Council meeting

By Zoom
Thursday, 22 April 2021

10.00 – Workshop

13.30 – Public session

Public business

1.	**Attendance and introductory remarks**	Nigel Clarke
2.	**Declarations of interest – public items**	Nigel Clarke
3.	**Minutes of the meeting held on 11 March 2021** *Minutes of the public session*	Nigel Clarke
4.	**Actions and matters arising**	Nigel Clarke
5.	**Risk appetite statement and risk management policy**	*21.04.C.01* Rob Jones
6.	**Update on the resumption of in-person hearings**	Paul Cummins
7.	**Minutes of the Audit and Risk Committee meeting held on 2 March 2021 – public items**	*21.04.C.02* Neil Buckley
8.	**Any other business**	Nigel Clarke

Confidential business

9.	**Minutes of the meeting on 11 March 2021** *Minutes of the confidential session*	Nigel Clarke
10.	**Update on Chair appointment process**	Laura McClintock
11.	**Minutes of the Audit and Risk Committee meeting held on 2 March 2021 – confidential items**	*21.04.C.03* Neil Buckley
12.	**Any other confidential business**	Nigel Clarke

Date of next meeting

Thursday 13 May 2021

Minutes of the Council meeting held on 11 March 2021

To be confirmed 22 April 2021

Minutes of the public items

Present:

Nigel Clarke (Chair)	Elizabeth Mailey
Yousaf Ahmad	Rima Makarem
Neil Buckley	Rose Marie Parr
Mark Hammond	Arun Midha
Penny Hopkins	Aamer Safdar
Ann Jacklin	Jayne Salt
Jo Kember	Selina Ullah

Apologies:

None

In attendance:

Duncan Rudkin	Chief Executive and Registrar
Carole Auchterlonie	Director of Fitness to Practise
Jonathan Bennetts	Director of Finance
Claire Bryce-Smith	Director of Insight, Intelligence and Inspection
Laura McClintock	Chief of Staff
Gary Sharp	Associate Director of HR
Mark Voce	Director of Education and Standards
Liam Anstey	Director for Wales
Laura Fraser	Director for Scotland

Rachael Oliver	Head of Communications
Janet Collins	Senior Governance Manager
Arvind Sandhu	Equality, Diversity and Inclusion Policy Manager
Liliana Corrieri	Equality, Diversity and Inclusion Policy Adviser

1. Attendance and introductory remarks

1.1 The Chair welcomed those present to the meeting.

2. Declarations of interest

2.1 The Chair reminded members of the Council to make any appropriate declarations of interest at the start of the relevant item.

3. Minutes of the last meetings – public sessions on 11 and 22 February 2021

3.1 The minutes of the public sessions held on 11 and 22 February 2021 were approved.

4. Actions and matters arising

4.1 Following the meeting on 22 February, the Executive had held further discussions with the Department of Health and Social Care about when it might be possible to bring further amended draft Rules back to Council for consideration. This was unlikely to be before September, due to the upcoming elections in Scotland and parliamentary recesses. This meant that there would be a gap between the expiration of the Rules previously agreed by Council (which would happen on 1 May 2021) and any potential permanent amendments coming into force. Further updates would be provided in due course.

5. Communications and engagement update

5.1 Rachael Oliver (RO) introduced **21.03.C.01** which updated the Council on recent communications and engagement activity. Much of this had related to the registration assessment which was due to take place on 17 and 18 March. Candidates had been provided with a large amount of information and the 'fit to sit' message was being repeated frequently.

5.2 This meant that candidates had been made aware that they could decide not to take part in the March sitting right up to the moment that the assessment began and that if they did so, the attempt would not count and they would have their fee refunded. The message was also being communicated to employers and others supporting the candidates.

5.3 Feedback would be sought from the candidates once the sitting was over to see which communications had landed best and which channels had been the most effective.

5.4 Lessons learned from the Covid-19 pandemic and the registration assessment would be taken into account in developing the new communications strategy, which would be coming to a future meeting for discussion.

5.5 The Chair thanked the Communications team, on behalf of the Council, for all the work they had been doing during the pandemic and specifically in relation to the registration assessment.

5.6 **The Council noted the communications and engagement update.**

6. Delivering equality, improving diversity and fostering inclusion: our strategy for change

6.1 Laura McClintock introduced **21.03.C.02,** the draft equality, diversity and inclusion (EDI) strategy which was being presented for approval for public consultation. Arvind Sandhu and Liliana Corrieri joined the meeting for this item.

6.2 The Chair and LM thanked the Council members who had been involved in the development of the draft strategy – Yousaf Ahmad, Mark Hammond, Jo Kember, Arun Midha and Aamer Safdar

6.3 LM described the development of the draft strategy including the significant input from the internal equality networks and staff focus groups. The draft was at an important stage where it now needed feedback and input from external stakeholders, from the consultation, meetings with stakeholders and external focus groups. The draft included an assurance framework which would be an important part of the strategic aims becoming embedded in the organisation's work and its culture.

6.4 The GPhC was a partner organisation to the Joint National Plan for Inclusive Pharmacy Practice which had just been published. While the plan only related to England, it was hoped that the principles behind it could be extended across the four countries.

6.5 Members welcomed the draft, including the intention to collect better data to provide an evidence base for change and the fact that it included an assurance framework; and discussed the timing of the consultation, which would run for 12 weeks.

6.6 **The Council approved the draft EDI strategy for consultation.**

7. Standing Financial Instructions

7.1 Jonathan Bennetts presented **21.03.C.03** which set out the draft Standing Financial Instructions (SFIs) for approval. The SFIs represented the final stage of the review of governance documents which had been undertaken and which included the Scheme of Delegation and Authority Framework approved by the Council in July 2020.

7.2 The draft SFIs had been reviewed by both the internal and external auditors and their feedback incorporated.

7.3 The Council discussed the draft and raised questions on some points of detail. The document would be due for review in Summer 2022 along with the other governance documents.

7.4 **The Council approved the Standing Financial Instructions.**

8. Council chair appointment 2022

8.1 Laura McClintock and Janet Collins presented **21.03.C.04**, which set out the suggested process for appointing a new Chair of Council to take office on 1 April 2022. The paper included a high-level timetable, updated selection criteria and a Diversity Action Plan to support the process; and asked members to advise on the term of office which should be advertised and on whether it wished a Council member to sit on the selection panel.

8.2 A question had been raised as to whether the post should be open to registrants as well as lay applicants. However, it was a lay vacancy which was to be filled and therefore a lay candidate which would be required. It was understood that the decision of another regulator to open its Chair vacancy to lay applicants and registrant Council members was a result of the recruitment being an emergency caused by the resignation of the Chair.

