Regulation of pharmacy premises

Purpose
To update Council on our pre-consultation engagement work to date as well as to discuss the proposed approach to the regulation of registered pharmacy premises and agree our proposed approach to the planned consultation in the New Year.

Recommendations
The Council is asked to note:

i. The pre-consultation engagement work carried out to date

And to consider and agree:

ii. The proposed approach to the planned consultation

1.0 Introduction

1.1 Although retail pharmacy business has long been subject to regulation, the Pharmacy Order 2010 provides a new legal framework for regulation of these. In particular, the Order makes provision in legislation for the setting of standards for owners and superintendents carrying on retail pharmacy business at a registered pharmacy as well as a range of powers in relation to inspection and enforcement.

1.2 There has been considerable work undertaken in relation to our premises project in the first year since the Council took on responsibility for pharmacy regulation. In addition to work carried out by the executive, Council has considered in two workshop sessions a number of relevant issues including, but not limited to, the registration criteria, the content and format of the standards in this area as well as wider discussions about risk in pharmacy. As
a result of this work and informed by our pre-consultation engagement work, a proposed framework for the regulation of registered pharmacy premises has been developed and is set out in the appendix to this paper.

2.0 **Key considerations**

2.1 The key considerations, including the legislative framework are set out in the appendix. However, Council will wish to note the principles which have underpinned our engagement and policy development to date. These are:

- *Early engagement*
  Before developing specific proposals we asked a range of stakeholders about the themes and issues they face in pharmacy (details on the meetings held are set out in the appendix).

- *Learning from other regulators*
  We have carried out research to ensure that we learn from experience and good practice in other health and non-health sectors as well as working to ensure we mitigate any risk of duplication as we develop further policy and operation planning.

- *Proposals based on a clear understanding of the legal framework*
  We reviewed the legislative framework, particularly in relation to registration of retail pharmacy businesses to ensure any policy proposals are consistent with the law.

- *Principles of good regulation will underpin all policy development work*
  The policy development has been tested, and will need to continue to be tested, against principles of good regulation as well as learning from previous failures in healthcare including the Mid-Staffordshire NHS Foundation Trust public inquiry.

2.2 The appendix to this paper sets out how we applied those principles and the conclusions we have reached in relation to the development of a regulatory model which reflects the Council’s vision and strategy.

2.3 In addition, the appendix sets out our next steps, and in particular the future consultation on draft standards which will require Council’s prior approval. The appendix describes how we propose to structure the future consultation including draft chapter headings. It specifically outlines the four core areas which we suggest are required to inform and explain the regulatory framework for registered pharmacy premises as well as the approach and timing of the consultation we plan to carry out. These are:

- Registration criteria for retail pharmacy businesses
- Draft standards for retail pharmacy businesses
- Compliance guidance for owners and superintendents of registered premises
- Decision framework on how we will apply our enforcement powers
3.0 Equality and diversity implications

3.1 Our preliminary analysis is that there will be no negative impact on equality and diversity as a result of the new regulatory approach for retail pharmacy businesses. However, we will be carrying out an Equality Impact Assessment and considering this draft EqIA as part of our formal consultation process.

4.0 Communications

4.1 What is set out in the appendix represents a significant change in the way in which registered pharmacy premises are regulated. We recognise that not only will we need to consult widely to test the proposals with key pharmacy stakeholders, but we will need to engage extensively across Great Britain with all other interest groups including patients and the public, other regulatory bodies, representative groups including owners and employers of pharmacy staff, commissioners and government.

4.2 We intend to consult for a minimum of twelve weeks once Council has approved the draft standards for consultation and we will deploy a range of quantitative and qualitative research mechanisms to ensure we get full and appropriate levels of feedback from all relevant groups and individuals.

4.3 In addition, we will structure the future consultation document in a way which sets out those areas where we believe we have flexibility in policy development and operational delivery and those areas where, if our interpretation is correct, we have little or none due to the legal framework. In cases such as this, we propose to consult only on our interpretation of the law, rather than a series of policy options.

