General Pharmaceutical Council

Council meeting

Thursday, 12 October 2023

Public meeting at 14.00

Public business

Standing Items

14.00	**1. Attendance and introductory remarks**	Gisela Abbam
14.00	**2. Declarations of interest – public items**	Gisela Abbam
14.05	**3. Minutes of the September meeting** *Minutes of the public session on 14 September 2023 – for approval*	**23.10.C.01** Gisela Abbam
14.05	**4. Actions and matters arising**	**23.10.C.02** Gisela Abbam
14.10	**5. Workshop summary – September meeting** *For noting*	**23.10.C.03** Gisela Abbam
14.15	**6. Strategic communications and engagement update – our new approach** *For discussion and noting*	**23.10.C.04** Duncan Rudkin

Regulatory functions

14.30	**7. Report on the June 2023 sitting of the registration assessment** *For discussion and noting*	**23.10.C.05** Mark Voce
14.50	**8. PSA performance review report 2022-23** *For discussion and noting*	**23.10.C.06** Duncan Rudkin

Governance, finance and organisational management

15.10	**9. Risk management policy** *For approval*	**23.10.C.07** Rob Jones
15.25	**10. Any other business**	Gisela Abbam

Confidential business[1]

Standing items

15.30	**11. Declarations of interest – confidential items**	Gisela Abbam
15.30	**12. Minutes of the September meeting**	**23.10.C.08**
	Minutes of the confidential session on 14 September 2023 – for approval	Gisela Abbam
15.30	**13. Matters arising**	Gisela Abbam

Regulatory functions

None at this meeting

Governance, finance and organisational management

15.35	**14. Update on organisational change**	Duncan Rudkin
15.45	**15. Any other business**	Gisela Abbam
	Meeting close	

Date of next meeting

9 November 2023 - online

[1] The Council's Governance Policy (GPhC0040, agreed December 2019) states that the Council may take business as confidential when the item:

a. may be prejudicial to the effective conduct of the GPhC's functions if discussed in public; or

b. contains information which has been provided to the Council in confidence; or

c. contains information whose disclosure is legally prohibited, or is covered by legal privilege; or

d. is part of a continuing discussion or investigation and the outcome could be jeopardised by public discussion; or

e. refers to an individual or organisation that could be prejudiced by public discussion; or

f. relates to negotiating positions or submissions to other bodies; or

g. could be prejudicial to the commercial interest of an organisation or individual if discussed in public session; or

h. could be prejudicial to the free and frank provision of advice or the exchange of views for the purpose of deliberation if discussed in public; or

i. needs to be discussed in confidence due to the external context, for example, during periods of heightened sensitivity such as during an election period.

General Pharmaceutical Council

Minutes of the Council meeting held on 14 September 2023

To be confirmed on 12 October 2023

Minutes of the public items

Present:

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

Apologies:

Penny Mee-Bishop

In attendance:

Duncan Rudkin	Chief Executive and Registrar
Jonathan Bennetts	Director of Adjudication and Financial Services
Claire-Bryce Smith	Director of Insight, Intelligence and Inspection
Hannah Fellows	Interim Director of Fitness to Practise
Mark Voce	Director of Education and Standards
Gary Sharp	Associate Director, HR and OD
Laura McClintock	Chief of Staff and Associate Director, Corporate Affairs
Liam Anstey	Director for Wales
Siobhan McGuinness	Director for Scotland
Janet Collins	Senior Governance Manager

Standing items

1. Attendance and introductory remarks

1.1 Gisela Abbam (GA) welcomed those present to the meeting. Penny Mee-Bishop had sent her apologies.

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 meeting (23.09.C.01)

3.1 The minutes of the public session held on 8 June 2023 were approved as a true and accurate record of the meeting.

4. Actions and matters arising (23.06.C.02)

4.1 The action log was up to date. There was one matter arising:

Registration assessment (minutes of the June meeting, section 4)

4.2 Mark Voce (MV) gave a brief update on the June sitting as this was the first Council meeting since the sitting. The assessment was delivered successfully with only a small number of technical issues which were resolved promptly on the day. Council would receive the usual breakdown of performance data from the assessment at the next meeting in October.

5. June workshop and July Awayday summaries (23.09.C.03)

5.1 The Council noted the summary of the workshop held on 8 June and the Awayday held on 12 and 13 July 2023.

5.2 The Chair thanked the staff and members involved in organising the Awayday.

Regulatory functions

6. Update on key developments in pharmacy (23.09.C.04)

6.1 Mark Voce (MV) presented the paper, which set out the most significant developments in the external pharmacy and wider healthcare regulatory environment in four main areas:

- developments in pharmacy practice, including consultations and legislative changes;
- pharmacy education and training;
- regulatory developments, including proposals and developments on regulatory reform and relevant work by other healthcare regulators; and
- other relevant healthcare and patient issues.

6.2 The developments covered in this paper were:

- a proposal for the use of patient group directions (PGDs) by pharmacy technicians;
- pharmacist prescribing pathfinder pilots;
- changes to legislation on original pack dispensing (OPD) and whole pack dispensing of medicines containing sodium valproate;
- a new training programme for pharmacy technicians;

- NHS England training for educational supervisors; and
- the General Medical Council's updated guidance on professional standards *Good Medical Practice 2024.*

6.3 In discussing the updates, MV noted that the criteria for the GPhC's work relating to pharmacy technicians had been discussed with pharmacy technician stakeholders over the summer. Stakeholders had agreed with the criteria but also requested more focus on particular pieces of work.

6.4 This was the first update of its kind provided to the Council and the paper also asked for members' feedback. The Council agreed that the paper was useful, particularly to lay members, and provided the right level of detail. Differences between the three countries had been noted, which was helpful. It was suggested that the position of the relevant governments could be included where appropriate.

6.5 Following the discussion, **the Council noted the updates**.

7. Update on Public and Committee Inquiries and other independent reports (23.09.C.05)

7.1 Laura McClintock presented the paper which updated the Council on recent work in connection with public and committee inquiries and other independent reports. These included the UK Covid-19 public inquiry, the Scottish and Welsh Covid-19 Inquiries and the Future of Pharmacy Inquiry, among others.