8.3 Draft selection criteria had been reviewed by the Council when it approved the policy on member and Chair appointments and re-appointments in September 2020. The criteria had subsequently been reviewed against other Chair roles and discussed with the current Chair with the result that a minor amendment was suggested, as set out in the paper.

8.4 The PSA guidance on appointments allowed for a Council member to sit on panels appointing Chairs but suggested that it should be a member who was not eligible for re-appointment. As all current GPhC members were eligible for re-appointment, the executive had agreed with the PSA that one of the members with the least time left to serve would be acceptable.

8.5 Members discussed the term of office which should be advertised. The current Chair had been appointed for four years and then re-appointed for a further four. However, it was open to the Council to suggest a different term of office should it choose to do so. With the prospect of regulatory reform and a move to a unitary board, the Council discussed whether a shorter term of office in the first instance might give greater flexibility should the needs of the organisation change.

8.6 Several members suggested that a stakeholder panel, while not having decision-making powers, could provide an additional perspective on the recruitment. This would be explored further, together with the question of whether the Council would have any liability if regulatory reform led to the term of office being shorter than was being suggested.

8.7 **The Council:**

i) **Considered the suggested process for appointing a new Chair and provided feedback;**
ii) **noted the high-level timetable for the process at Appendix 2;**
iii) **approved the updated selection criteria and competences at Appendix 3;**
iv) **agreed that the term of office to be advertised should be three years;**
v) **confirmed that it wished a member of Council to sit on the appointment panel; and**
vi) **noted the Diversity Action Plan at Appendix 4.**

9. Deputising arrangements for the Chair

9.1 Janet Collins presented **21.03.C.05** which set out the proposed deputising arrangements for the Chair, should he be unavailable.

9.2 The proposal was for Ann Jacklin to act as deputy from 1 April to 30 September 2021 and for Neil Buckley to do so from 1 October 2021 to 31 March 2022.

9.3 **The Council noted the arrangements for the deputy Chair between 1 April 2021 and 31 March 2022.**

Rima Makarem left the meeting

10. Initial Education and Training for pharmacists (IETP) – implementation update

10.1 Mark Voce presented **21.03.C.06** which updated the Council on the implementation of the IETP standards which had been published in January 2021.

10.2 An Advisory Group co-chaired by one registrant and one lay member of Council (Rose Marie Parr and Arun Midha) was overseeing the implementation of the standards. Its work since January had focussed on governance, changes to the Foundation Training Year from July 2021 and the transition to incorporating independent prescribing into the initial five years of education and training.

10.3 The current pre-registration year would become a Foundation Training year from July 2021 and the Advisory Group had been exploring how the transition could be managed, particularly in light of the pressures on employers arising from the pandemic. Some interim amendments had been made to the new learning outcomes reflecting the fact that it would not be possible to introduce all the measures relating to prescribing this year. Employers who had already submitted their training plans for July 2021 would not be required to re-submit them for formal approval.

10.4 The next meeting of the Advisory Group would be considering a paper on a number of issues related to the introduction of prescribing skills, and a further paper would then come to Council.

Rose Marie Parr and Arun Midha left the meeting

10.5 The role of the chairs of the Advisory Group had evolved significantly in the six months since the Council had approved the governance arrangements for this work and now involved both an increased time commitment and increased responsibility. It was therefore proposed the role should be remunerated in the same way as the chairs of the non-statutory committees with an additional payment of £2,500 per annum for each Chair with effect from 1 April 2021 until the Group ceased to exist or until the nature of the role significantly reduced, subject to Council approval. This figure was provided for in existing budgets.

10.6 **The Council noted the update and agreed that the co-chairs of the Education Advisory Group should be remunerated with an additional payment of £2,500 per annum for each chair**

Rose Marie Parr and Arun Midha returned to the meeting

11. Registration assessment update

11.1 Mark Voce gave an update on the registration assessment which was due to take place on 17 and 18 March 2021. Council had been updated on this previously as the situation had been developing.

11.2 A number of candidates had experienced problems with booking their places. The issues for candidates who had been invited to book afternoon slots instead of morning ones had been resolved. Candidates who had asked to sit the assessment at home for reasonable adjustment reasons, whether in the UK or overseas, had all been accommodated.

11.3 Some candidates had expressed concern at being required to travel to a test centre. While this had always been the case and most had to travel a much shorter distance than usual this year, some still had to travel further than they felt comfortable with.

11.4 Candidates were receiving advice on the practicalities of sitting the assessment.

11.5 Dates for the summer and autumn sittings were being finalised and would be made public as soon as possible.

11.6 Members noted the huge amount of work which had gone into setting up and arranging the assessment. While some candidates had experienced difficulties, it should be acknowledged that the vast majority had been able to book a place with no problems. This did not diminish the concerns of those who had faced issues and the Chair referenced the apology given by Duncan Rudkin to those affected.

11.7 **The Council noted the update.**

12. Minutes of the Audit and Risk Committee meeting on 9 February 2021.

12.1 The Council noted the minutes of the public items considered at the meeting of the Audit and Risk Committee on 9 February 2021.

13. Any other business

13.1 There being no further business, the meeting closed at 14.15.

Risk Management Policy and Risk appetite statement cover paper

Meeting paper for Council on 22 April 2021

Public

Purpose

To seek approval from Council on the proposed risk management policy and risk appetite statement.

Following feedback at the Council workshop on 11 March 2021, revisions have been made to the risk management policy and risk appetite statement. We are now seeking formal approval of these documents.

Recommendations

Council is asked to approve the risk management policy and risk appetite statement at **Appendix 1.**

1. Introduction

1.1 In 2019, a decision was made to reset our risk management process. Since then, workshops have been held with Council, the Audit and Risk Committee (ARC) and the Senior Leadership Group (SLG), to determine our revised approach to risk management.

1.2 Steady progress has been made and significant work done across the organisation to understand the risks we face and to ensure that activity is being undertaken to manage risk in the interim.

1.3 On 15 December 2020, we asked that ARC consider the risk management policy and risk appetite statement, to ensure they were content with the direction of travel. We then held a Council workshop on 11 March 2021 to discuss the risk management policy and risk appetite statement and seek feedback.

1.4 Following these sessions, amendments have been made. We now request that Council approve the risk management policy and risk appetite statement.

1.5 We have developed a strategic risk register, with input from SLG, that has been subject to scrutiny and amendment from ARC and our internal auditors on three occasions. As Council will take ownership of this document, with the administration being undertaken by the Audit

and Risk Manager together with SLG, Council will need time to engage with the proposed risk profile.