5.0 Resource implications

5.1 It is important to state from the outset that we are fully committed to the principles for inspection and enforcement as set out in the Hampton Report (as they apply to a pharmacy setting), in particular a commitment to avoiding all unnecessary regulatory burdens, as well as the five principles of good regulation as originally described by the Better Regulation Executive.

5.2 We will need to carry out further analysis and carry out an Impact Assessment in advance of the consultation. This will take into account both the Department of Health’s analysis carried out as part of the consultation on the Pharmacy Order, and our own estimates of time and cost should the regulatory approach be approved.

6.0 Risk implications

6.1 Council has set out its ambition to be a risk-based regulator. The proposed approach to regulating premises is consistent with this ambition where the focus is protecting the public and ensuring our resources are targeted appropriately.
6.2 There are additional risks in relation to implementation and ensuring that we test proposals and monitor their impact. We have built into the project additional flexibility around timings to minimise this risk, alongside communication resources.

**Recommendations**

The Council is asked to note:

i. The pre-consultation engagement work carried out to date

And to consider and agree:

ii. The proposed approach to the planned consultation

Hugh Simpson, Director of Policy and Communications
General Pharmaceutical Council
hugh.simpson@pharmacyregulation.org, tel 020 3365 3516

7 November 2011
A proposed regulatory framework for retail pharmacy business

Introduction
The purpose of this appendix is to provide a high level overview of our proposed framework for the regulation of the carrying on of retail pharmacy business at a registered pharmacy premises. The approach set out below will form the basis of the necessary additional policy and operational development as we take forward our regulatory responsibilities in this area. It is also a necessary precursor to the finalisation and scheduled consideration by Council of draft standards for retail pharmacy businesses in January 2012 in advance of a full public consultation.

Background
Registration of pharmacy premises has formed part of the regulatory model in pharmacy for some time. However, the Pharmacy Order 2010 sets out a new legal framework for regulation in relation to pharmacy premises. In particular, the Order makes provision in legislation for the setting of standards for owners and superintendents carrying on retail pharmacy business at a registered pharmacy. It also provides a range of powers to the Council in relation to inspection of registered premises and securing compliance with those standards including powers of enforcement.

In approving the Pharmacy Order 2010, much of the debate in Parliament set out the potential benefits for ensuring a holistic approach to the delivery of pharmaceutical services. A key challenge in developing the new standards will be to explain how the regulation of individual registrants, dovetails with the regulation of registered pharmacy premises.

Owners and superintendent pharmacists\(^1\) are responsible for ensuring that any published standards for retail pharmacy business are met and they are accountable for doing so. However, all registered pharmacists and pharmacy technicians will also need to be familiar with these standards. We also want the users of services from retail pharmacy businesses, patients and the public, to be able to consult these standards to understand better the standards they can expect to find when using services provided by a registered pharmacy.

---

\(^1\) superintendent pharmacist is a pharmacist who is a superintendent of a retail pharmacy business owned by a body corporate. In hospitals this may be the chief pharmacist.
As a professional regulator the law provides a number of mechanisms by which we set and maintain standards to secure the safe and effective practice of pharmacy by individual professionals, in whatever context they are working. These mechanisms include: the registration of individual pharmacists and pharmacy technicians ("registrants"); GPhC standards of conduct, ethics and performance; guidance addressed to registrants; the continuing professional development rules, standards and framework; and associated fitness to practise procedures.

However, the Pharmacy Order 2010, by setting out a range of powers in relation to the regulation of retail pharmacy businesses, within the context of Parliament’s desire for a holistic approach to regulation, sets out some additional mechanisms for the setting and upholding of standards in relation to the carrying on of retail pharmacy business. These include: the registration of pharmacy premises; standards in relation to retail pharmacy businesses; inspection of registered premises; and, action to secure compliance with standards at registered premises.

