

Modernising pharmacy regulation:

A consultation on the draft standards for
registered pharmacies

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Please return your responses by 5 May 2012. This consultation is available online (insert link)

Foreword (tbc)

Bob Nicholls CBE

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About this consultation

This document sets out how we intend to modernise pharmacy regulation with the publication of draft standards for registered pharmacies. We have developed these proposals having met with stakeholders, taken learning from other regulators, developed a clear understanding of the legal framework and tested our approach against the principles of good regulation¹:

Although the focus of this consultation is the draft standards, there are three 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 and standards: An overview of which premises we intend to register and the draft standards we are proposing for registered pharmacies (page x)
3. Compliance and enforcement: How we plan to secure compliance against the proposed standards and our approach to enforcement activity

We are seeking the views from a wide range of individuals and organisations including patients and the public, pharmacy professionals including owners and superintendents, professional and representative bodies as well as other organisations who may be interested in how we propose to safeguard the health and wellbeing of patients and the public. 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 it to remain confidential to GPhC staff.

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

The deadline for responding to this consultation is 5 May 2012.

¹ Better Regulation Executive five principles of good regulation www.bis.gov.uk

Summary of the proposals

We propose to insert a summary of the proposals we are seeking views on and where to find the relevant pages here in the document

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SECTION 1

INTRODUCTION

Introduction

Pharmacy does a great deal of good. 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. By contrast, the wrong medicine, at the wrong time, in the wrong way, with wrong information and bad advice, can – at best – mean that the medicine may not work as it should. At worst, serious harm and even death can result.

There are lots of people, organisations and laws with a part to play in getting this right.



Medicines themselves need to be safe and effective. The Medicines and Healthcare Products Regulatory Agency has the regulatory responsibility here. The two other key factors 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 bodies, such as the General Medical Council and the Nursing and Midwifery Council for other health professionals such as doctors and nurses. And secondly, we register and regulate premises at which pharmacy services are provided to the public on a retail basis. This consultation is about new standards we propose to set for this third important corner of the public protection triangle.

One of the reasons we are doing this now is because of important changes in pharmacy. In England, Scotland and Wales the way in which pharmacy care and services are organised is changing. And pharmacy has the potential to do even more good than it has so far. Pharmacists and pharmacy technicians have knowledge and skills which can help to promote, protect and improve the health of individuals and the public. This enhanced role – and the good that pharmacy does – goes way beyond dispensing medicines on prescription. This greater scope for doing good brings with it the potential for new risks, of course. Whether medicines 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.

So it is important that those responsible for running pharmacy services from the premises 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.

In setting the standards that all registered pharmacies must meet it is important that we don't give business 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 can't take on the responsibilities that rightly sit with business 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 are concerned with what matters to patients and the public. Namely, not the minutiae of how professionals and businesses organise themselves (which they rightly have the freedom to do), but what they achieve – results for patients. This is why we plan to set standards which:

- describe the outcomes from safe and effective practice which must be achieved;
- make clear the responsibilities of those involved to show that they are doing so; and
- enable professionals to take decisions in the best interest of their patients, rather than against a detailed step by step rule book from the regulator.

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. And we will also 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 a 'system regulation' links to our regulation of individual pharmacists and pharmacy technicians.

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What we think good regulation looks like

We believe that one of the first principles of regulation is that regulator needs to be open and honest with the public and those it regulates about what outcomes we believe regulation can achieve, as well as explaining what regulation cannot do on its own.

In part this is about recognising that sometimes mistakes happen in healthcare which either regulation cannot prevent, or that steps to prevent harm would be so disproportionate that patients would actually be disadvantaged with, for example, reduced or limited access to services. It is also important for patients and the public that they know who is responsible for upholding standards and other requirements including relevant law.

In the vast majority of cases, much will fall to the individual who will use their own judgement, informed by their own professionalism and in reference to their regulatory standards and relevant guidance to ensure safe and effective delivery of care.

Colleagues and fellow healthcare professionals will also have a role to play; supporting colleagues but also pointing out potential problems or where improvements need to be made.

Employers have a critical role to play as they set many of the rules for staff and in many cases will provide the investment for the buildings and equipment.

Finally, there is a role for national regulatory bodies like the GPhC to set standards which all registered pharmacists and pharmacy technicians should meet, or the standards required for all registered premises.

This approach to viewing regulation, first described by the General Medical Council as a four-layer model, (http://www.gmc-uk.org/ar_2004.pdf_25417172.pdf) and the respective roles in regulation is, we believe, a helpful way to explain responsibilities to the public, but also to ensure regulatory duplication and overlap is avoided.