7.2 The GPhC had given oral evidence to the Public Services Committee on Homecare medicines services and responded to the Committee on Standards in Public Life's request for feedback on artificial intelligence and its use in public life. The paper summarised the relevant responses and also gave an overview of upcoming work.

7.3 Following a brief discussion, **the Council noted the udpate**.

8. Board Assurance Framework Report for 2023/24 Quarter 1 (23.09.C.06)

8.1 Duncan Rudkin introduced the BAF report for Q1 of 2023/24. Four of the seven services covered in the report had met their performance measures the majority of work planned for the quarter had been achieved.

8.2 Three areas had been escalated for Council's attention:

- Information governance performance;
- Fitness to Practise performance; and
- the progress against strategic aim 2, *Deliver effective, consistent and fair regulation*.

8.3 The information governance issue was a reportable data breach which had come about through an isolated human error. The incident had been reported but the Information Commissioner's Office had decided that no action was necessary.

8.4 Capacity to deliver both regulatory responsibilities and an ambitious agenda remained an issue. The organisation had grown as staff were asked to do more and different things and it might be

necessary for the Council to consider, as new pieces of work arose, whether there were things that the organisation could or should stop doing.

8.5 Issues with medicines supply were impacting patients and registrants (via concerns raised with FtP). The GPhC was having discussions on various issues with a number of stakeholders.

8.6 **Following a discussion, the Council noted the Board Assurance Framework report.**

9. Standing Financial Instructions (23.09.C.07)

9.1 Vanessa Clarke presented the updated Standing Financial Instructions (SFIs) which set out the principles and controls underpinning the management of the organisation's finances.

9.2 The SFIs had been reviewed but had only required minor updates. A further review would be carried out in 2024 to take account of upcoming changes, including to the procurement process.

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

10. Committee memberships and Terms of Reference (23.09.C.08)

10.1 Janet Collins presented this paper, which set out the non-statutory committee memberships from September 2023 and reviewed the Terms of Reference (ToRs) of those committees.

10.2 The ToRs of the Audit and Risk, Finance and Planning and Workforce Committees had not been changed. The ToRs of the Quality and Performance Assurance Committee (QPAC) had been updated now that it had been operational for a year. There were minor changes to its functions, to better reflect the reality of the work that the Committee was doing and the number of Council members who could sit on the Committee had been raised to eight. This would be reviewed again in 2024.

10.3 Rima Makarem, Chair of the Committee, noted that this was because the work of the Committee tended to be theme-based, rather than having one specific focus such as finance or audit. All members of the Council were welcome to attend QPAC meetings.

10.4 Following the discussion, **the Council confirmed the committee memberships effective from September 2023 and approved the Terms of Reference for the Audit and Risk, Finance and Planning, Quality and Performance Assurance and Workforce Committees, including the updates to those for the QPAC.**

11. Minutes of the Audit and Risk Committee – public items (23.09.C.09)

11.1 Neil Buckley presented the minutes of the public items discussed at the Audit and Risk Committee meeting on 25 May 2023. He noted that the result of the Health and Safety audit provided the Council with substantial assurance.

11.2 The Council **noted the minutes of the public items of the Audit and Risk Committee meeting held on 25 May 2023.**

12. Any other business

12.1 Further regional roundtables would be held in Birmingham in October and London in December.

12.2 The meeting closed at 3.35 p.m.

Date of next meeting: Thursday 12 October 2023

General Pharmaceutical Council

Council action log – October 2023

	Open and on track
	Overdue
	Rescheduled
	Complete

No.	Status	Minutes	Action	Lead	Update	Due date
8	Open	December 7.6	Further status update on the temporary register to be provided in 12 months	MV		December 2023
9	Open	February	ARC to provide further information to Council on the Committee's assurance of FtP improvement work	JB	Update included in the paper on the PSA report	October 2023

General Pharmaceutical Council

Council workshop summary

Meeting paper for Council on 12 October 2023

Public

Purpose

To provide an outline of the discussions at the Council workshop on 12 September 2023.

Recommendations

The Council is asked to note the discussions from the September 2023 workshop.

1. Introduction

1.1 The Council often holds a workshop session alongside its regular Council meetings. The workshops give Council members the opportunity to:

- interact with and gain insights from staff responsible for delivering regulatory functions and projects;
- receive information on projects during the development stages;
- provide guidance on the direction of travel for workstreams via feedback from group work or plenary discussion; and
- receive training and other updates.

1.2 The workshops are informal discussion sessions to assist the development of the Council's views. A summary of the workshop discussions in presented at the subsequent Council meeting, making the development of work streams more visible to stakeholders. Some confidential items may not be reported on in full

2. September workshop summary

(a) Board effectivenss

2.1 In the first part of the workshop, the Council and executive took part in a Board Effectiveness session.

(b) Strengthening pharmacy governance

2.2 Mark Voce and Annette Ashley presented a session on the developing Standards for Chief Pharmacists.

2.3 The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 and the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.)

Order 2022 mean that the GPhC is required to produce standards for Chief Pharmacists (CPs), Superintendent Pharmacists (SPs) and Responsible Pharmacists (RPs). The standards would provide a framework to enable professional judgement, based on context and risk, and would need to be applicable in different settings and to different models.

2.4 The Department of Health and Social Care would be consulting on supervision in the autumn and any changes to primary legislation could have an impact on the standards for SPs and RPs, so the GPhC would be consulting on the standards for CPs first.

2.5 The extension of defences in relation to dispensing errors to hospitals required that the setting must have a CP with defined responsibilities. The standards would set out the responsibilities and accountabilities of CPs.

2.6 There had been engagement with a wide range of relevant stakeholders and the feedback from those sessions had been coded and analysed to identify the main themes, which had been used in the draft standards.

2.7 The consultation proposals would be brought to Council in November and it was hoped that the consultation would be launched in December.

3. Recommendations

The Council is asked to note the discussions from the September 2023 workshop.