These powers, aimed at upholding standards within retail pharmacy business, are used to require those responsible for the conduct of retail pharmacy businesses, to meet required standards including those in relation to the physical environment and also the organisation and delivery of pharmaceutical services. A number of these regulatory powers, such as the power to issue improvement notices and place conditions on registration, are consistent with those of the Care Quality Commission, the health and social care regulator for England and reflect the role of the GPhC as a systems regulator. Analogous powers are held by the Healthcare Inspectorate Wales and Healthcare Improvement Scotland.

What the Pharmacy Order introduced was a significantly different legislative framework for the regulation of pharmacy premises from that which went before. It established the GPhC explicitly as a ‘systems regulator’, generally referred to as a regulator of service providers, in addition to its role as a regulator of individual registrants through professional regulation. This makes us unique amongst health professional regulators such as the General Medical Council, Nursing and Midwifery Council or General Dental Council.

**Principles which have underpinned our work to date**

Given the range of powers provided for in the Pharmacy Order and that regulation of premises will change under a new regulatory body, we have used the following principles to underpin our work to date.
1. **Early engagement**  
Before developing specific proposals we asked a range of stakeholders about the themes and issues they face in pharmacy (see annex 1 of meetings)

2. **Learning from other regulators**  
We have carried out research to ensure that we learn from experience and good practice in other health and non-health sectors as well as ensuring we avoided duplication in policy development

3. **Proposals based on a clear understanding of the legal framework**  
We reviewed the legislative framework, particularly in relation to registration of retail pharmacy businesses to ensure any policy proposals were consistent with the law

4. **Principles of good regulation will underpin all policy development work**  
The policy development has been tested, and will need to continue to be tested, against principles of good regulation as well as learning from previous regulatory failures in health including the Mid-Staffordshire NHS Foundation Trust public inquiry

**Early engagement**

Although the new powers are designed to contribute to upholding patient safety by maintaining and improving standards within registered pharmacy premises, we recognised that the powers are wide ranging and have the potential for significant impact on the pharmacy professions and pharmacy businesses.

We therefore undertook, on Council’s behalf, considerable scoping and engagement work to consider how best to ensure that any proposals in relation to the setting or enforcement of standards were consistent with both the established five principles of good regulation\(^2\) and the principles set out in the Hampton Report on inspection and enforcement\(^3\).

Annex 1 includes a summary of all the pre-consultation meetings held to date and the events we have hosted. Our approach can be summarised as follows:

- **To identify and discuss issues, not specific proposals:** We wanted to listen to a range of stakeholders from pharmacy (including pharmacists and technicians) as well as other stakeholders (including patients and the public)

---
\(^2\) [www.bis.gov.uk](http://www.bis.gov.uk)  
\(^3\) Ibid
about what they perceived to be the main issues to enable these to influence our proposals in advance of formal consultation.

- **To focus on major themes, rather than issues of detail:** We identified three key areas for consultation: which premises should be registered and therefore regulated by us; the content and format for our standards in relation to premises; and, the risks within pharmacy.

- **To use the meetings and events as a prelude to consultation:** All our meetings and events were designed to inform early stages of policy development but not as an alternative to widespread consultation and engagement which will follow the publication of our consultation in the new year.

**Pre-consultation themes**

As part of our pre-consultation engagement, we considered three major themes as part of our discussions on the regulation of premises. These were:

- **Registration criteria:** there is an opportunity to clarify a range of issues in relation to the retail pharmacy business registered with the regulator, including but not limited to the criteria hospitals need to use to decide whether they are required to register with the GPhC.

- **Standards for retail pharmacy businesses:** what areas should be covered in the standards and the intention to use outcome focussed standards in relation to pharmacy premises, in line with Council’s regulatory standards policy.

- **Risk in pharmacy:** what information on risk in pharmacy exists and how can we use it to inform a risk-based model of pharmacy inspection and regulation.

**Learning from other regulators and the wider context**

We have carried out a number of meetings at Chief Executive and Director level, as well as operational level to learn from best practice as well as ensuring that our proposals do not lead to duplication of regulation from others in our sector, including but not limited to the Care Quality Commission and the Medicines and Healthcare products Regulatory Agency. Extensive desk based and interview based research has also been carried out to assess: current best practice in regulation; theory and practice in risk-based regulation; and, risk profiling methodology.