1.6 As such, we will be coming back to Council at a further workshop, to discuss the content of the strategic risk register in detail.

2. Key considerations

2.1 **Risk management policy**

2.2 The risk management policy sets out at the highest level how risk should be managed within the organisation, including:

- The process for identifying risks and recording in risk registers;
- How and when risks should be escalated to SLG and ARC/Council if appropriate;
- The reporting process, which includes updates on the strategic and corporate operational risk registers at every ARC meeting and the strategic risk register going to Council twice a year;
- Roles and responsibilities of various different bodies, groups and individuals; and
- The process for recording risk registers in operation throughout the organisation, via a register of risk registers.

2.3 Council is asked to approve this document.

2.4 The policy will be supplemented by a full risk management manual, which will detail the risk management process in full, user guide format, and which will be developed in 2021.

2.5 **Risk appetite statement**

2.6 We have developed a risk appetite statement which features our proposed risk appetite for seven key categories of risk:

- Patient safety and public health
- Standards and quality
- Health, standards of safety, and wellbeing
- Financial health
- Productivity and efficiency
- People resourcing, deployment and development
- Compliance and legal

2.7 The categories and the proposed appetite for risk in respect of each is set out in some detail. Following the work we did with SLG and in workshops with a number of teams, a prevailing theme was that a document setting out Council's risk appetite covering the organisation's risk profile in specific terms would be more helpful to the Executive in making decisions as to how to manage risk, than a more generic type risk appetite statement.

2.8 Reputational risk is not set out as a specific risk category, but following feedback at the Council session and some discussion on this, it was agreed that explicit reference to why this

has not been included as a category of risk would be made and that it will instead be treated as a strand running through all areas of risk.

2.9 Support will be given, by the Risk and Audit Manager, to teams in applying the risk appetite statement to policy and project work and in considering the level of priority hazard risks should be given. Workshops are in the diary for April and May 2021 to start the roll out.

2.10 Council is asked to approve the risk appetite statement.

3. Equality and diversity implications

3.1 There are no direct equality and diversity implications associated with this paper, though equality, diversity and inclusion are key considerations in the formulation of our responses to both operational and strategic risk.

4. Communications

4.1 At the point these documents are approved by Council, we will communicate the policy to key staff directly and to others by communications channels such as Sharepoint. Support will be given, by the Risk and Audit Manager, to teams in applying the risk appetite statement to policy and project work and in considering the level of priority hazard risks should be given.

5. Resource implications

5.1 The implementation and roll out of this policy has been included within the Finance and Procurement Directorate service plan for 2021/22, and will be managed within existing resource.

6. Risk implications

6.1 A consistent, proportionate risk management policy is key to the strategic and operational success of any organisation. We must ensure that the risk management policy, which we will implement in the interim prior to Council's approval, meets the requirements of the organisation and that ARC are content with the direction of travel.

7. Recommendations

Council is asked to approve the risk management policy and risk appetite statement at **Appendix 1.**

Rob Jones, Risk and Audit Manager
General Pharmaceutical Council

15 April 2021

Appendix 1

Risk Management Policy

[Policy reference number] Version 0.8

This policy sets out the risk management process at the General Pharmaceutical Council.

Policy details

Policy reference	[Policy reference number]
Version	0.8
Policy author	Rob Jones, Risk and Audit Manager
Approved for issue by	[Approved by], [Approved date]
Effective from	[Effective date]
Next review	[Review date]

Version control tracker

Version	Approved date	Description of change	Amendments by
0.7		Changes made following comments by ARC to Chief Executive's and Director of Finances responsibilities. Changes also made to section on ARC review of registers to reflect alternating between corporate operational and strategic risk registers at meetings.	Rob Jones
0.8		Visual diagram of risk process added. Changes made to risk appetite statement following Council workshop feedback.	Rob Jones

Contents

1. Introduction

1.1 Every organisation must take, and is exposed to risks, in pursuit of achieving its objectives. Being risk aware means approaching this proactively to manage down the threats we face and make the most of the opportunities. The price of getting this wrong is high: not using our resources efficiently and a failure to deliver our objectives, which may ultimate lead to patient safety being compromised, reputational damage and a loss of confidence in the organisation's ability to deliver its core functions.

1.2 That is why it is essential we understand and manage our risks well across the organisation, whether they come from external events or from our own activities. We need an approach that ensures we address the right risks at the right time, with the right people involved. Whilst we recognise it is important that each team manages its own risks at an operational level and feel supported in doing so, we want to ensure that we identify and where appropriate, mitigate those risks that affect the organisation as a whole, which might not be easily managed within existing resources and which need a strategic response.

1.3 The Council and the Senior Leadership Group (SLG) will make risk management central to all our decision making. The Council has overall responsibility for the leadership of the risk management policy, for ensuring that its risk appetite is set and communicated to the SLG, and that an appropriate risk culture exists within the organisation.

1.4 Risk management should not be a remote, 'box-ticking' activity undertaken exclusively in SLG and Council meetings. We want good risk conversations to be a natural part of how we manage our business, at every level of the organisation. Each of us commits to using risk-based decision making in our everyday work, and to support those we work with to do the same. There is already a proportionate, effective risk management process and culture in place. This document is part of helping to embed it, to spread it further, and to ensure that the Council sets the strategy and leads by example.

1.5 This document should be read in conjunction with the Incident Management Policy document.

2. Purpose

2.1 The Council Risk Management Policy aims to:

- provide a consistent and standardised approach to the identification, management and mitigation of risk by which future problems can be prevented or at least addressed;
- support the Council to focus on those risks which might compromise the achievement of the GPhC's strategic objectives;
- support ongoing compliance with statutory requirements;
- support decision making on the future provision and development of services and enabling the challenges of different delivery models (e.g. collaboration) to be systematically assessed and controlled;
- assist staff in knowing when to escalate risks to the Senior Leadership Group, Audit and Risk Committee, and Council; and
- encourage the sharing of good practice and learning lessons across the organisation.

3. Scope

3.1 This policy covers all risk management activity within the GPhC.

4. Exclusions

4.1 Not applicable.

5. Definitions

5.1 **Risk** - HM Treasury's Orange Book (2019) defines risk as "an UNCERTAIN future event, which if it occurs will have positive or negative effects on the delivery of corporate objectives."

5.2 **Risk appetite** - the phrase used to describe how much risk, and the different categories of risk, an organisation is willing to accept.

5.3 **Risk tolerance** - the potential impact of a risk that the organisation can literally cope with.

5.4 **Strategic risk register** – the risk register logging and detailing the organisation's risks at a strategic level, owned by Council.

