Strategic review of risks

Purpose
To consider the key risks facing the GPhC

Recommendations

The Council is asked:

i. to discuss and note the risk review summarised in this paper.

1.0 Introduction

1.1 The General Pharmaceutical Council’s risk management guide includes the following:

Reviewing and Reporting

“The management of risk should be reviewed regularly to monitor whether or not the risk profile is changing, to gain assurance that risk management is effective, and to identify when further action is necessary. Procedures should be put in place to review regularly whether risks still exist, whether new risks have arisen, whether the likelihood and impact of risks has changed, report significant changes which adjust risk priorities, and deliver assurance on the effectiveness of control. In addition, the overall risk management process should be reviewed at least once a year to deliver assurance that it remains appropriate and effective.

Key players in the review and reporting processes are the Audit and Risk Committee and the assurance and advisory work of Internal Audit. However, it is important to note that neither Audit Committees nor Internal Audit can substitute for management ownership of risk or for an embedded review system carried out by the various staff who have executive responsibility for the achievement of organisational objectives.
In addition to regular review of the organisation’s risk management arrangements and the risk register by the Audit and Risk Committee, the GPhC Council conducts a strategic risk review on at least a quarterly basis. This review is informed by a strategic risk review paper prepared by the chief executive which draws on the risk register, highlighting all red risks, together with amber risks where the residual risk score is not coming down. The risk register itself is not appended to the Council paper and remains a management tool and reference.

The chief executive’s strategic review of risks for Council includes a summary of the Audit and Risk Committee’s most recent view of the state of risk management in the organisation.”

1.2 This paper is to support the Council’s strategic review of the organisation’s risks.

2.0 Key considerations

2.1 Since the last strategic review of risks by Council, the Audit and Risk Committee has been established. The Committee has seen and commented on the organisation’s risk management policy and process document, and has conducted a first review of the risk register.

2.2 This review does not assume that the organisation’s risks can be neatly classified as either “strategic” or “operational”/”tactical”. The risk management process recognises that operational risks can have a strategic significance. Therefore the approach taken is to present for Council’s review an overview of the risks with the highest risk rating (the “red risks”) and those medium-rated risks where the risk rating is not reducing.

2.3 Since the last Council strategic review of risks in July of this year, key changes to the context of our risk management discussions include:

- The General Pharmaceutical Council is now operational as the pharmacy regulator.

- The Audit and Risk Committee has held an informal meeting in July, followed by its first formal meeting on 29 October.

- Internal and external auditors have been appointed.
2.4 The work being undertaken on risk management systems and processes is important, but it ought to be regarded as secondary to work being done to create the right culture and ethos within the organisation. The aim here is to continue the approach, which Council has supported, of embedding risk management in the attitudes and behaviours of the management and staff, such that formal risk management activity should be a matter of documenting what is happening anyway. To this end, recent work has included:

- continuing to embed risk review in routine executive team meetings
- a zero-based risk assessment workshop has been carried out with the wider management group, to validate the risk register
- beginning to establish norms around local, department risk management necessary to underpin corporate-level activity
- a joint Audit and Risk Committee/management workshop, which usefully clarified the respective roles and responsibilities of committee members, managers and auditors.

2.5 The Appendix contains an overview of key risks, which is informed by the current edition of the corporate risk register. At its meeting on 29 October, the Audit and Risk Committee reviewed the format and content of the risk register and provided some useful feedback to the executive, including a reminder to ensure that risk management covers external risks fully.

3.0 Equality and diversity implications

3.1 This paper does not propose any new or amended policies, so there is no equality and diversity impact assessment indicated.

4.0 Communications implications

4.1 The Council is committed to operating in a way which is transparent and accountable. Open and frank discussion of risks is itself not risk-free in a media-political culture in which regulatory failure has a high news value. We will need to continue to ensure that any negativity which transparent risk assessment might generate is explained in a positive context, as we have done for example in relation to the Fitness to Practise due diligence exercise.

5.0 Resource implications

5.1 The integrated approach we are seeking to follow, in which the management of risks is part of the ongoing management of the organisation’s activities rather than a parallel process (see paragraph 2.4 above), means that resource planning for risk management activity is part of the routine budgeting and resource allocation process.
6.0 **Risk implications**

6.1 Risk issues are integral to this paper.

**Recommendations**

The Council is asked

i. to discuss and note the risk review summarised in this paper.

_Duncan Rudkin, Chief Executive and Registrar_
*General Pharmaceutical Council*

duncan.rudkin@pharmacyregulation.org, tel 020 3365 3501

9 November 2010
# Appendix 1

## Strategic review of risks

### 1 Strategic objective: registration and information systems generally

*Maintain the register of pharmacy professionals and pharmacy premises*

**Risk assessment**

Two risks to this objective are currently highlighted in the corporate risk register:

1. The risk that our information systems may not function as they should
2. The risk that users (including applicants and registrants as well as GPhC staff) do not understand or use the system (and related administrative processes, e.g. fee payment) as intended

These risks encompass ongoing maintenance and functionality of the register as well as the 2010/2011 renewal process and the introduction of anniversary-based registration periods.