**Understanding the legal framework for registration**
A key theme we explored during pre-consultation engagement has been confusion about the requirements for registration of premises with the regulator. This has been very helpful in exploring issues in relation to the different delivery models and how we might register, inspect and enforce standards in the future. However, we have also done some detailed analysis of the legal framework which, although complex, appears to provide clarity about what the Pharmacy Order and Medicines Act set out in relation to retail pharmacy businesses and the definition on premises. This analysis appears to demonstrate that there is little flexibility of the regulator in this area and a key chapter in our consultation in the New Year is likely to focus questions on our interpretation of the law, rather than a policy position.

*Embedding the principles of good regulation*

Council has publicly set out its commitment to regulating in a way which is consistent with the accepted five principles of good regulation (referenced above) and that our work in relation to inspection and enforcement of retail pharmacy businesses takes full account of the 2005 Hampton Review and further follow up work overseen by the Department for Business Industry and Skills (and its predecessor departments). Amongst the key eight Hampton principles a number are particularly pertinent to the GPhC’s premises:

1. Regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources on the areas that need them most

2. Regulators should be accountable for the efficiency and effectiveness of their activities, while remaining independent in the decisions they take

3. No inspection should take place without a reason

4. Businesses should not have to give unnecessary information, nor give the same piece of information twice

5. The few businesses that persistently break regulations should be identified quickly and face proportionate and meaningful sanctions

6. Regulators should provide authoritative, accessible advice easily and cheaply

7. Regulators should be of the right size and scope, and no new regulator should be created where an existing one can do the work
8. Regulators should recognize that a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection.

However, our policy development work has also been informed by the ongoing debate in relation to the development of quality regulation within the wider NHS as well as both the initial inquiry into Mid Staffordshire NHS Foundation Trust⁴ and the ongoing public inquiry⁵ chaired by Sir Robert Francis QC. The Inquiry has considered and taken evidence on a whole range of subjects including, but not limited to: the interaction between professional and system regulation; the role of professional standards in driving improvements in healthcare delivery; the role of inspections in assuring minimum standards and promoting high standards of care; as well as the use of data in risk profiling. The inquiry’s hearings are expected to be completed by 1 December 2011 and we will continue to monitor developments closely.

Conclusions: towards a new model for regulating retail pharmacy business

There are a number of questions that have been raised, either by Council or external stakeholders to which we feel we can begin to answer and which will inform the development of a new regulatory model for pharmacy premises. These are set out below.

Are the standards only for superintendents and owners of pharmacy?

Professional regulation in pharmacy starts from the basis that registrants will be held to account against the professional standards set out in Conduct, Ethics and Performance. A common question as part of our engagement work from registrants has been, “If something goes wrong, who is to blame?” The first part of our answer would always be that as a regulator our purpose is not to apportion blame. Underpinning our regulatory functions here is a question about fitness to practise and whether action should be taken against an individual’s registration in order to protect the public and pharmacy service users.

Although superintendents and owners will remain responsible for ensuring compliance with the standards for premises, our regulatory action will primarily focus on the ‘system’ and what improvements need to be made to mitigate the risk to patients or whether conditions need to be placed on the registration of the retail

⁴ http://www.midstaffsinquiry.com/
⁵ http://www.midstaffspublicinquiry.com/
pharmacy business. This focus on compliance with the standards is also consistent with the principles of Hampton and the government's follow up report which argued for a greater focus on securing compliance and away from crude enforcement activities. Any question about the fitness to practise of individuals operating within the premises will be part of a different decision making process although all professionals operating within the retail pharmacy have a duty to comply with the standards and contribute to the delivery of safe and effective care. It is therefore our intention that the standards for retail pharmacy business will detail what is required within the retail pharmacy business, rather than simply the duties of the owner or superintendent.