5.5 **Corporate operational risk register** – the highest level risk register looking at operational matters within the organisation.

5.6 **Departmental risk register** – a risk register owned by a department, looking at risks directly facing that department on a more granular level.

5.7 **Project risk register** – the risk register used to log and manage risk associated with a project or particular piece of work.

6. Responsibilities

i. Council

6.2 The Council has overall responsibility for risk management and more specifically for:

- leading by example by supporting a positive risk culture, focussed on learning from mistakes and not seeking to attribute blame, and encouraging openness and discussion of real business issues in a realistic manner;
- setting the risk appetite and risk management policy for the organisation; and
- agreeing and reviewing the Strategic Risk Register.

6.3 The Strategic Risk Register is routinely reviewed by the Council twice yearly. At each Council meeting (where the full Risk Register is not being reviewed), an update on key risk movements, 'Never Events' and newly added risks will be reported to the Council if appropriate. Key risks will be addressed in each paper presented to the Council to ensure that the management of risk associated with Council decisions is not considered to be remote to the decision itself.

ii. Audit and Risk Committee

6.4 The Council is the governing body of the GPhC and determines the governance policy and framework for the organisation. The Audit and Risk Committee (ARC) supports the Council by reviewing and advising the Council on the operation and effectiveness of the arrangements which

are in place across the whole of the Council's activities that support the achievement of the Council's objectives. With regards risk management, ARC will review the adequacy of:

- All risk and control related disclosure statements, together with any accompanying internal audit statement, external audit opinion or other appropriate independent assurances, prior to endorsement by the Council; and
- The underlying assurance processes that indicate the degree of the achievement of corporate objectives, the effectiveness of the management of principal risks and the appropriateness of the above disclosure statements.

6.5 ARC will have sight of the strategic risk register and corporate operational risk register at each meeting, but alternate between the two in terms of detailed focus. ARC will have a duty to provide advice to the Council where significant concerns about risk assurance arise. In reviewing risk management arrangements, ARC should draw attention to areas where:

- risk is being appropriately managed, and controls are adequate (no action needed)
- risk is inadequately controlled (action needed to improve control)
- risk is over-controlled (resource being wasted which could be diverted to another use)
- there is a lack of evidence to support a conclusion (if this concerns areas which are material to the organisation's functions, more audit &/or assurance work will be required).

iii. Chief Executive Officer

6.6 The Chief Executive, supported by the ARC, should:

- take overall responsibility for establishing the organisation's overall approach to risk management and defining its risk profile;
- periodically assess whether the organisational values, leadership style, opportunities for debate and learning, and human resource policies support the desired risk culture;
- ensure that expected values and behaviours are communicated and embedded at all levels to support the appropriate risk culture;
- designate an individual to be responsible for leading the organisation's overall approach to risk management, who should be of sufficient seniority and should report to a level within the organisation that allows them to influence effective decision-making; and
- ensure the allocation of appropriate resources for risk management, which can include, but is not limited to people, skills, experience and competence.

iv. Director of Finance

6.7 The Director of Finance, supported by the ARC, should:

- work on behalf of the Chief Executive to establish the organisation's overall approach to risk management; and overall risk profile; and
- demonstrate leadership and articulate their continual commitment to and the value of risk management through developing and communicating a policy or statement to the organisation and other stakeholders, which should be periodically reviewed.

v. Risk and Audit Manager

6.8 The day-to-day oversight of and reporting on risk management is dealt with by the Risk and Audit Manager, whose responsibilities are:

- establish risk management activities that cover all categories of risk and processes that are applied at different organisational levels;
- ensure the design and systematic implementation of policies, procedures and practices for risk identification, assessment, treatment, monitoring and reporting;
- to report to the ARC on risk management activity within the organisation;
- to provide strategic direction on the risk management of the GPhC;
- to keep an up to date register of risk registers held within the organisation (Appendix C);
- to ensure the strategic and corporate operational risk registers are updated at least quarterly;
- to review the strategic and corporate operational risk register with the SLG on a routine basis, and at least quarterly;
- to lead and encourage proportionate risk management practices, consistent with the principles set out in this policy;
- to ensure that the SLG support a positive risk culture, focussed on learning from mistakes, not seeking to attribute blame;
- to encourage openness and discussion of real business issues in a realistic manner; and
- to identify, assess and manage the risks faced by the organisation, keeping the important risks visible and recognising when risks are changing, and taking the appropriate action.

vi. Senior Leadership Group

6.9 The day-to-day management of the risks identified within each respective directorate is led by the SLG, whose responsibilities are:

- to understand the Council's risk appetite and to ensure that matters within their remit are being managed with this in mind;
- to work with the Chief Executive, Director of Finance, and Risk and Audit Manager to ensure that proportionate risk management practices, consistent with the principles set out in this policy, are in operation within their directorates;
- to support a positive risk culture, focussed on learning from mistakes, not seeking to attribute blame; and
- to encourage openness and discussion of real business issues in a realistic manner.

vii. Project boards

6.10 Project boards will be responsible for:

- providing SLG and Council with assurance that the risks associated with the project it oversees is managed appropriately and within Council's risk appetite; and
- providing strategic direction to the project team in the management of risk within the project.

6.11 For guidance on the process for the formulation of policy, please see the guidance **here.**

viii. Risk owners

6.12 Risk owners (including project teams) will be identified within risk registers. They are responsible for:

- coordinating activities related to the identified risk, including working with control owners and owners of planned actions to ensure progress;
- ensuring that action plans for the risks that they own are reflected in the annual business plan if appropriate;
- working with the Risk and Audit Manager to ensure that the record of the risk is up to date within the risk register;
- ensuring that the target risk score is aligned with Council's stated risk appetite;
- to escalate to SLG (or the project board if applicable) when a risk cannot be managed to within Council's stated risk appetite.

i. GPhC Staff Members, associates and partners

6.13 Are required:

- to be aware that everyone has a role to play in risk management;
- to apply risk management in carrying out day-to-day processes and procedures;
- to identify and report to the SLG, the head of department and/or the Risk and Audit Manager new or changing risks facing the organisation;
- to report incidents in line with the GPhC's incident management policy;
- to work together as an organisation to monitor, manage and reduce the GPhC's risk where appropriate; and
- to take responsibility for mistakes and to learn from them with the support of the SLG and Risk and Audit Manager.

7. Policy

i. What is risk?

7.1 Risk is an inevitable consequence of making decisions, taking action or failing to do either. It is a part of everything we do and increases proportionately in volatile, uncertain, complex and ambiguous circumstances, where we have less direct control, or work at the edge of our knowledge and experience. Risk is inevitably higher during periods of change or when delivering new projects and initiatives.