Janet Collins, Senior Governance Manager
General Pharmaceutical Council

22/09/2023

General Pharmaceutical Council

Strategic communications and engagement update: our new approach

Meeting paper for Council on 12 October 2023

Public

Purpose

To update Council on key strategic communications and engagement, including Chair and Chief Executive engagement with external stakeholders, in a new, regular report.

Recommendations

The Council is asked to discuss and note the format and content of this update.

1. Introduction

1.1 Our organisation-wide **Communications and Engagement strategy** (launched in 2022), is designed to develop and improve our approach over the next few years. The strategy includes important aims and objectives around building public and patient voice into our work, driving improvements in patient safety by sharing our data, insights and examples of good practice and producing high-quality and accessible communications.

1.2 To help deliver on these commitments, the Executive Office and Communications team have worked together to develop a new approach to enhancing our strategic communications and impact through regularising and refreshing our approach to external Chair and CEO engagements.

1.3 As part of this work, we have also reviewed with the Chair and CEO our approach to planning and scheduling of their strategic engagement activity. With all of this in mind, we have decided to change our standard communications and engagement update paper to Council; moving away from providing lists of meetings attended by senior staff and instead focussing on sharing key insights and information arising from key Chair and CEO strategic engagements and wider events. This paper is the first update to Council in the new format. It also responds to suggestions from Council about the value of a Chair and CEO report as a regular agenda item.

2. Chair and CEO strategic engagment

2.1 Chair and CEO engagements are designed, amongst other things, to improve our understanding of the external stakeholder environment; influence and mobilise other leaders; exchange ideas to shape strategy and policy; communicate GPhC narrative and key

messages at senior level; raise the profile and visibility of our work; and build relationships, enhancing our reputation and creating strong networks.

2.2 Our Senior Leadership team, and our Director for Scotland and Director for Wales and other colleagues also engage in an extensive ongoing programme of engagement with a wide range of stakeholders. Updates from those meetings will be included as and when relevant, however, the primary focus of this paper going forward will be Chair and CEO strategic engagements.

2.3 Below is a summary of key Chair and CEO engagements and the issues discussed:

Regulatory leaders

2.4 The Chair attended a meeting with the Chairs of the health and care regulators, convened by the PSA. Topics included regulators' strategic priorities, regulatory reform and approaches to addressing fitness to practise backlogs.

2.5 The CEO and Chair continued to meet with other regulatory Chairs and CEOs on an individual basis. Most recently, this included meeting with the GMC where discussions focused on the EEA standstill and EEA Free Trade Agreement, expanding clinical roles in pharmacy, and the relevance of proposed changes to original pack dispensing to dispensing doctors.

2.6 We also facilitated a session between the CEOs of the regulatory bodies and the Centre for Research Equity, to launch a discussion about promoting inclusive clinical research and the role of regulators in this context.

Pharmacy leaders

2.7 The Chair and CEO heard from Pharmacist Support about key issues in the profession (such as high levels of potential burnout), the impact on the charity and other strategic priorities. We are now exploring how the GPhC might help to raise awareness of the support available to members of both pharmacy professions at different points in their careers.

Public and patient leaders

2.8 The CEO met with Janet Williams and Emma Murphy, co-founders of patient group INFACT. We are continuing to work closely with INFACT to help us understand patient experience and to do all we can to remind pharmacy professionals of their responsibilities in ensuring that valproate is dispensed and supplied safely. GPhC also continue to be members of the MHRA's Valproate Stakeholder Network and Valproate Implementation Group.

Parliamentarians and policy makers

2.9 The Chair recently attended the All-Party Parliamentary Group (APPG) on Pharmacy and discussed the challenges and opportunities within the pharmacy sector. In addition, the CEO attended a recent All-Party Parliamentary Health Group (APHG) meeting, chaired by Dr Lisa Cameron MP. The group discussed the current challenges the UK pharmaceutical industry is facing; the role of pharmacy professionals and their patients in clinical trials was a key talking point.

3. Strategic engagement events

3.1 The GPhC delivers an extensive programme of engagement activities. Below is a summary of key strategic engagement events.

3.2 Council members receive invites to attend our strategic engagement events. **Our programme of forthcoming engagement events** is listed on our website.

GPhC Regional roundtables event, Wrexham

3.3 On 4 July 2023 we hosted our second in-person regional event as part of a series of events planned for 2023/24. The Chair and Chief Executive gave opening and closing remarks and participated in table discussions.

3.4 The event created an opportunity for us to hear directly from our stakeholders about the issues and topics that matter to them. It also included a networking element, offering an opportunity for us to meet our stakeholders, and for our stakeholders to meet each other.

3.5 Themes which emerged during the roundtable discussions were wide ranging and included the value and sustainability of pharmacy; workforce pressures; supply issues; leadership in the profession; independent prescribing; and the evolving role of pharmacy technicians.

3.6 Our next regional roundtables events will be on 15 October 2023 in Birmingham and on 6 December in London.

Stakeholder forums

3.7 In Spring 2023 we launched three stakeholder forums as part of our commitment to increasing our engagement with our audiences under our communications and engagement strategy.

3.8 The forums enable us to listen to members' experiences, needs, and views, and to identify insights, intelligence, and issues. The forums facilitate direct two-way conversations about key issues. The forums met in June and September 2023.

Pre-registration Trainee Pharmacy Technician Forum

3.9 At the June meeting we were joined by Nicola Stockmann, Vice-President, Association of Pharmacy Technicians UK.

3.10 Members shared positive experiences of accuracy checking being integrated into training but felt supervisors and registered Pharmacy Technicians were not fully aware of this change.

3.11 Members also shared the wide range of settings and roles they were working and training in and highlighted how they can help take the pressure off pharmacists and that working effectively as a team benefits everyone, including patients and the public.

3.12 Members discussed how new technology is changing the scope of practice. Generally, members felt technology can assist and may free up time but will not replace people. Human oversight will continue to be needed and professionals will still need to apply their judgement when working alongside new technologies.

3.13 The group raised that the process for registering as a pharmacy technician is complex. We have worked with forum members to develop a new step-by-step **guide to registering as a pharmacy technician** which is available on our website and being proactively shared.