**Risk management commentary**

The immediate transfer-related risks are behind us. The current concern in relation to renewals is not with the system so much as with registrant take-up of the renewal process. A supplementary communications programme was planned in case of this risk arising, and that is now being implemented.

In relation to the introduction of the “rolling register” from 2011, the risk will continue to score highly until the necessary development work has been fully implemented and satisfactorily tested. The need for an explicit IT strategy has been identified and work is in hand to develop it.

### 2 Strategic objectives: fitness to practise

- Safeguard patients through our responsibilities for investigating and acting on concerns about the fitness to practise of pharmacy professionals, or the practice of pharmacy from registered pharmacy premises.
- Respond promptly to concerns received about the fitness to practise of pharmacy professionals or the practice of pharmacy from registered pharmacy premises.
- Improve the fitness to practise procedures and build on the strengths of the inspectorate

**Risk assessment**

The key risks to these objectives are:

1. Information system risks, including the risks presented by lack of essential management information and lack of integration between the different databases in use with an FTP aspect to them
2. Lack of essential information impedes our ability to project resource requirements accurately, including hearings capacity and the type and amount of legal services required, exacerbating the inherent financial risks of the fact that our fitness to practise work is demand-driven
3. Risk that the Council’s values and strategic priorities may not be fully reflected in case decisions
4. Risk that we de-prioritise positive development work due to operational fire-fighting whilst dealing with legacy cases
Risk management commentary
Risk management priorities and actions in relation to risks summarised at 1-3 above are covered in the paper reporting on the legacy caseload.
The risk summarised at point 4 above encompasses the risk that we fail to engage in a timely fashion with issues around the *effectiveness* of the fitness to practise process. The focus of our work on managing these risks is the development of a new model for regulatory services. This has been the subject of an executive paper which was then discussed at an informal Council workshop session, the outputs from which are now being used by the executive to inform further development of the thinking for another Council discussion.

3 Strategic objective: standards
*Inform patients and the public about the standards for pharmacy professionals and retail pharmacy and work with pharmacy professionals and pharmacy owners to support the maintenance and development of standards in practice*

Risk assessment
The public and patient information objective is not as far advanced as Council would wish, due to the operational and profession-facing focus of the transition and the immediate aftermath of the transition, including registration renewals.
Risks with respect to the profession particularly relate to the disappearance, associated with transition, of a large number of RPSGB policy and guidance statements of various kinds which are neither replicated in GPhC standards and guidance nor [yet] re-issued by the Society in professional leadership mode.

Risk management commentary
In relation to public and patient information and engagement around standards, we have begun work in terms of:
- developing the equalities scheme with a public and patient engagement component
- creating opportunities for public and patient input into the pharmacists education standards consultation
- working to identify resources available for public and patient engagement.
These themes are expanded upon in another of today’s Council papers.

In relation to profession-facing risks around standards, risk management activity includes:
- working with the professional media on features explaining the nature of GPhC standards and guidance
- strategic and day to day collaboration with the RPSGB to ensure a common understanding of our respective roles and activities in relation to standards
- the GPhC standards development programme.

4 Strategic objective: revalidation
*Develop an effective system of revalidation*

Risk assessment
There is a risk of actual or perceived loss of political (in the widest sense) direction, leadership and momentum on this issue.

Risk management commentary
Our approach to managing these risks is about:
- applying GPhC values and the principles of good regulation to the design of all our systems and processes for ongoing assurance of fitness to practise of GPhC registrants
- building on the strengths of Continuing Professional Development in pharmacy
- looking to strengthen the positive assurance of fitness to practise within the GPhC's existing legal framework without assuming that “Revalidation” legislation will be required

This approach is consistent with the direction of travel of government policy in this area.

### 5 Strategic objective: working with partners

*Collaborate with organisations and influence regulatory policy and systems in the UK and the rest of Europe*

**Risk assessment**
The Council’s risk management strategy in the run-up to the transfer focused, rightly, on ensuring continuity of regulatory services and assurances; inevitably this has involved a considerable focus on internal business. With so much change and uncertainty in the external environment, there is a risk of the GPhC becoming side-lined or left behind if all our focus is on solving yesterday’s problems.

**Risk management commentary**
Recent engagement activity has re-prioritised the need to engage positively with other health professions regulators, and a wide range of other bodies and processes (e.g. Medicines and Healthcare Products Regulatory Agency, the Care Quality Commission, Medical Education England, Modernising Pharmacy Careers, NHS Education Scotland etc.).