7.2 HM Treasury's Orange Book (2019) defines risk as "an UNCERTAIN future event, which if it occurs will have positive or negative effects on the delivery of corporate objectives."

7.3 In contrast, an issue is defined as a relevant event which has happened or is happening and has resulted in a consequence, was not planned, and requires immediate management action. In this regard, it differs from a risk, which is defined as a future event which has yet to happen.

7.4 Risk Management is the co-ordinated activities designed and operated to manage risk and exercise internal control within the organisation.

7.5 For the purposes of this policy, strategic risk are risks that affect or are created by the organisation's business strategy and strategic objectives.

7.6 Tactical risks are risks associated with the means of delivering change, i.e. projects.

7.7 Operational risks are major risks that affect the organisation's ability to execute its strategic plan.

7.8 A 'risk owner' is an accountable point of contact for a risk, who coordinates efforts to mitigate and manage the risk with various individuals who own parts of the risk. The individuals who own parts of the risk and mitigating controls, are known as 'control owners'.

ii. Risk appetite

7.9 'Risk appetite' is the phrase used to describe how much risk, and the different categories of risk, an organisation is willing to accept. Where a risk exceeds the risk appetite something will usually need to be done to reduce the risk. Risk appetite may vary for different risks, for example, the organisation may be more willing to cope with uncertainty around future funding levels but have a very low appetite risk which may result in the organisation not complying with the law.

7.10 The GPhC acknowledges that risk management involves judgement about situations and actions, and that the GPhC's risk profile is constantly changing. The Council's risk appetite will vary according to the nature of the risk and cannot be defined by one statement which applies to all of the GPhC's activities.

7.11 'Risk tolerance' is the potential impact of a risk that the organisation can literally cope with. The GPhC's risk appetite statement can be seen at Appendix 1.

7.12 The target score within the risk register will be determined by Council's stated risk appetite in the category of risk that the identified risk best fits. It is the responsibility of risk owners to ensure that when they identify risks, they assess the current risk score against Council's stated risk appetite and escalate the matter to SLG if they consider that the risk cannot be managed appropriately within existing resource. Project boards will be responsible for overseeing the risk management activities specific to the project that they oversee and ensuring that the project team are managing risk in line with Council's stated risk appetite.

7.13 For further guidance on how to assess the risk against Council's stated risk appetite, please contact the Risk and Audit Manager.

iii. Risk management plan

7.14 **Identification and Assessment of Risk**

7.15 The GPhC has two main risk registers, which record and track risks faced by the GPhC. These are the strategic risk register, which considers matters which may affect or are created by the organisation's business strategy and strategic objectives. The corporate operational risk register considers the broad operational risks that the organisation faces at the highest level. The risk register template (Appendix 2) is a key tool within the GPhC's Risk Management framework. A Risk Owner/Controller is specified.

7.16 The strategic and corporate operational risk registers are reviewed at least quarterly at SLG meetings. New risks are added and consideration is given initially to the causes and effects of the

risk. The Council should be notified of any new risks added to the Strategic Risk Register at the earliest opportunity so that full consideration of the matter and the proposed scoring can be undertaken.

7.17 There are two elements:

- Likelihood is generally considered to be a combination of the probability and frequency of a risk occurring.
- Significance is considered to be the magnitude of the impact of the risk being realised.

7.18 The risk score is applied using a formula: x (likelihood) multiplied by y (significance). The controls and mitigation already in place are then added.

7.19 Scores are calculated for the 'inherent risk', 'current risk' and 'target risk', by defining a 'likelihood' and 'significance' for each.

7.20 The risk appetite is then defined by the Council, using one of the five gradings set out in the risk appetite document ('low', 'low/medium', 'medium', 'medium/high' and 'high').

7.21 Once the current risk score is calculated, if it is higher than the target score (which will be determined by Council's risk appetite), additional actions should be identified to mitigate the risk, in an attempt to lower the risk to within Council's risk appetite.

7.22 **Monitoring and control of identified risks**

7.23 Having assessed the risk and identified controls and any additional mitigating actions, the risk is then managed on a day-to-day basis. The Risk and Audit Manager is responsible for monitoring the progress of the actions and controls identified, and where a change to a plan is necessary, ensuring that risk owners can provide justification for this. Progress on managing the risk is reviewed at SLG meetings and each risk is subject to review. It is sometimes appropriate, dependent upon the risk identified, for the risk to be the subject of Committee or Council discussions and deliberations, and detailed scrutiny by the ARC into specific aspects may be appropriate.

7.24 **Departmental risk registers**

7.25 Whilst we encourage cross directorate working and shared ownership of key operational risks, it may be appropriate at times to develop departmental and project risk registers linked to specific risks, corporate objectives, projects, core processes or key dependencies. It is the responsibility of the risk register owner to inform the Risk and Audit Manager that the register has been created so that it can be logged within the Register of Risk Registers (Appendix 3).

7.26 **Review process and escalation**

7.27 It is only the Strategic Risk Register that will routinely be reviewed by the Council, with other matters being reported by exception or if the SLG or ARC consider that a particular risk cannot be managed within the Council's stated risk appetite.

7.28 It is accepted that in some cases, despite robust actions and controls being put in place, some risks cannot be reduced to within the Council's stated risk appetite. The SLG will seek to reduce the risk to a level that is as low as is reasonably practicable and report back to the Council where it is not possible, within existing resources, to bring the risk within the Council's risk appetite. The Council

will need to consider whether it is appropriate to undertake further action, which may require additional resource, or to reconsider their risk appetite.

7.29 The risks will also be considered when the GPhC is setting priorities and agreeing the annual Business Plan and budget, to ensure that the GPhC's resources are correctly targeted to risk.

7.30 A flow chart for the GPhC's risk management process is set out at Appendix 4.

7.31 **Internal Audit**

7.32 An internal audit programme agreed between management and the ARC also forms a strong part of the GPhC's management of risk. The programme provides assurance on the internal controls and on specific areas of risk which arise through the GPhC's operations. Reviews are undertaken and reported both to SLG and the ARC, and where appropriate a timetable for improvement is agreed and then monitored. The work plan is drawn up based on the risks, priorities and opportunities faced by the GPhC.

7.33 An internal audit of the GPhC's risk management structure will be undertaken at least every three years.

8. Training requirements

8.1 Workshops focussing on risk identification for different teams, and roles and responsibilities should take place at least every three years, as part of the wider review cycle of the risk management process.