3.14 At the September meeting discussions focused on training available for newly qualified pharmacy technicians; revalidation; and raising awareness of the value pharmacy technicians bring to healthcare teams and patients.

Student Voice

3.15 The June meeting discussion focused on communication, with a clear message from members that they would like to have more information from GPhC in the early years of their education and training. Members also wanted to better understand the roles and responsibilities of different organisations in the pharmacy sector. We worked with members, and with sector organisations to create a **Guide to pharmacy organisations**, which we have published on our website and are proactively sharing.

3.16 In September, we were joined by colleagues from Pharmacist Support for a discussion on wellbeing. Members highlighted that the transition from studying to work can be challenging. They also shared that there is some hesitancy about seeking support with mental health challenges because of a concern that this could affect their registration or fitness to practise.

Patient and Public Voice

3.17 At the June meeting members shared their views on the Government announcement of Pharmacy First in England. While generally welcoming the announcement of additional pharmacy services in England, members had questions around how it would work in practice. Members noted that pharmacies are already very busy, and that if can be difficult for patients to know when they should go to a pharmacy and when to a different healthcare service.

3.18 Members also discussed pharmacist prescribing. Generally, members felt that an increase in pharmacist prescribers would be welcomed, enabling people to access more services for minor conditions in a pharmacy. However, people wanted to be reassured that some controls would remain in place. Members shared that new and changing services can be confusing for people, especially those with long term conditions who have got to use to how systems currently work. The public need to understand where to go to get the care they need, and some people may not feel they are able to make that decision themselves. Choice is positive, but too much choice can leave people more confused.

3.19 In September members discussed climate change and pharmacy. We shared our commitment to play our part in addressing climate change as a regulator and as an employer. Members shared their own priorities which included more medication reviews and de-prescribing and better support to help patients switch to more sustainable medicines. As well as wanting to be able to dispose of unused medicines in a safe and sustainable way and to see excess packing of medicines reduced.

Language barriers and health inequalities roundtable, 18 September 2023

3.20 We've recently started to host a series of equality focussed roundtables and events, to help shape our regulatory work, informed by the experiences our stakeholders. This links directly to the commitments in our strategy to help tackle the different types of discrimination within pharmacy and to support an open and inclusive culture where pharmacy teams are empowered to meet their professional and legal obligations.

3.21 This roundtable focused on language barriers and health inequalities for a patient and pharmacy professional perspective. We will also be hosting a second roundtable on Racism in Pharmacy on 10 October 2023.

3.22 Further information will be shared with Council through our regular EDI strategy update in November 2023.

South West Chief Pharmacists conference, 20 September 2023

3.23 The Chief Executive spoke on 'Regulating the changing role of pharmacy' and covered the changing context; GPhC priorities; our continued focus on equality, diversity, and inclusion; education and training reform; pharmacist independent prescribing; assurance of post-registration practice; our focus on pharmacy technicians; and strengthening pharmacy governance.

APTUK conference, 23-23 September 2023

3.24 The Chief Executive gave a keynote address on 'Pharmacy technician regulation: An evolving profession in a changing healthcare landscape', covering the change healthcare context; our guiding criteria for our regulatory approach to pharmacy technicians; pharmacy technician education and training; leadership and development; and strengthening pharmacy governance.

3.25 Attendees responded positively at the conference, engaging with us on our exhibition stand. Social media conversations at and following the conference also welcomed the challenge to pharmacy technicians to explain the value they bring and skills they have, rather than describe the profession by the tasks they do.

Joint webinar on Fitness to Practise myth-busting for pharmacy technicians, 26 September 2023

3.26 We hosted a joint webinar with the Association of Pharmacy Technicians UK about our approach to managing concerns which was attended by pharmacy technicians and pre-registration trainee pharmacy technicians. This is the first a series of joint webinars we are planning.

4. Recommendations

The Council is asked to discuss and note the format and content of this update.

Laura McClintock, Chief of Staff
Laura Turton, Stakeholder Engagement Manager

General Pharmaceutical Council

29/09/2023

General Pharmaceutical Council

Report on the June 2023 Registration Assessment sitting

Meeting paper for Council on 12 October 2023

Public

Purpose

To update the Council on candidate performance in the June 2023 sitting of the Registration Assessment.

Recommendations

The Council is asked to note:

i) the candidate performance data at Appendix 1; and

ii) the Board of Assessors' report to Council at Appendix 2 and the assurance it provides about the June 2023 sitting.

1. Introduction

1.1 Passing the GPhC/PSNI Registration Assessment is a pre-requisite for applying to register as a pharmacist in Great Britain or Northern Ireland. Normally, there are two sittings every year, in Summer and Autumn. This is the GPhC's report on the June 2023 sitting.

1.2 Responsibility for the Registration Assessment is split between the GPhC and the Board of Assessors (the 'Board'). The Board sets and moderates the Registration Assessment and agrees reasonable adjustments for candidates with specific needs; the GPhC is responsible for operational matters and for overseeing the setting and publishing of papers, in collaboration with partner organisations.

1.3 The Board is responsible for the Registration Assessment through delegated authority in the GPhC's Scheme of Delegation.

2. The assessment – candidate performance

2.1 2805 candidates sat the assessment in June 2023 and the pass rate was 76.6%. This is comparable to the pass rates for previous assessments taken in the summer when most candidates sit the assessment at the end of their Foundation training year.

2.2 The candidate data at **Appendix 1** relates to those sitting the assessment for the first time. Those who are unsuccessful have a further two attempts to sit the assessment and the vast majority of candidates are ultimately successful.

2.3 In the year since the June 2022 sitting, we have engaged with three schools whose pass rate was concerningly low. All three have been subject to reaccreditation, all three reaccreditation reports are available publicly on the GPhC's website and a full account of the actions taken will be presented to the Quality and Performance Assurance Committee (QPAC).

2.4 As well as the three schools under close scrutiny already, pass rates for three others – Hertfordshire, Lincoln and Portsmouth – are a cause for concern. We will evaluate their graduates' performance in the November sitting and then take further action to address this.

