Council meeting 15 September 2011

Public business

Regulatory standards guidance

Purpose
To confirm the process and authority for the production of guidance to accompany GPhC standards.

Recommendation

The Council is asked to confirm the process and authority for the production of guidance in line with paragraph 1.5 of this paper.

1.0 Introduction

1.1 The GPhC regulatory standards policy was agreed by Council on 20 October 2010. It explains the importance of having a consistent approach to the development of regulatory standards across the organisation.

1.2 The GPhC has published its core standards for conduct, ethics and performance, training and education and interim premises standards. The regulatory standards policy states that we will issue guidance to support the understanding and implementation of our standards and explain how pharmacy professionals can meet the standards set by us.

1.3 Our guidance does not set out new policy but instead explains how registrants can meet the standards set by Council. We recognise that there may be more than one way to meet our standards and pharmacy professionals may adopt alternative methods to meet our standards. Our guidance is essentially a communication tool that supports the standards set by the Council.

1.4 Previous discussions about guidance did not include finalising specifically the approval process. A number of new guidance documents are required, and it is important that we work to a process which Council supports.
1.5 The GPhC has been operational since September 2010 and to date has issued two pieces of guidance. Practice to date has been that Council Members have had an opportunity to comment informally on draft guidance, and the production and finalisation of guidance has rested with the executive. The recommendation is that this should be confirmed.

2.0 Key considerations

2.1 When identifying new guidance that needs to be produced, we take into account a variety of factors, not limited to but including the standards that Council has set, issues identified through our fitness to practise processes, the enquiries we have received, feedback and recommendations from the Council for Healthcare Regulatory Excellence (CHRE), information and good practice from other regulators and the wider regulatory agenda.

2.2 Taking these factors into account, we are proposing to produce draft guidance on the following topics:

- Obtaining Consent
- Confidentiality
- Raising Concerns
- Maintaining professional boundaries
- Pre-registration training

2.3 The arrangement summarised in paragraph 1.5 has a number of advantages. It appears to be consistent with the principles behind the Council’s governance policy and preserves the important distinction between regulatory standards (the Council’s exclusive preserve) and guidance documents which are essentially supporting material. It also enables flexibility over the form of engagement to be used and over timing, which might vary importantly according to subject and current context, for example if a need arises for guidance to be prepared urgently, in response to events. Council would have responsibility for holding the chief executive accountable for the quality and appropriateness of guidance, with reference to the standards policy and the Council’s strategic aims.

2.4 If Council were to reserve the approval of guidance to itself that would enhance the status of guidance documents and ensure that Council as a whole took responsibility for them, although there could be more scope for confusion as between standards and guidance. Such an arrangement would have some
practical disadvantages (the corollary of the practical advantages summarised in paragraph 2.3 above) and might extend the time taken to approve them.

3.0 **Equality & Diversity implications**

3.1 We are currently developing an equality assessment tool which we expect to use to help with the analysis and quality control of proposed guidance in terms of equality and diversity.

4.0 **Communications implications**

4.1 We need to ensure that we when producing guidance, we actively and effectively engage patients and the public, with registrants and with our other stakeholders. This will include identifying the most appropriate people to engage with; using a variety of different engagement tools, and also ensuring a cross section of people are consulted with.

5.0 **Resource implications**

5.1 Relevant staff resources and the costs involved with engagement activities are covered within existing budgets.

6.0 **Risk implications**

6.1 If the process and authority for the production and approval of guidance are not clear, its status and effect could be unclear, which would be unhelpful.

**Recommendation**

The Council is asked to confirm the process and authority for the production of guidance in line with paragraph 1.5 of this paper.

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