9. Monitoring and compliance

9.1 This Risk Management Policy outlines the GPhC's policy on managing risk. To be effective, managing risk must be understood and accepted as an important area of the GPhC's responsibilities, ensuring that the GPhC considers and responds to risk in an effective way. The following review cycles will take place:

- The Risk Management Policy will be reviewed by the Council once a year, following advice from ARC;
- Council will review the strategic risk register twice yearly;
- ARC will review the strategic risk register and corporate operational risk register at each meeting, alternating its primary focus;
- SLG will review the strategic risk register and corporate operational risk register on a quarterly basis; and
- Requirements for reporting on incidents are set out within the Incident Management Policy.

10. References

10.1 The Incident Management Policy referenced at paragraphs 1.5 and 9.1 can be seen here.

10.2 The Strategic Risk Register referenced throughout this policy can be seen here.

10.3 The Corporate Operational Risk Register referenced throughout this policy can be seen here.

10.4 The Register of Risk Registers, referenced at paragraphs 6.8 and 7.25, can be seen here.

11. Associated documentation

11.1 Incident Management Policy

11.2 Strategic Risk Register

11.3 Corporate Operational Risk Register

11.4 Register of Risk Registers

12. Appendices

12.1 Appendix 1 is the risk appetite statement.

12.2 Appendix 2 is the risk register template and scoring matrix.

12.3 Appendix 3 is the template for the register of risk registers.

12.4 Appendix 4 is a flow chart for the risk management process.

Appendix 1

Risk appetite statement

The General Pharmaceutical Council's (GPhC) Risk Appetite Statement forms part of our risk management policy. It articulates the level and type of risk the Council will accept in the strategic positioning and day-to-day running of the organisation. This statement is the result of a careful evaluation of how risks affect our ability to achieve our objectives and Vision 2030 and may be amended by the Council as required.

'Risk appetite' is the phrase used to describe how much risk, and the different categories of risk, an organisation is willing to accept. Where a risk exceeds the risk appetite something will usually need to be done to reduce the risk. Risk appetite may vary for different risks, for example, the organisation may be more willing to cope with uncertainty around future funding levels but have very little appetite for risks which could damage the organisation's reputation or for not complying with the law.

The GPhC acknowledges that risk management involves judgement about situations and actions, and that the GPhC's risk profile is constantly changing. The Council's risk appetite will vary according to the nature of the risk and cannot be defined by one statement which applies to all of the GPhC's activities. 'Risk tolerance' is the potential impact of a risk that the organisation can literally cope with.

As a statutory body, with protecting patients as its fundamental purpose, the GPhC is naturally risk-averse and its risk tolerance is relatively low due to its statutory duties and the level of available resources. The GPhC generally therefore works to minimise and control risk, by taking an appropriate and proportionate approach to risk.

However, the GPhC acknowledges that being risk-averse also has its costs, in terms of measures put in place to control and mitigate risk. Being too risk averse may also mean that opportunities are missed or that the costs of mitigation outweigh the benefits. Some risks cannot be controlled and managed, and the GPhC must take decisions to accept that some risks will remain, whilst ensuring that appropriate controls and actions are in place. Our approach is not intended to stifle innovation or initiative, which help to achieve our strategic aims.

An explanation of the categories of risk the GPhC is exposed to is included in the risk appetite statement, with the agreed appetite relating to each recorded. This should form the basis for decision making at all levels. It should also act as a vehicle for the escalation of risks which exceed the Council's appetite, but which cannot be managed within existing resources. This should be taken as an aid to decision making and guide as to when to escalate to a colleague of appropriate authority rather than an absolute doctrine directing every decision we make.

With regards the strategic risk register, risk appetite is considered against individual risks on an ongoing basis, and the risk appetite agreed by the Council. The Council must be satisfied that the current risk falls within the agreed risk appetite, and if not, identify further actions to try and mitigate the risk further (or amend the risk appetite if this is not appropriate).

There are also certain risks, classed as 'Never Events'. The organisation's risk appetite in respect to these specific events is extremely low and regular updates will be given to ARC and Council as to how well these risks are being managed. These are not defined in this document.

Levels of risk

The definitions of the different levels of risk the Council is prepared to accept in specific areas is set out below (please see the Risk Management Policy for method calculating risk score).

Appetite	Descriptions	Indicative target score*
Low	Avoidance of risk and uncertainty is a key organisational objective.	6 or below
Low-medium	Preference for safe options that have a low degree of inherent risk, **but may** only have a potential for limited reward.	6 to 10
Medium	Preference for safe options that have a low degree of risk, but prepared to explore more progressive solutions.	8 to 12
Medium-high	Willing to consider all options, provided reasonable and rational plans can be put in place to manage to associated risks. Risks with a significant impact, which cannot be mitigated significantly, will still usually be avoided.	12 to 15
High	Eager to be innovative and to choose options offering potentially higher business rewards, regardless of potential greater risk.	15 and above

***where the 'impact' of a risk remains 'catastrophic' (rated 5) regardless of mitigation put in place, tolerance of that risk where the 'likelihood' is above '2' must be signed off by the Chief Executive and flagged to the Audit and Risk Assurance Committee (ARC).**

Categories of risk

As well as setting a risk appetite for specific strategic risks, the Council has defined its risk appetite for the different categories of risk at a project and operational level. The seven broad areas of risk that statements will be set for are:

- Patient safety and public health
- Regulatory standards and quality

- Health, standards of safety, and wellbeing
- Financial health
- Performance
- People resourcing, deployment and development
- Compliance and legal

Each category will be nuanced and there will be variations to Council's risk appetite for different types of risk within each risk category.

This risk appetite will form the basis for the approach taken to individual risks identified by the management team on project and operational risk registers. Project and operational risks that cannot be managed within the Council's risk appetite will be escalated to the SLG, and if necessary, the ARC and/or Council.

Reputational risk is not included as a separate category of risk. The reason for this is that we consider that reputational damage is a consequence of actions or events in these other areas of risk, rather than a category of risk in its own right. We do however define and seek to mitigate reputational risk through our organisation risk register and our wider approach to communications and stakeholder engagement.

Patient safety and public health

Council has a low appetite for risk relating to patient or public safety, and this shapes our approach to managing information that may indicate a registrant or premises poses a potential threat in this respect. Council also has a low risk appetite for anything that may impact the accuracy or integrity of the register, as it is this document which helps guide the public in the decisions they make when seeking treatment and employers.

We do however recognise the need to be proportionate and that investigations must be undertaken promptly so as not to impact premises, the lives of registrants and patients and families going through the process any more than is necessary. As such, we have a duty to manage risks associated with externally driven delays to investigations (such as enquiries or investigations by other bodies) as far as we possibly can, whilst recognising that we must not sacrifice patient safety to achieve this. Delays caused by performance or capacity issues are covered in the section on 'Productivity and Efficiency'.