2.5 At present, data is presented to Council as a snapshot after each sitting. We intend to develop this to produce a more comprehensive report and analysis which details trends over a period of time from sitting to sitting. This will provide a more useful way of identifying whether the interventions we are making are having the desired effect and whether differences in pass rate are part of a more systemic issue. We will also be discussing our overall approach to quality assurance and assessment with Council at the workshop on 12 October.

2.6 Five allegations of misconduct were reported to the GPhC. One candidate admitted misconduct and four chose to proceed to a principal hearing. Two allegations were upheld.

3. Question balance

3.1 The balance of questions was consistent with the requirements of the Registration Assessment Framework.

	June 2023	**Permitted range**
Total % of questions mapped to high weighted areas	65	60–70
Total % of questions mapped to medium weighted areas	25	25–35
Total % of questions mapped to low weighted areas	5	Up to 10

4. Operational considerations

4.1 As was the case in November 2022, there were no significant operational concerns in June 2023. The operations team spent a significant amount of time with our supplier to ensure that the sitting ran to a high standard with no significant issues. Operational preparation for the November 2023 assessment will be discussed at the QPAC meeting on 17 October.

5. Equality and diversity implications

5.1 There remains a disparity with pass rates based on age, ethnicity and the sector in which training is carried out. Our new standards require education providers to provide a breakdown of performance annually based on protected characteristics, with documented action to address differences. The quality management of Foundation training is designed to address inconsistency in the fifth year. This forms part of our aim for interventions and identification of support at earlier stages in the five years of education and training leading up to the assessment.

5.2 Operationally, there are an increasing number of reasonable adjustment requests made by candidates to accommodate specific learning needs. The overwhelming majority of these requests were granted and the necessary adjustments made. The number of requests created some operational challenges, particularly where sole occupancy rooms were requested and we need to review this as part of our ongoing management of the assessment.

6. Communications

6.1 Candidates received all planned communications on time and we have received broadly positive feedback on these.

7. Resource implications

7.1 The sitting was resourced within the allocated budget.

8. Risk implications

8.1 The risks arising from the June 2022 sitting of the registration assessment were mitigated.

9. Recommendations

The Council is asked to note:

i) the candidate performance data at Appendix 1; and
ii) the Board of Assessors' report to Council at Appendix 2 and the assurance it provides about the June 2023 sitting.

Mark Voce, Director of Education and Standards
Damian Day, Head of Education
Sarah Stein, Head of Registration and Customer Services

General Pharmaceutical Council

05/10/2023

Appendix 1

June 2023 Registration Assessment performance breakdown by characteristic[1]

Table 1a: *Overall performance*

		Part 1		Part 2	
		Total marks available	Average mark	Total marks available	Average mark
No. of candidates	Overall Pass Rate %				
2805	76.6	39	77.28	119	74.2

*In a sitting, there are 40 questions in Part 1 and 120 questions in part 2. The Board of Assessors may remove a question on the basis of its performance at the post-assessment stage, if there is statistical evidence to support doing so. In this sitting, the Board of Assessors removed one question from Part 1 and one from Part 2.

Table 1b: *Paper pass marks*

Paper	Number of questions required to pass each part
Part 1	25 (out of 39)
Part 2	77 (out of 119)

To pass the Registration Assessment, both parts must be passed.

The number of questions required to pass each part may vary from paper to paper and year to year depending on the difficulty of questions and papers.

Note that the number of questions required to pass is the standard and the pass rate is the percentage of candidates who met the standard.

[1] Note that all percentages are rounded and that numbers are subject to change marginally as appeals, withdrawals and outcomes of allegations of misconduct are taken into account.

Table 2: *Performance by sitting attempt*

Sitting attempt	No. of candidates	Overall Pass Rate % (rounded)
1st	2353	79.2
2nd	229	49.8
3rd	99	58.6

Note that data in Table 3 onwards are for 1st attempt sitters not the full cohort

Table 3: 1st attempt by sex

			Average % mark	
Sex	**No. of candidates**	**Pass rate %**	**Part 1**	**Part 2**
Male	629	77.74	78.65	74.04
Female	1693	79.74	77.94	75.92

Note: 'Not recorded', 'Other' and 'Prefer not to say' are not recorded here

Table 4: 1st attempt by age range

			Average % mark	
Age Range	**No. of candidates**	**Pass Rate %**	**Part 1**	**Part 2**
36 and over	97	64.95	69.05	71.30
26 - 35	336	66.07	73.47	73.04
25 and under	1920	82.19	79.42	75.64

Table 5: 1st attempt by country of training

			Average % mark	
Country	**No. of candidates**	**Pass Rate %**	**Part 1**	**Part 2**
England	2040	78.82	77.81	74.81
Scotland	211	82.94	80.97	76.61
Wales	102	78.43	78.88	76.33
Northern Ireland data are not available				

Table 6: 1st attempt by sector

			Average % mark	
Sector*	**No. of candidates**	**Pass Rate %**	**Part 1**	**Part 2**
Community	1222	69.64	75.57	71.97
Community/GP	191	72.77	74.01	74.25
Hospital	626	94.73	84.41	79.76
Hospital/GP	157	94.27	82.98	80.00
Multisector	139	81.75	80.42	76.98
Other sectoral combinations have not been reported				

Table 7: 1st attempt by ethnicity (≥ 75 candidates in a category)

			Average % mark	
Ethnicity	**No. of candidates**	**Pass Rate %**	**Part 1**	**Part 2**
Arab	137	75.91	76.25	74.54
Asian or Asian British - Bangladeshi	89	76.40	77.53	74.23
Asian or Asian British - Chinese	126	90.48	85.90	78.20
Asian or Asian British - Indian	279	79.2	77.81	74.07
Asian or Asian British - Other	141	75.1	76.70	72.89
Asian or Asian British - Pakistani	391	74.6	75.84	73.48
Black or Black British - African	312	66.99	71.47	72.23
Prefer not to say	90	65.50	73.50	71.34
White - British	533	89.6	84.06	79.08
White - Other	109	85.3	78.08	71.12

Table 9: MPharm degree 1st attempt by School of Pharmacy (≥ 15 candidates)