We are also committed to ensuring that our approach to regulation is proportionate and increasingly risk-based. Remaining focussed on patient safety but always testing if there is a way we can reduce burdens on those pharmacies which present a lower risk and enabling us to focus attention on areas of genuine risk. In developing the approach 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 (<http://www.bis.gov.uk/policies/bre/policy/five-principles-of-good-regulation>), as well as the principles for inspection and enforcement proposed by Sir Philip Hampton (<http://www.bis.gov.uk/files/file22988.pdf>) and the Council for Healthcare Regulatory Excellence's document Right-touch Regulation (<http://www.chre.org.uk/policyandresearch/336>).

SECTION 2

REGISTRATION CRITERIA AND DRAFT STANDARDS

Registering a pharmacy with us

(Box out intro to be inserted)

When we spoke with pharmacy professionals and stakeholders while developing our proposals, they stressed the importance of being clear about the premises that need to be registered with us, and therefore those that need to meet our new standards. This section provides information on how we propose to make those decisions.

We also want to be clear about the circumstances which would lead to initial conditional registration, and that is set out on page x.

Our proposals

We intend using a two stage test for the registration, or renewal, of registered pharmacies:

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

The eligibility test is based on our interpretation of medicines legislation² (see our Glossary at page x).

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.

² The Medicines Act 1968, The Pharmacy Order 2010 and associated Rules.

The registration model

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

Diagram 1: The registration model

Business Models - Applying the Eligibility Test

Our primary concern is the safe and effective delivery of pharmacy practice. We know that various business 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 business³. Therefore to decide if the business model would pass the eligibility test, we will ask ourselves the following question:

'Will the business include over the counter sale of pharmacy medicines for human use or the supply of pharmacy or prescription only medicines against a prescription for human use?'

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 business consists **solely** of:

³ Section 132 of the Medicines Act 1968

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. supplies made in the course of the business of a 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 on page X.

Initial Conditional Registration

We have legal powers⁴ to impose 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'*.

Our proposals

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 pharmacy premises

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 pharmacy business being open, operating and trading at the premises 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 premises will only be registered for a short time before, during and after the event.

3. Closed pharmacies

⁴ Section 74D of the Medicines Act 1968

We receive applications for pharmacies that do not have premises that are open for patients and the public to visit in person. These are referred to as 'closed pharmacies' and will often be mail order or internet pharmacies. We will impose a condition that the pharmacy cannot open for patients and the public to visit in person until we are notified so that we can determine whether the premises meet the standards.

4. A registered pharmacy that intends to undertake substantial manufacturing

We believe that the manufacture of unlicensed medicines carries a relatively high degree of risk. Therefore, while registered pharmacies are exempt from the need to hold a special manufacturers licence, we will impose a condition of registration. This condition will require that where substantial manufacturing is carried out, under an exemption, the owner or superintendent pharmacist will be required to make sure that substantial manufacturing is done in a way that is consistent with the requirements of the MHRA's Good Manufacturing Practice (GMP).

5. Manufacturers who hold a special manufacturers licence

We receive applications from holders of special manufacturers' licences who wish to register a pharmacy premises so that they can supply these medicines against prescriptions to patients.

We will impose a condition that the substantial manufacture of medicines supplied must be under the terms of the special manufacturers licence that they hold.

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 they are fundamental healthcare services. You must take account of this when applying these standards.

Responsibility for meeting the standards lies with the pharmacy owner, unless the registered pharmacy is owned by a 'body corporate' (for example a company). In this case the superintendent pharmacist also carries responsibility. 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 or superintendent pharmacist must make sure they comply with all relevant legislation and regulatory standards – for example, 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 the level of service they should expect when they receive pharmacy services 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.

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 pharmacist who is the appointed superintendent pharmacist for a body corporate, and
- the 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.

Applying the standards

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

We know that a pharmacy owner, or superintendent pharmacist, may be accountable for one, a few or a large number of registered pharmacies. We expect the pharmacy owner 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.

Standards for registered pharmacies

The structure of this standards document

We have grouped the standards under five main 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 and are all equally important.

Principle 1: The governance arrangements that are in place 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, unless the registered pharmacy is owned by a 'body corporate' (for example a company). In this case the superintendent pharmacist also carries responsibility.

If a registered pharmacy is owned by a body corporate, we expect the board to enable the superintendent pharmacist to:

- comply with their professional and legal obligations, and

- use their professional judgement in the best interests of patients and the public.

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.

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Principle 1: The governance arrangements that are in place 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 Patients and the public can raise concerns about the registered pharmacy, the pharmacy services and the staff and these are dealt with appropriately
- 1.6 Reports from the GPhC and any other organisations with whom you have statutory obligations, are taken into account and action is taken where appropriate
- 1.7 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
- 1.8 All necessary records for the safe and effective running of the registered pharmacy are kept and maintained appropriately
- 1.9 The confidentiality of patient and public information is properly managed
- 1.10 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 premises
- 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 affected
- staff have undergone appropriate child protection training.

Principle 2: 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 'no blame'.

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.