Regulatory standards and quality

Alongside the approach we take with patient safety matters and the integrity of the register, we recognise that we must keep pace with technological developments and society more generally. This may mean there will be times where action must be taken to modernise the service we deliver, sometimes to reduce existing or emerging risks, and we must accept risks in delivering these changes. Where this is the case, careful consideration will be given by Council to the importance of the change, the risks that exist and our confidence in managing these risks down to a reasonable level. We accept that we may not be able to eliminate risk entirely from technological transformation of services, but that at times we will need to act regardless, particularly where the risk of not acting is significant.

The standards we set and how we quality assure those are vitally important to effective regulation in the longer term, and in building a regulatory model which is proactive rather than reactive. However, we must accept a greater degree of risk in maintaining and updating these standards, as to be too risk averse, or conservative, in setting standards could become counter-productive and mean we fail to deliver a regulatory model that meets society's and pharmacy's needs. Similarly, with regards our quality assurance tools for education standards and our inspection regime, we must accept that the resource available to conduct these activities is finite. This means being innovative in creating models which provide assurance that standards are being met by the highest number of institutions and premises, with the resource that we have available. We must therefore accept a greater degree of risk in pursuing associated objectives.

Health, standards of safety, and wellbeing

Council has a low risk appetite for pursuing opportunities or managing hazards relating to the safety standards, wherever our people are working, and the health of members, staff, associates, partners and visitors. We recognise that there is a distinction between health and wellbeing and that whilst health and safety standards are largely quantifiable, that the wellbeing needs of staff vary greatly and are highly individualised.

We will endeavour to manage risks associated with staff wellbeing down wherever practicable and reasonable, whilst recognising that it is an infinitely complex subject.

Financial Health

We have a medium risk appetite around the setting of fees and expenditure. An overly conservative approach to our financial management may result in an even greater risk materialising of not being able to afford to regulate in a way that is fit for purpose and therefore fails to protect patients and the public. It is also imperative that the organisation remains financially secure and sustainable for the long term. We therefore need to ensure that our approach to managing our assets and income enable these goals to be delivered. Therefore, a more pragmatic cautious to balance approach had been adopted for the management of our cash balances over a long-term investment horizon to mitigate the risk of capital loss, provide protection against inflation and generate a modest level of income to support funding our activities. Because of the reliance on fee income to fund the cost of regulation and the large lag time between adjusting fee levels, we have increased our appetite around fees to a more proactive and managed approached. We do however recognise the need to seek best value in the services and products we procure, to ensure that confidence remains that the fee we set is proportionate and that we are managing the revenue it generates responsibly.

We maintain a low risk appetite for deficiencies in financial stewardship, internal controls and meeting external obligatory financial reporting requirements.

Productivity and efficiency

In line with our Vision 2030 to be a good quality regulator, with a strategic aim to deliver effective consistent and fair regulation, we are committed to delivering a performance and reporting framework which provides a balance and transparency between productivity, efficiency and effectiveness. In doing

so this creates the right culture to ensure our priority is on securing the right regulatory outcomes, supporting continuous improvement and encouraging innovation in our own services. This also enables us to flex in an ever-changing environment to ensure we remain fit for purpose as a regulator. As such we have a medium risk appetite for risks that may affect productivity, as we recognise that at times to achieve our aims, we may need to risk short term disruption to our operations.

People resourcing, deployment and development

We recognise that to develop and maintain an effective and productive organisational culture, we need to be innovative and open to opportunity. We accept a medium/high level of risk in delivering a dynamic approach to resourcing, deploying and developing our people. We see this level of appetite as consistent with our vision to operate as a professional and lean organisation, to enable a flexible and high skilled, specialist and dynamic workforce. We do however consider that some posts, particularly where there is an associated single point of failure, require more caution and will seek to manage these risks down to a low-medium level, as proportionate to the organisation's available resource. We are also mindful of creating a culture where bullying and harassment is dealt with swiftly and robustly and that success must not come at the expense of colleagues' dignity.

We have a medium tolerance for risks associated with delivering our diversity and inclusion responsibilities. This means that we are prepared to consider progressive solutions and pursue opportunities, despite risks to delivery or productivity that may remain. We accept that as a result, we will not always get it right, but commit to tackling issues positively and with the intention of delivering our equality, diversity and inclusion strategy.

Equality, as distinct from diversity and inclusion, carries with it legal and compliance implications and as such, we will have a low tolerance for risks that may impact on our ability to meet our obligations with regards equality.

Compliance and legal risks

Whilst we recognise that there is little upside presented by deviating from corporate governance codes or information governance/cyber security standards, managing these areas to the lowest possible level would be extremely costly and prevent us from making the right decisions quickly, in times of critical urgency. We will however commit to be mindful of our size and status, and the type of organisation we are, when managing compliance related activities, and resourcing this activity. As such, we will do our best to manage all risks relating to legal compliance, including compliance with information governance and equality legislation to the lowest possible level. We will strive to use our existing resource as effectively as we can to manage these risks down to the lowest possible level, which will mean that our approach will often be conservative and innovation may not be prioritised, except where the magnitude of the decision we are expected to make requires urgent action for good reason.

We have a medium/high appetite for legal challenge to our regulatory decision-making. Our strategic vision, Vision 2030, commits us to responding robustly to concerns about patient safety, wherever they arise, and with this comes a need to be prepared to face legal challenge. We will place a strong emphasis on ensuring our approach to making regulatory decisions of all kinds is fair, transparent, proportionate and compliant with the law and our own policies. Where we are confident that we have

worked to these principles, we will do what we consider to be the right thing, notwithstanding the potential for legal challenge.