			Average %	
School of Pharmacy*	**No. of candidates**	**Pass Rate %**	**Part 1**	**Part 2**
Aston University	121	77.69	77.24	73.61
University of Bath	55	96.36	82.42	78.59
University of Birmingham	55	92.73	86.29	79.40
University of Bradford (4-year continuous degree)	24	87.50	77.56	78.99
University of Bradford (5-year sandwich degree)	28	85.71	75.18	76.62
University of Brighton	91	72.53	74.33	73.07
Cardiff University	113	87.61	82.26	77.79
University of Central Lancashire	58	55.17	68.66	70.23
De Montfort University	84	63.10	73.26	69.24
University of East Anglia (4-year continuous degree)	52	84.26	78.90	73.45
University of Hertfordshire	67	59.70	69.50	69.53
University of Huddersfield	77	83.12	75.86	74.79
Keele University	87	64.37	74.54	71.85
King's College London	106	82.08	79.39	73.16
Kingston University	55	89.09	79.53	75.91
Liverpool John Moores University	86	81.40	77.49	74.64
University of Lincoln	30	50	70.43	70.50
University of Manchester	99	89.90	82.41	78.32
Medway School of Pharmacy (universities of Greenwich and Kent)	61	67.21	73.21	73.05
University of Newcastle	62	91.94	82.42	79.70
University of Nottingham (4-year continuous degree)	161	91.30	84.34	79.54

University of Portsmouth	64	57.81	73.07	69.54
University of Reading	80	70.10	74.71	72.95
The Robert Gordon University	80	75.00	79.49	74.50
University of Strathclyde	115	85.22	81.52	77.01
University of Sunderland	65	85.16	78.97	79.74
University of Sussex	18	77.78	78.35	75.30
University College London	116	85.34	83.24	76.99
University of Wolverhampton	67	65.67	73.75	71.49

General Pharmaceutical Council

Pharmaceutical Society NI
Protecting Registering Regulating

Report on the June 2023 Registration Assessment sitting from the Board of Assessors

1. Introduction

1.1 The initial education and training of pharmacists leading to eligibility to register in Great Britain (GB) and/or Northern Ireland (NI) is:

- passing a four-year MPharm degree accredited by the GPhC/PSNI; then
- passing 52 weeks of foundation training; and
- passing the GPhC/PSNI Registration Assessment (hereafter the Registration Assessment[1]).

or

- passing a five-year MPharm degree, with integrated foundation training, accredited by the GPhC; and
- passing the Registration Assessment.

or

- passing a five-year MPharm degree, with a preparatory year, accredited by the GPhC; then
- passing 52 weeks of foundation training; and
- passing the Registration Assessment.

or

- passing a one-year Overseas Pharmacists' Assessment Programme (OSPAP) accredited by the GPhC; then
- passing 52 weeks of foundation training; and
- passing the Registration Assessment.

1.2 During foundation training, trainees are signed-off on four occasions by a designated pharmacist supervisor (in GB) or Educational Supervisor (in NI). To be eligible to sit the Registration Assessment in NI candidates must have completed 45 weeks of training successfully – this is a legal requirement. In GB and NI trainees must have been signed off as 'satisfactory' at 39 weeks to be eligible to sit.

[1] Alternatively called the Common Registration Assessment.

1.3 The Registration Assessment is a computer-based examination with two papers - Part 1 and Part 2. It is based on the Registration Assessment Framework, which covers:

- the outcomes to be assessed;
- the weighting - that is, the number of questions in three categories of practice: high relevance, medium relevance & low relevance;
- therapeutic areas which can be assessed;
- high risk drugs which can be assessed;
- paediatric issues which can be assessed and the proportion of paediatric questions in papers; and
- the types of pharmaceutical calculations to be assessed.

1.4 *Part 1*: Part 1 is two hours long (120 minutes) and comprises 40 calculations questions with free text responses. Approved models of calculators are permitted in Part 1, as are on-screen calculators.

1.5 *Part 2*: Part 2 is two and a half hours long (150 minutes) and comprises 120 questions: 90 are single best answer questions (SBAs) and 30 are extended matching questions (EMQs). Calculators are not permitted in Part 2 because, from a numerical perspective, the questions in that part test general number sense and calculators are therefore not required.

1.6 Candidates with a recognised and documented disability are able to apply for a reasonable adjustment to be made in the conduct of the Registration Assessment.

2. Reporting to the councils

2.1 Normally, there are two sittings of the Registration Assessment every year, in June/July and September/November, and the Board of Assessors reports to the GPhC and PSNI councils after each one. This is the Board's summary report for June 2023.

3. June 2023 summary statistics

Candidate categories	Candidate numbers – June 2023	% of total candidates – June 2023	% of total candidates – June 2022 (for comparison)
Total number of candidates	2805	100%	100%
First sitting candidates	2353	83.9%	78.52%
Second sitting candidates	229	8.2%	6.97%
Third sitting candidates	99	3.5%	4.41%
Note: NI sitting data are not included which is why the three sitting percentages do not equal 100%			

Candidate performance – pass rates	Number of passes	% pass rate
Overall pass	2150	76.7%
Overall fail	655	23.3%
First sitting candidates	1863	79.2%
Second sitting candidates	114	49.8%
Third sitting candidates	58	58.6%
England	1767	75.2%
Scotland	185	82.2%
Wales	106	78.3%
Note: All data are rounded and do change over time as appeals and nullifications are taken into account.		

4. Paper and question analysis

Question performance

4.1 A set of example questions was made available to candidates. Both live and example questions are written by the same group of question writers, to the same standard using the same style guide All the example questions have been used previously in recent assessment sittings or are similar to questions that have been used.

4.2 Overall, questions performed well in both parts but two were removed – one due to ambiguity and one due to its difficulty which, having analysed candidate performance, was judged to be too difficult. The pass mark for both parts was recalculated on that basis.

5. Passing standard

5.1 The methodology used for deriving the pass standard for June 2023 was the same as for recent sittings. First, the Board analyses the suitability and performance of questions based on its professional expertise in pharmacy practice and healthcare education. Then the Board uses Item Response Theory (IRT), an established statistical method, to corroborate and confirm its professional analysis.

