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 three times a year. 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 Risk management assurance

2.1 At its meeting on 29 May 2012, the Audit & Risk Committee reviewed the risk management arrangements and the corporate risk register.

2.2 Section 3 contains an overview of key risks, which is informed by the current edition of the corporate risk register and includes the Audit & Risk Committee’s opinion in relation to some specific risks.

2.3 The committee noted the two risk workshops which had been undertaken with Council and staff in the previous two months; the Council workshop in March and the management group workshop in April. The outputs from both workshops were used to verify the corporate risk register and to inform the latest updates to it.

2.4 The Audit and Risk Committee considers that the arrangements in place for managing risks are operating effectively to provide assurance that risks are being identified and managed.

3.0 Strategic review of risks

3.1 This review does not assume that the organisation’s risks can be neatly classified as either “strategic” or “operational”/”tactical.” Our risk management approach recognises that operational risks can have a strategic significance.

3.2 GPhC risk scoring gives a score to each risk by reference to impact and likelihood. Risks with a score of 5 or less are green; 6-10 are amber; 12-25 are red.

3.3 Key points raised by the Committee:
The committee noted that we have a number of risks that relate to IT or where required mitigation is dependent on IT improvements; upgrading our databases, changing IT supplier, security of our IT systems. The committee agreed that it needed to understand more fully the nature of the IT-related risks and the mitigation action being taken. The committee asked that the executive produce a report for the committee’s next meeting in order to inform a more detailed review by the committee of cross-cutting IT-related risks.

3.4 High risks (red) – Total 3

a. Absence of an integrated system prevents identification of registrants/groups of registrants presenting most risk to patients and the public, and therefore, risk-based, targeted regulatory action
   - Current risk score is 16; risk score remains unchanged.
   - Mitigation against this risk, which is reflected in one of our objectives in the corporate plan for 2012-2015, is underway. The consultancy programme for the IT project (corporate plan item 2.1) is currently in progress.
   - Pending the new IT system, the risk score remains unchanged.
   - Target completion date 2013.
   - The Committee suggested that the nature of this risk and the analysis of the mitigation be re-considered in order to focus more fully on the absence of a framework for evidence-based risk profiling, IT being a secondary issue in this instance, compared to the need to establish first the policy to inform data and functionality requirements in relation to risk.

b. Decisions are made by statutory committee members that expose the GPhC to legal and/or reputational risk
   - Current risk score is 16; a new risk.
   - Systematic review of all decisions is now routine and evidence based feedback is being provided.
   - Target completion date 2013.

c. We do not have enough staff resources to deliver required policy development across all our regulatory functions including our new powers in relation to registered pharmacies.
   - Current risk score is 12; risk score remains unchanged.
   - The wording of this risk has changed to better reflect that this risk relates
to resources.

- Additional pressure on staff time as a result of the Law Commission work means that this risk score remains unchanged.
- Once a functional head is in post and the new team members within policy have passed their probationary/learning period, the executive expect the risk score to reduce.
- Target completion date Sept 2012.

### 3.5 Medium risks (amber) where the risk score is not reducing – Total 8

#### a. Significant information security breach causes reputation damage and/or liability for compensation claims and/or compliance action by the Information Commissioner’s Office

- Current risk score is 9; risk score remains unchanged.
- Due to conflicts with staff resources, the planned start for the information security (ISO) project has been rescheduled to start in Sept 2012.
- Until the project starts the risk score remains unchanged.
- Target completion date Apr 2013.
- In light of the deferment of the internal audit on data security to the 2012/13 audit plan (due to a combination of scheduling challenges around the auditor’s availability and the work required internally to effect the transfer of IT support from the RPS to the new commercial supplier) the Committee sought additional assurance as to data security testing.

#### b. Changes to the NHS in England result in breakdown of local networks through PCTs resulting in issues currently resolved at local level being referred to the GPhC

- Current risk score is 9; risk score remains unchanged.
- We have been briefed by NHS employers and the NHS Commissioning Board on the emerging arrangements for NHS performance management.
- The risk score remains unchanged pending further discussions.
- Target completion date end 2012.

#### c. Our policy making and approach to regulation is based on assumptions about perceptions, rather than evidence of views, or involvement in policy making and lack of confidence of GPhC as regulator

- Current risk score is 9; risk score remains unchanged.
- With staff resources focused on the registered pharmacies consultation,
actions to mitigate this risk have been limited. As such this risk score remains unchanged.

- Target completion date Mar 2013.

d. Our work duplicates the work of other regulatory bodies at national and local level

- Current risk score is 9; risk score remains unchanged.
- We continue to seek to improve the necessary engagement and liaison activity, an example of which includes the recently held discussions with MHRA and the GMC in relation to medicines issues.
- The executive continue to monitor this risk.
- Target completion date 2013.

e. Management and governance information needs are not capable of being met, inhibiting both the executive’s capacity to plan and allocate appropriate resources (within Regulatory Services) and the Council’s capacity to ensure that the organisation is achieving adequate progress

- Current risk score is 8; risk score remains unchanged.
- We continue to progress the tasks to mitigate this risk, which includes the commissioning of the development of the new performance monitoring framework (as set out in our Corporate Plan 2012-2015 item 2.2).
- Target completion date early 2013.

f. In moving to outcome focussed standards, key audiences including the pharmacy profession and patients and the public, lose confidence in us as a regulator and other pharmacy leadership bodies fail to provide guidance required to support good practice

- Current risk score is 6; risk score remains unchanged.
- Further progress to mitigate this risk will depend on the decisions to be taken by Council on the registered pharmacy standards.
- Target completion date Jul 2012.

g. Law Commission review result in recommendations which are not helpful in terms of Council priorities

- Current risk score is 6; risk score remains unchanged.
- This risk was previously part of a combined risk with the CHRE cost efficiency and effectiveness review (see risk below), which has now been split into two risks as they are separate issues.
- The risk score will next be reviewed substantively when we see the Law
Commission’s final proposals.

- Target completion date 2014.

h. CHRE efficiency and effectiveness review result in recommendations which are not helpful in terms of Council priorities

- Current risk score is 6; risk score remains unchanged.
- This risk was previously part of a combined risk with the Law Commission review (see above risk), which has now been split into two risks as they are separate issues.
- The risk score remains unchanged as we await the results of the review.
- Target completion date June 2012. This has been amended (was previously March), to reflect CHRE timetable change.

4.0 Equality and diversity implications

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

5.0 Communications implications

5.1 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.

6.0 Resource implications

6.1 Our integrated approach to risk, in which the management of risks is a mainstream part of the ongoing management of the organisation’s activities rather than a parallel process means that resource planning for risk management activity is part of the routine budgeting and resource allocation process.

7.0 Risk implications

7.1 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

30 May 2012