Appendix 2

Risk description			Inherent risk		Total inherent risk (x*y)	Current Mitigation/key controls and owners	Current risk		Total Current Risk (x*y)	Risk appetite	Planned actions	Timeframes and action owner
Risk/Control Owner	Cause	Effect	Likelihood (x)	Significance (y)			Likelihood (x)	Significance (y)				
1. RISK EVENT DESCRIPTION												

Formula: (X*Y) x- Likelihood y= Significance

Catastrophic/ Never Event	5	5	10	15	20	25
Major	4	4	8	12	16	20
Moderate	3	3	6	9	12	15
Minor	2	2	4	6	8	10
Insignificant	1	1	2	3	4	5

significance

1	2	3	4	5
Remote	Unlikely	Possible	Probable	Highly Probable

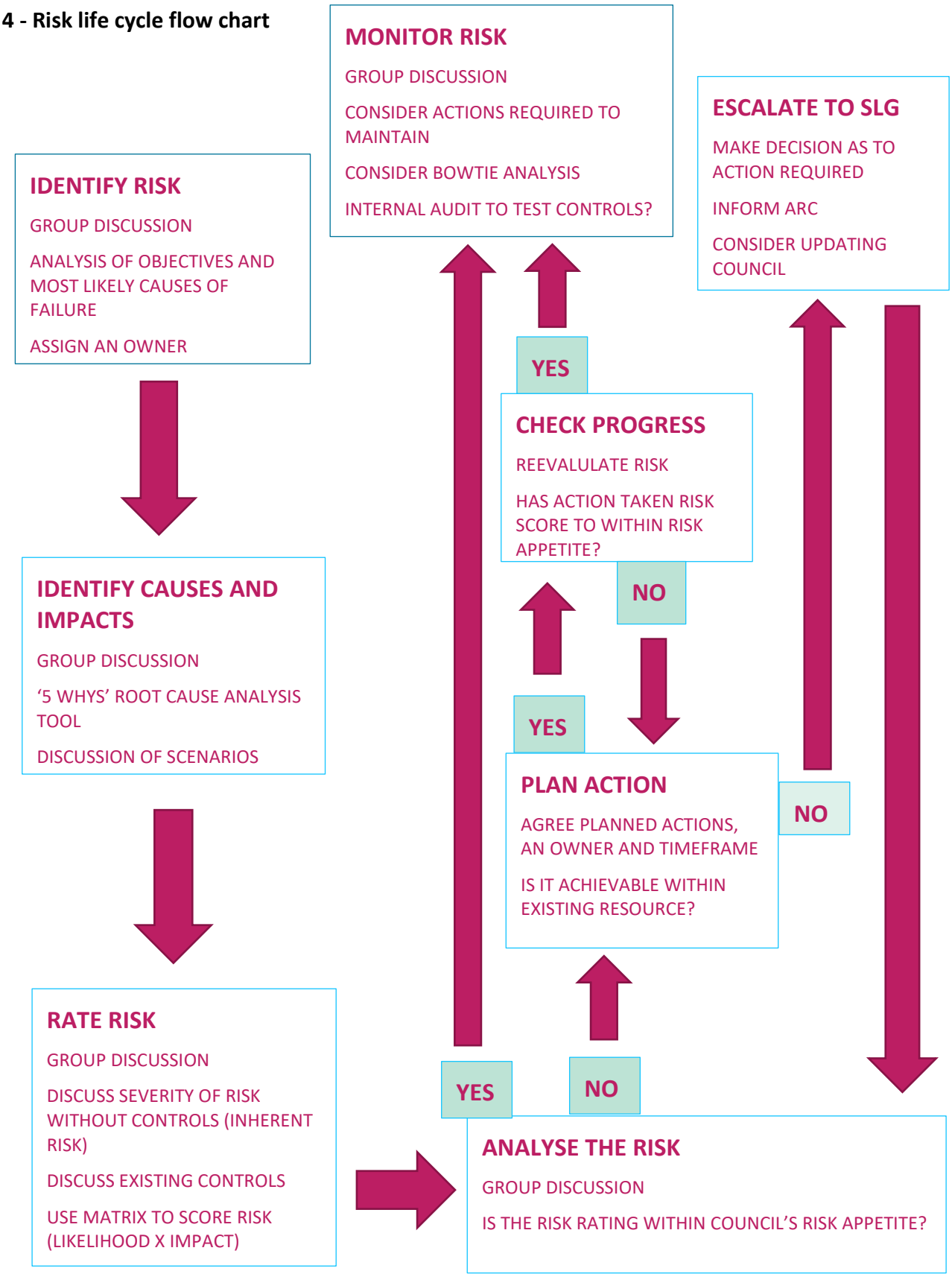
Likelihood

Appendix 3

Register of Risk Registers

	Register	**Owner**	**Last review**
Strategic/Corporate Level	Strategic Risk Register Corporate Operational Risk Register	Council and Chief Executive and Registrar Chief Executive and Registrar	
Project	TBC	TBC	
Operational	Never Event Register	Senior Leadership Group	

Appendix 4 - Risk life cycle flow chart



Risk appetite statement

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We maintain a low risk appetite for deficiencies in financial stewardship, internal controls and meeting external obligatory financial reporting requirements.

Productivity and efficiency

In line with our Vision 2030 to be a good quality regulator, with a strategic aim to deliver effective consistent and fair regulation, we are committed to delivering a performance and reporting framework which provides a balance and transparency between productivity, efficiency and effectiveness. In doing so this creates the right culture to ensure our priority is on securing the right regulatory outcomes, supporting continuous improvement and encouraging innovation in our own services. This also enables us to flex in an ever-changing environment to ensure we remain fit for purpose as a regulator. As such we have a medium risk appetite for risks that may affect productivity, as we recognise that at times to achieve our aims, we may need to risk short term disruption to our operations.

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We have a medium tolerance for risks associated with delivering our diversity and inclusion responsibilities. This means that we are prepared to consider progressive solutions and pursue opportunities, despite risks to delivery or productivity that may remain. We accept that as a result, we will not always get it right, but commit to tackling issues positively and with the intention of delivering our equality, diversity and inclusion strategy.

Equality, as distinct from diversity and inclusion, carries with it legal and compliance implications and as such, we will have a low tolerance for risks that may impact on our ability to meet our obligations with regards equality.

Compliance and legal risks

Whilst we recognise that there is little upside presented by deviating from corporate governance codes or information governance/cyber security standards, managing these areas to the lowest possible level would be extremely costly and prevent us from making the right decisions quickly, in times of critical urgency. We will however commit to be mindful of our size and status, and the type of organisation we are, when managing compliance related activities, and resourcing this activity. As such, we will do our best to manage all risks relating to legal compliance, including compliance with information governance and equality legislation to the lowest possible level. We will strive to use our existing resource as effectively as we can to manage these risks down to the lowest possible level, which will mean that our approach will often be conservative and innovation may not be prioritised, except where the magnitude of the decision we are expected to make requires urgent action for good reason.

We have a medium/high appetite for legal challenge to our regulatory decision-making. Our strategic vision, Vision 2030, commits us to responding robustly to concerns about patient and public safety, wherever they arise, and with this comes a need to be prepared to face legal challenge. We will place a strong emphasis on ensuring our approach to making regulatory decisions of all kinds is fair, transparent, proportionate and compliant with the law and our own policies. Where we are confident that we have worked to these principles, we will do what we consider to be the right thing, notwithstanding the potential for legal challenge.