5.2 *Pass requirements*: In order to pass the Registration Assessment, both Part 1 and Part 2 must be passed in the same sitting. There are no exceptions, on the basis that on any given day in practice a pharmacist must be both numerate and able to apply relevant clinical knowledge.

6. Feedback to candidates

6.1 Feedback to candidates is issued separately by the Board and will be posted on the GPhC's website,

7. Delivery of the Assessment

7.1 The Board was pleased to note that as was the case in November 2022, the Assessment was delivered to a high standard and wishes to record its view that previous delivery issues have been resolved. Also, it notes that having members of the GPhC's operations team at its meetings are welcome. Their first-hand experience of delivering the Assessment, and the opportunity to discuss operational matters with them, is appreciated by and reassuring for the Board.

8. Psychometrics (statistics relating to candidate performance)

8.1 The Board wishes to record its continuing appreciation for the support provided by AlphaPlus, the GPhC's psychometricians, who were able to reassure the Board that the pass/fail marks were true and accurate.

9. 2023 sittings

9.1 An overview report of both 2023 sittings will be presented to Council later in 2023.

Dr Mat Smith, Acting Chair, on behalf of the Board of Assessors
5th October 2023

General Pharmaceutical Council

Professional Standards Authority: annual performance review 2022/23

Meeting paper for Council on 12 October 2023

Public

Purpose

To present the outcome of the annual performance review

Recommendations

The Council is asked to note the outcome of the 2022/23 performance review

1. Introduction

1.1 The Professional Standards Authority (PSA) carries out an annual performance review of each of the ten health and social care regulators, assessing their performance against the Standards of Good Regulation.

1.2 This report looks at the GPhC's performance during the period July 2022 to June 2023. This was a fuller review than that which took place in 2021/22, as it was a 'periodic review' (carried out every three years, with 'monitoring reviews' inbetween).

1.3 The Standards of Good Regulation against which performance reviews are carried out include general standards relating to information provision, the application of policies, EDI, performance reporting, corporate complaints, how we address learning from public enquiries and other relevant reports. The standards also cover registration, education, fitness to practise (FtP) and standards/guidance.

1.4 The PSA's report is attached as **Appendix 1**.

2. Key findings

2.1 The PSA concluded that the GPhC met all but one of the Standards of Good Regulation.

2.2 All of the general standards were met, as were all standards relating to guidance and standards; education and training; and registration. Four out of the five standards for Fitness to Practise (FtP) were met, while one was not. More detail is set out below.

General Standards

2.3 Under Standard 3, on our work on EDI, the PSA noted that "the volume and breadth of the GPhC's work in this area this year has been impressive" and suggested that our work to

improve the diversity of the Council could be helpful to other regulators (see page 4 of the report).

2.4 We were also pleased to note that the PSA acknowledged that we have engaged a broad range of stakeholders in our work, that we are building collaborative working arrangements and that stakeholder feedback to the PSA had been largely positive (pages 6 and 7).

Education and Training

2.5 The PSA has indicated that it is content with actions taken in response to the lessons learned from the June 2022 sitting of the registration assessment and has noted the work being done with universities with lower pass rates (page 11). The report also noted the largely positive feedback on the new accreditation process.

Fitness to Practise

2.6 In recent years, we have not met Standards 15, 16 and 18. The PSA has previously identified concerns in relation to the transparency and clarity of the intitial assessment and investigation process, decision-making, support for the parties involved and the documenting of risk assessments and timeliness.

2.7 Staff in FtP and across the organisation have worked hard to improve performance in this vital area, with oversight from the Council, its committees and an internal FtP Standards Board.

2.8 This year, we have regained Standards 16 and 18, in relation to decision-making and support for the parties involved in a case respectively.

2.9 In relation to Standard 16, the PSA notes that the audit carried out in 2022/23 demonstrated that we have addressed their previous concerns about decision-making at the intial assessment and investigation stages of the FtP process and that the new initial assessment guidance has been implemented well (pages 19 and 20).

2.10 It is also worth noting that the PSA had no concerns about the decisions of the Fitness to Practise Committees in 2022/23 and did not appeal any decisions.

2.11 In relation to Standard 18, the PSA noted improvements in the support provided to the parties involved in a case, including “good examples of tailored and compassionate communication” (page 22).

Fitness to Practise - timeliness

2.12 The most significant adverse point in this latest PSA report is their finding that we have again failed to meet Standard 15, with their concerns under this heading relating principally to timeliness. In line with their escalation protocol, the PSA wrote to the Secretary of State and the Chair of the UK Parliament Health and Social Care Committee. We wrote to them ourselves to re-affirm the Council’s commitment to progressing cases in a timely fashion and to highlight the comprehensive action plan we are delivering in order to achieve this outcome. Copies of the relevant correspondence have been circulated by email.

2.13 Council continues to scrutinise our FTP performance regularly, complemented by the more detailed oversight of the Audit and Risk Committee. The Committee considered these matters again at its most recent meeting, in September. The issue was raised in the Chief Executive’s report to the Committee, and in a report from the interim Director, which covered: encouraging aspects of recent performance; an update on our “Operation Resolve”

workstreams; our new cases action team; our aged cases project; steps taken to widen the pool of both decision-makers and administrative support, drawing on the wider resources of the organisation; and our plans for a significant surge in hearings activity in the first months of 2024. The completion of the work identified in the End to End review and our ongoing focus on *people*, *process* and *technology* were also addressed.

2.14 The Audit and Risk Committee identified the need for further detailed analysis of the trajectory towards achieving timeliness, which will be reviewed by the Committee at an additional meeting before December. That work will in turn inform Council's ongoing scrutiny of our progress.

3. Equality and diversity implications

3.1 The standard relating to EDI ('The regulator understands the diversity of its registrants and their patients and service users and of those who interact with the regulator and ensures that its processes do not impose inappropriate barriers or otherwise disadvantage people with protected characteristics') was met.

3.2 The PSA has reviewed its approach to assessing this standard and the criteria required to meet it will change as a result. We took an active part in the discussions between the regulators and the PSA and will work to ensure that we continue to meet this standard.