What is a retail pharmacy business?

We have carried out detailed analysis of the legal issues and legislative framework around the definition of retail pharmacy businesses and premises. The legislation is principally set out in the Medicines Act 1968 and the Pharmacy Order 2010. In particular, section 132 of the Medicines Act 1968, defines what a retail pharmacy business is. The Pharmacy Order 2010 refers back to section 132 of the Act.

Considering this research and legal assessment it has become clearer that the law provides little flexibility in relation to what the GPhC could either choose to register as a retail pharmacy business or choose not to register. If the applicant meets the legislative requirements and definitions of a retail pharmacy business then they are eligible to register and we will require them to meet our standards.

As a result, we propose to set out the key principles and conclusions within the consultation document and, recognising the legal requirements upon us, to consult simply on whether consultees agree with our interpretation of the legislation.

What do you mean by principles-based and outcomes-focussed standards?

Feedback has been generally supportive of the intention for the standards to be principles-based and outcome focussed. In part this support appears to be in recognition of the wider trend to look at the outcome of regulation and, in the case of pharmacy regulation, a focus on the patient and what the outcomes are for them, but also a desire to move away from a prescriptive set of rules. We recognise that there is a wide-spectrum between, on the one hand, very high level outcome-focussed standards which do not translate into practice easily, and on the other hand, overly-
prescriptive or codified rules which compromise professionalism and remove focus from the service user or patient. We believe what we are proposing recognises the need to avoid either end of the spectrum and will provide a more flexible approach for professionalism in pharmacy to operate and enables a more proportionate enforcement regime to operate.

**How will I know if I’ve complied with outcome-focussed standards?**

Although there has been support for outcome focussed standards, there has been some concern about how we communicate this change and explain what it means in practice. The standards are currently being drafted to take account of this concern. Specifically we plan to set out some ‘indicative behaviours’ we would expect of registrants to help them understand better the implications of the standards and in so doing, recognising the cultural change this will mean for some in pharmacy.

In addition, we recognise that with the introduction of a new regulatory framework, and with new standards, comes a responsibility to set out in a more formal way, guidance on how to comply with the standards. We will set out the structure for this guidance in our consultation document in the New Year, but the detail will be developed alongside further testing of the standards with the profession and as part of the work of our inspectorate, as well as taking into account the consultation responses to the standards.

**How will you decide if the standards have been breached?**

As with all system regulators with enforcement powers, we will need to publish some form of decision framework. This will take into account our driving principles around proportionality and will reflect our commitment to openness and transparency. Above all, however, the decision framework will be developed with a focus on genuine risks to patient safety and risk, rather than technical breaches of standards where we do not believe patient safety is threatened. The key focus will remain on securing compliance and protecting the patient, rather than mechanistic or heavy-handed approaches to enforcement of the standards.

**How will you develop a new risk-based model of inspection?**

Risk-based regulation – targeting and allocating our resources at those areas of greatest risk and reducing our resources in areas of lower risk – is something the GPhC is fully committed to working towards. To be done effectively a far more sophisticated data and research will be required and it is our intention to put the steps in place alongside the consultation on the standards for retail pharmacy
businesses. We have carried out research on risk-based models in regulation, including how risk-profiling is done in other sectors and by, for example, the Care Quality Commission and we are committed to developing a model bespoke to pharmacy which keeps to an absolute minimum any bureaucratic burden on retail pharmacy business.

**Key elements will include identifying a base level of information, for example at the point of registration so we know far more about those businesses on the register than has been known previously, as well as redesigning our inspection model to reflect the new standards.**
What do we propose to include in the consultation document?

We recognise that the new framework and model for the regulation of retail pharmacy business will represent a significant change from the past. The new legislative framework, set out in the Pharmacy Order 2010, provides us with significant powers of enforcement and it is our intention to consult widely and in a meaningful way.

