Regulatory standards policy

Purpose
To consider and agree the updated regulatory standards policy

Recommendations
The Council is asked to agree:

i. The regulatory standards policy set out in Appendix 1

1.0 Introduction

1.1 The Council considered a draft of the regulatory standards policy at its meeting in October 2010.

1.2 It was agreed that the remit of the policy should relate to our standard for pharmacy professionals, for registered pharmacies as well as our education standards.

1.3 Council approved the regulatory standards policy should be reviewed towards the end of 2011 to ensure it remained up to date and took into account both Council's strategic approach to regulation as well as any learning from our own work in setting and enforcing standards.

1.4 A subsequent decision was taken that the review of the standards policy should only be carried out, and the policy updated, once Council had approved the Standards for Registered Pharmacies and any feedback could be incorporated into the policy.
1.5 There have been a number of drafting changes to the policy to reflect both Council’s updated strategic plan and learning from the recent process to develop standards for registered pharmacies. The updated policy is set out in the appendix.

2.0 **Key Considerations**

2.1 The regulatory standards policy was used as the basis for early development and subsequent amendment and revision to the draft standards for registered pharmacies.

2.2 The policy sets out the principles that should underpin the development of our regulatory standards. These principles have not been changed although we would draw Council’s attention to their content and we would seek feedback as to whether they are wide enough in scope and continue to reflect Council’s view.

3.0 **Equality and diversity implications**

3.1 It is important that all of our regulatory standards reflects our commitment to equality and diversity.

3.2 Our commitment to engagement will help to mitigate any risks as well as our equality, diversity and inclusion policy and associated commitment to carry out equality impact analysis and compliance with the GPhC equality scheme.

4.0 **Communications implications**

4.1 The policy sets out a commitment to develop our standards through collaboration and engagement with our stakeholders.

5.0 **Resource implications**

5.1 There are no additional resource implications associated with the updated policy.

6.0 **Risk implications**

6.1 There are significant risks for Council if it fails to set standards and to consult widely in the development of those standards. The policy provides a framework to ensure that these risks are avoided.
Recommendations

The Council is asked to agree

i. The regulatory standards policy set out in Appendix 1

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

7 February 2013
1.0 Introduction

1.1 The Pharmacy Order 2010 sets out the general functions and duties of the General Pharmaceutical Council, including where we have powers and duties in relation to the setting of regulatory standards.

1.2 We are required to set standards in three broad areas. These are:

- to set and promote standards for the safe and effective practice of pharmacy at registered pharmacies;
- to promote the safe and effective practice of pharmacy by registrants (including, for example, by reference to any code of conduct for, and ethics relating to, pharmacy);
- to set standards and requirements in respect of the education, training, acquisition of experience and continuing professional development that it is necessary for pharmacists and pharmacy technicians to achieve.

1.3 Our standards form an integral part of our regulatory framework.

2.0 Purpose of policy

2.1 This policy sets out our approach to developing, publishing, monitoring and reviewing our standards and related guidance. It also sets out the status of these documents, and the way in which these standards should be used by pharmacy professionals.

3.0 Policy statement

Principles

3.1 We will ensure that our standards:

- define the core requirements for all pharmacy professionals
- remain relevant and up-to-date
- are outcome focussed, describing what needs to be achieved for patients and avoiding, where possible, prescribing how it must be done
- enable pharmacy professionals to exercise their professional judgement
- inform patients, the public, pharmacy professionals and pharmacy owners about the standards they can expect from pharmacy professionals and registered pharmacy premises.
Development

3.2 We will develop our standards through collaboration with all key interest groups, both from the pharmacy professions and those who engage with or affected by pharmacy practice. They will be subject to full consultation and appropriate models of engagement.

3.3 Where appropriate, we will issue guidance to support the understanding and implementation of our standards. Guidance to support our professional regulatory standards will provide further information to explain how pharmacy professionals can meet the standards set by us. Guidance which supplements our standards for registered pharmacies will do the same for owners of pharmacies and superintendents.

3.4 We recognise that there may be more than one way in which a pharmacy professionals, owners and superintendents can meet the standards. Therefore, a pharmacy professional, owner, or superintendent whose practice diverges from the guidance will need to be able to demonstrate that the standards have been met, their reasons for diverging from the guidance and that there was no negative impact on patient safety or undermining of confidence in the profession.

3.5 We recognise that other organisations, such as professional leadership bodies, trade associations, defence organisations and other agencies may also issue guidance. Pharmacy professionals should consider the availability of such guidance, particularly about detailed practice and use it to inform decision making where appropriate.

Publishing

3.6 The standards for conduct, ethics and performance and continuing professional development have been sent to all registered pharmacists and pharmacy technicians.

3.7 The standards for registered pharmacies have been sent to all registered pharmacists (including superintendent pharmacists), pharmacy technicians and owners of registered pharmacies.

3.8 All of our standards will be published on our website.

3.9 All guidance documents that we produce are published on our website.

Monitoring

3.10 A pharmacy professional’s conduct will be judged against the standards. As a regulator one of our primary concerns is a registrant’s fitness to practise. The standards and any relevant supplementary guidance will be central to any decision about whether we need to take any regulatory action against an individual’s registration.

3.11 Pharmacy professionals must use their professional judgement when deciding on a course of action and should use our standards and relevant supplementary guidance as a basis for making those decisions.
3.12 We will monitor our standards using a variety of methods. We will work with colleagues, for example the inspectorate and fitness to practise teams, to ensure our standards remain relevant, appropriate to current practice, accessible and fully understood by the professions. We will also continue to develop relationships with external stakeholders, including pharmacy professionals, patients and the public and others to generate continuous feedback on our standards.

3.13 Our standards for registered pharmacies describe the outcomes we expect for patients receiving services from registered pharmacies.

3.14 Owners and superintendents have responsibility for meeting the standards for registered pharmacies, although all pharmacy professionals working with in registered pharmacies should be familiar with the standards.

3.15 We will inspect all registered pharmacies and make decisions as to whether these standards have been met and what action needs to be taken to ensure patient safety is protected.

3.16 We will monitor the standards within registered pharmacies, and make decisions informed by risk, through a variety of means including information received at the point of registration or renewal, the reports from inspections as well as third party information including feedback from patients and the public, employers and commissioners of pharmacy services.

Review

3.17 We will keep our standards under review taking into account factors such as new or updated legislation, developments in practice, feedback from stakeholders as well as information and intelligence we gather through our regulatory operations.

3.18 Decisions about whether a formal review of GPhC standards is necessary is a matter for Council. Feedback and a recommendation will be presented to Council on each set of standards three years after initial publication.

3.19 Through appropriate monitoring and review we will also identify areas where guidance and support may be necessary and whether the GPhC is the appropriate body to do so.

4.0 Application of policy

4.1 The Director of Policy and Communications is responsible for the application of this policy.

5.0 Measurement and evaluation

4.2 The policy will be reviewed and reported to Council annually.