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

The appropriate management of medicines includes arrangements for obtaining, keeping, handling, using and supplying medicinal products and medical devices, as well as security and waste management. Medicines and medical devices are not ordinary commercial items. The way they are managed is fundamental to ensuring the health, safety and wellbeing of patients and the public who use pharmacy services.

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 medicines and medical devices are stored in takes into account 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 depending on 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.

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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.

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SECTION 3

SECURING COMPLIANCE AND APPROACH TO ENFORCEMENT

Our focus on compliance

(Box out intro to be inserted)

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.

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 the extemporaneous preparation of medicines
- Compliance guidance for registered premises undertaking significant levels of manufacturing under an exemption from MHRA licensing requirements.

Framework for decision-making and enforcement action

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. As much of the work in this area will be based on feedback from the consultation, we are not asking questions on these topics at this stage.

Decision making and enforcement

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

In addition to providing compliance guidance we propose to do this by visiting and inspecting premises. 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.

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 to 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

BOX OUT – 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.

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, but 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.

Box out: 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 premises 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 will be considering as part of this consultation how the inspection model might develop to take into account new standards once they are approved. 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 which keeps burdens on the registered pharmacy to a minimum.

Some of the evidence might be gathered by reviewing information supplied by the premises 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, 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 compliance⁵: 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 those premises.

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, we would use the powers⁶ 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 made⁷.

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,⁸

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.

⁵ These are working titles only at this stage

⁶ Article 13, Pharmacy Order 2010

⁷ If the Registrar considers it necessary, he may also impose immediate conditions on the premises, under the s74(D)(2) of the Medicines Act 1968.

⁸ Article 14, Pharmacy Order 2010

Disqualification of a body corporate

In addition to specific powers of enforcement as set out above, we also have the ability, following proper process⁹, 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 disqualification¹⁰.

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. 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.

⁹ S80 Medicines Act 1968 as amended

¹⁰ S81 Medicines Act 1986 as amended

How to give us your comments

You can respond to the consultation in a number of ways:

Email: consultations@pharmacyregulation.org

go to: www.pharmacyregulation.org/xxxxxx and respond online

write to:

Standards for Registered Pharmacies consultation
C/O Standards Advisory Team
General Pharmaceutical Council
129 Lambeth Road
London SE1 7BT

Telephone 020 3365 3506

Other formats

There is a Welsh Language version of this consultation document available at:

This information can be made available in alternative formats or languages. To request an alternative format please email us at consultations@pharmacyregulation.org or call us on 020 3365 3506.

How to get involved

We will be hosting a number of meetings and events as part of this consultation. If you are holding a meeting or event and would like us to attend to talk about these proposals, please contact us at consultations@pharmacyregulation.org or call us on 020 3365 3506.

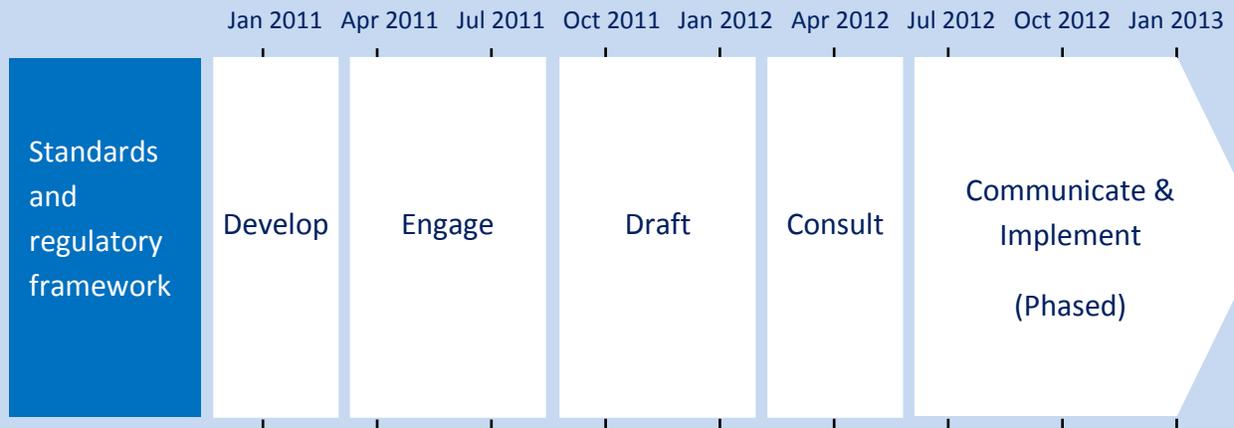
We will be publishing updates on the consultation on our website, in our registrant bulletin, Regula+te, and in our e-bulletin, Upda+te. You can also follow the progress of the consultation via Twitter, LinkedIn and Facebook.

The consultation ends on 5 May 2012.

Next steps

We will reflect on your responses and produce a report based on those responses. We will make a report on feedback available on our website and can send copies to those who participated in the consultation.

Timeline flowchart



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