Given the analysis above, the intention is to structure the consultation document in chapters as set out below. These chapters will set out the legal framework and what we are proposing to do. In some cases we propose to set out our interpretation of what the legislation requires asking whether our analysis of the law is shared by consultees. In other areas, such as the draft standards, we will be asking a number of detailed questions on issues including format of the documentation, detailed feedback on drafting, scope of the content and how it is presented.

Overview of consultation

<table>
<thead>
<tr>
<th>Registration criteria</th>
<th>Content</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>What we register and why</td>
<td>Agreement on our interpretation of law</td>
</tr>
</tbody>
</table>

| Standards             | Draft standards | Consultation on draft standards |

| Compliance guidance   | Our approach to providing guidance | Seeking views on our approach |

| Decision framework    | Information on enforcement, sanctions and appeals | For information and feedback on principles |

The draft chapter headings are set out below:

Chapter 1 – Introduction to a new regulatory model

This chapter would set out, briefly, the recent history in pharmacy regulation and the new legislative framework
Chapter 2 – the GPhC’s approach to regulation

This chapter would set out our vision and commitment to risk-based and proportionate regulation.

Chapter 3 – Registration criteria

We intend to set out the draft registration criteria which are based on legal analysis of what we are required to register as a retail pharmacy business. Any consultation question is likely to ask simply whether there is agreement on our interpretation of the law.

Chapter 4 – Standards for retail pharmacy business

We will publish in full the draft standards for consultation with consultation questions on the proposed approach as well as on the detailed drafting of the standards.

Chapter 5 - Guidance on compliance with standards for premises

It would only be appropriate to publish draft guidance on compliance once the standards have been consulted on. However, we intend to set out, perhaps in an indicative format, what guidance will look like. We would consult on the approach we propose to take.

Chapter 6 – Enforcement and decision framework

We will set out the powers that we have and the principles which will underpin the development of our decision framework. The consultation document is likely to set out the principles which will underpin our approach to enforcement and ask for feedback. The decision framework will necessarily be developed at a later stage and further consultation will be required as a result.

Chapter 7 – Timing schedule

We will need to set out both the schedule for consultation, but also a draft implementation timetable.
Annex 1

Organisations contacted as part of our pre-engagement on premises standards

- Association of Pharmacy Technicians UK (APTUK)
- Association of Teaching Hospital Pharmacists
- Care Quality Commission (CQC)
- Centre for Pharmacy Postgraduate Education (CPPE)
- Community Health Councils Wales
- Department of Health
- Community Pharmacy Scotland
- Long Term Conditions Alliance Scotland
- National Clinical Assessment Service (NCAS)
- National Pharmacy Association (NPA)
- NHS Education for Scotland (Pharmacy) (NES)
- NHS Employers
- Pharmaceutical Services Negotiating Committee (PSNC)
- Pharmacy Law and Ethics Association
- Pharmacy Voice
- Royal Pharmaceutical Society
- Welsh Centre for Professional Pharmacy Education (WCPPE)
- Association of Independent Multiple Pharmacies (AIMp)
- British Pharmaceutical Students’ Association
- Welsh Assembly Government
- Scottish Government
• Department of Health, Social Services and Public Safety (Northern Ireland)
• Community Pharmacy Wales
• Council for Healthcare Regulatory Excellence (CHRE)
• Guild of Healthcare Pharmacists (GHP)
• Independent Pharmacy Federation
• Medicines & Healthcare Products Regulatory Agency (MHRA)
• National Patient Safety Agency
• National Prescribing Centre
• National Voices
• Pharmaceutical Society of Northern Ireland (PSNI)
• Pharmacists’ Defence Association (PDA)

• In addition we have met with a range of additional individual and organisation/corporate stakeholders, either as part of regular meetings or as part of meetings facilitated by umbrella groups.

• We have held five round-table meetings with pharmacy professionals (including both registered pharmacists and pharmacy technicians) across Great Britain as well as a larger event in seminar format in London.

• We have also held four engagement meetings with patients and their representative organisations. Two in England and further meetings in Scotland and Wales.
Annex 2 – Draft timetable

Consultation timelines