events over the consultation period - you can find our calendar of events at registeredpharmacies.org/events. If you would like us to attend a meeting or event to talk about these proposals, please contact us at consultations@pharmacyregulation.org or call us on 020 3365 3506. We will bring copies of the consultation document and questionnaire to meetings and events. The consultation ends on 7 May 2012.

Timeline flowchart

Standards and regulatory framework

Develop

Engage

Draft

Consult

Communicate & Implement (Phased)

Body Corporate
A body corporate includes entities and organisations such as limited companies: a Limited (Ltd) company, Public Limited Companies (PLC); a Trust; a Co-operative; and a Limited Liability Partnership (LLP).

Herbal medicines
These are defined in section 132 of the Medicines Act 1968 and the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005. These are medicines which have been produced by subjecting plants to a process which may include drying, crushing and mixing with other herbal products, inert substances or water. Herbal medicines are classed as medicinal products and can be classed as GSL, P or POM.

Homeopathic medicines
These are defined in section 7 of the Medicines Act 1968 (and Article 1 of the 2001/83 EC Directive). These are medicines which have been produced from a variety of different substances in accordance with the homeopathic manufacturing procedure described in official reference sources called pharmacopoeias. Homeopathic medicines are classed as medicinal products and can be classed as GSL, P or POM.

General Sale List (GSL) medicines
The definition can be found in Section 51 of the Medicines Act 1968 and only applies to medicines for human use. This is a group of medicines which can be sold in registered pharmacies, (without the supervision of a pharmacist), and from other retail outlets, (such as supermarkets and petrol stations), that can “close so as to exclude the public”. Medicines can be classed as GSL either because of their marketing authorisation (product licence) or because they are listed in legislation in the Medicines (Products other than Veterinary Drugs) (General Sale List)Order 1984.

Medicines for animal use
Certain classes of licensed animal products can be sold from a registered pharmacy to members of the public without the need for a prescription from a vet. Other classes of licensed animal products need a prescription to lawfully supply them. Registered pharmacies can also supply medicines for animals against prescriptions (written by vets).

MHRA
The body responsible for human medicines legislation, (the Medicines and Healthcare products Regulatory Agency, MHRA) is currently carrying out an exercise to consolidate and review relevant legislation.
A person lawfully conducting a retail pharmacy business

The definition can be found in Section 69 of the Medicines Act. This is a person who is carrying on a retail pharmacy business, which meets all the necessary legal requirements. The person can be:

- an individual pharmacist
- a partnership of pharmacists (in England and Wales all the partners must be pharmacists; in Scotland only one partner needs to be a pharmacist)
- a body corporate
- under certain conditions a representative (for example following death or bankruptcy of an individual pharmacist who carries on a pharmacy business)

Pharmacy (P) medicines

The definition can be found in Article 1 of the Medicines (Pharmacy and General Sale – Exemption) Order 1980 and only applies to medicines for human use. These are medicines that can only be sold or supplied from registered pharmacies by, or under the supervision of, a pharmacist. There are exceptions to this restriction which allow hospitals, doctors, dentists and some others to also supply P medicines under certain conditions.

Prescription Only Medicines (POMs)

The definition can be found in Article 3 of the Prescription Only Medicines (Human Use) Order 1997 and only applies to medicines for human use. These are medicines that can only be sold or supplied from registered pharmacies under the supervision of a pharmacist against a prescription. There are exceptions to this restriction which allow hospitals, doctors, dentists and some others to also supply POMs under certain conditions. Medicines can be classed as POM either because of their marketing authorisation (product licence) or because they are listed in legislation in the Prescription Only Medicines (Human Use) Order 1997.

The Register

The definition can be found in Articles 3 and 19 of the Pharmacy Order 2010. The Register which is maintained by the GPhC consists of a list of pharmacists, pharmacy technicians and registered pharmacy premises. The Register has a public facing search facility and members of the public, and others, can search for registered pharmacy premises, pharmacists and pharmacy technicians on our website at www.pharmacyregulation.org.
Responsible pharmacist
The definition can be found in Sections 70, 71 and 72A of the Medicines Act 1968. This is the pharmacist who is appointed and is in charge of the registered pharmacy during a specified time. They are responsible for the safe and effective running of the pharmacy.

Retail sale (and circumstances corresponding to retail sale)
The definitions can be found in Section 131 of the Medicines Act 1968. This means selling General Sale List or pharmacy medicines and supplying medicines against a (private or NHS) prescription.

Superintendent pharmacist
The requirements for meeting this definition can be found in Section 71 of the Medicines Act 1968. This is a pharmacist who is appointed to act on behalf of a body corporate which wishes to conduct a retail pharmacy business.

The supply of medicines in the course of the business of the hospital
The definition can be found in Section 55 of the Medicines Act 1968. The supply of POMs, (and P medicines), is restricted to being supplied from registered pharmacies only. There is an exemption from this restriction which allows medicines to be supplied by a hospital, or health centre, for the purpose of being administered in accordance with the directions of a doctor or dentist. Supplies that meet this definition include supplies made from the hospital pharmacy department to the hospital’s wards or to the hospital’s inpatients, on its wards, or to the hospital’s out-patients.

Wholesale of medicines
The definition can be found in Sections 8 and 131 of the Medicines Act 1968. This is the supply of medicines as stock to a separate organisation, or person; it is not supply directly to patients. Supplying by wholesale usually requires a licence from the MHRA, and the people and organisations requesting the stock must be listed in law as being able to obtain this stock. Registered pharmacies can currently carry out a small amount of wholesale supply without the need for a licence. Examples of the wholesale supply of stock includes the supply of stock from a wholesaler to a pharmacy and the supply of stock from a registered pharmacy to a doctor who will administer the medicines during their professional practice.
Annex B – Collated consultation questions

Q1 Do the proposals provide sufficient clarity about the premises that need to be registered with us as a pharmacy?

Q2 Do you have any comments or observations about the proposed two stage test for registration or renewal of registered pharmacies?

Q3 The document sets out three situations where we think it may be appropriate to impose conditions on registered pharmacies. In what, if any, other situations should conditions be applied?

Q4 Do you have any other comments or observations to make with regard to these specific proposals?

Q5 Is it clear where the responsibility for meeting the standards lie?

Q6 What is unclear?

Q7 The introduction to the standards should set the context and clarify and explain how the standards are relevant to different audiences. What else if anything should be added to the introduction?

Q8 The standards are grouped under five main principles. Under each principle there are three sections – the principle itself, the standards that relate to that principle and examples of how compliance would be shown. Does the structure work well?

Q9 How could it be improved?

Q10 Are the standards under each principle clear?

Q11 What is unclear?

Q12 Is anything missing from the standards under each principle?

Q13 What standards should be added?

Q14 Are the compliance indicators clear?

Q15 What is unclear?

Q16 The indicators are examples only and do not represent a complete list of everything that might indicate compliance with the standards. What if any additional or alternative indicators would it be helpful for us to include here?

Q17 To what extent do you agree or disagree that the standards and compliance indicators provide pharmacies with a clear and usable framework?
Q18 What, if any, further support tools or information would pharmacy owners or superintendent pharmacists need to be able to meet these standards?

Q19 What if any concerns do you have about the practical implications of implementing these standards in registered pharmacies?

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