4. Communications

4.1 The report has been published on the GPhC and PSA websites.

5. Resource implications

5.1 As this was a full periodic review it required considerable staff resource, particularly in supporting the audit of Fitness to Practise. However, the revised review process (which involves the PSA taking more information from regular data, scrutiny of our website, attendance at Council meetings and holding regular meetings with the Executive) has reduced the resource required at the end of the review period.

5.2 The resources required to work with the PSA on audits and performance reviews are factored into our annual planning.

6. Risk implications

6.1 The PSA report provides constructive feedback on the GPhC's performance and it is important that we respond to it in order to improve the way we regulate, for the benefit of patients, the public and the profession. Previous feedback and action plans developed in response have already helped us to regain two of the Standards.

6.2 The continued implementation of the FtP action plan, the strategy for managing concerns and the outputs of the end-to-end review of the FtP process will allow us to build on the continuing improvement which the PSA has noted.

6.3 We remain confident in our ability to take swift effective action where risk of harm is elevated. The PSA are satisfied that we continue to apply promptly for interim orders once we receive information indicating the need for one. We are assured that the issues relating to timeliness do not represent a risk to patient and public safety.

6.4 The Audit and Risk Committee is monitoring progress and taking an assurance role, as set out above.

7. Monitoring and review

7.1 We monitor progress and developments in all areas of performance and Council will continue to receive regular information via the Board Assurance Framework. Further assurance about aspects of organisational performance comes from the audits which are carried out across the business and reported to the ARC.

7.2 The next PSA performance review cycle started in July of this year and the report should be completed before the end of September 2024.

8. Recommendations

The Council is asked to note the outcome of the 2022/23 performance review

Janet Collins, Senior Governance Manager

Duncan Rudkin, Chief Executive and Registrar
General Pharmaceutical Council

04/10/2023

professional standards authority

General Pharmaceutical Council

Performance Review

Periodic review 2022/23

General Pharmaceutical Council

Performance review report 2022/23

Contents

About our performance reviews

We have a statutory duty to report annually to Parliament on the performance of the 10 regulators we oversee. We do this by reviewing each regulator's performance against our Standards of Good Regulation and reporting what we find. Our performance reviews are carried out on a three-year cycle; every three years, we carry out a more intensive 'periodic review' and in the other two years we monitor performance and produce shorter monitoring reports. Find out more about our performance review process on our website. This is a periodic review report on the General Pharmaceutical Council (GPhC) and covers 1 July 2022 to 30 June 2023.

About the GPhC

The GPhC regulates the practice of pharmacists, pharmacy technicians and registered pharmacies in Great Britain. It has 62,654 pharmacists, 25,555 pharmacy technicians and 13,577 registered pharmacies on its register (as at 30 June 2023).

About the GPhC's performance for 2022/23

Our review this year included an audit which is relevant to Standards 15,16, 17 and 18. The GPhC met 17 out of 18 of our Standards of Good Regulation. These Standards provide the benchmark against which we review performance. Meeting or not meeting a Standard is not the full narrative about how a regulator is performing. Our report provides more detail about the GPhC's performance this year.

Standards of Good Regulation met 2022/23

General Standards	5 out of 5
Guidance and Standards	2 out of 2
Education and Training	2 out of 2
Registration	4 out of 4
Fitness to Practise	4 out of 5
Total met	**17 out of 18**

Standards met 2020-22

2021/22	15 out of 18
2020/21	15 out of 18

Key findings

Fitness to practise timeliness

We have had concerns about the time it takes the GPhC to deal with fitness to practise cases in recent years. The position has not improved this year. Although the GPhC is taking steps to improve its performance, it is still taking too long to progress cases through the system, and the number of open older cases has increased. Due to the serious and ongoing delays we have concluded that Standard 15 is not met. As this is the fifth year in a row that the GPhC has not met our Standard for timeliness in fitness to practise, we have taken action under our escalation policy. We have written to the Secretary of State for Health and Social Care and the Health and Social Care Committee to raise our concerns and we will monitor the GPhC's work to improve its performance in this area.

Fitness to practise decisions

We carried out an audit of Standard 16 this year. We found the large proportion of decisions we reviewed were reasonable, with clear, accurate and detailed reasons recorded. We only saw a small number of issues in relation to decisions and were reassured to see that the GPhC has implemented learning when issues arise. We are satisfied that the GPhC has addressed the concerns we have previously raised, and we are pleased to report that it has met Standard 16 this year.

Fitness to practise support to parties

We also carried out an audit of Standard 18 this year. The GPhC has been working to address the concerns we have previously raised and introduced a number of measures to improve the support it offers to parties during the fitness to practise process. We saw good examples of tailored and compassionate communication, notably to complainants with supportive tone of voice. The GPhC has therefore met Standard 18 this year.

General Standards

1 The regulator provides accurate, fully accessible information about its registrants, regulatory requirements, guidance, processes and decisions.

1.1 The GPhC's website contains all the information we would expect to see covering its regulatory functions. It has a built-in accessibility tool which offers a range of functions, including text-to-speech, adjustable font size, different colour schemes, language translation (including Welsh) and dyslexia software. The GPhC is also developing a new website which is set to launch towards the end of the year.

1.2 The GPhC continues to publish information about its role, regulatory requirements, guidance, and activities. In August 2022 the GPhC updated its Guide to Information[1] document. This sets out the information the GPhC makes routinely available to meet its commitments under the Model Publication Scheme for Health Regulators and includes helpful links under each heading and relevant statutory function.

Conclusion

The GPhC continues to provide information about its registrants, regulatory requirements, guidance, processes and decisions which is accurate and accessible. We are satisfied that this Standard is met.

2 The regulator is clear about its purpose and ensures that its policies are applied appropriately across all its functions and that relevant learning from one area is applied to others.

2.1 The GPhC continues to progress delivery of its Strategic Plan for 2020-2025 (the Plan), the first of two five-year plans to help it achieve its Vision 2030. In February 2023, Council approved an updated Strategic Plan for year four onwards, including:

- a new programme of work 'to review what we register, the basis of registration and the information we collect and use at registration and renewal'
- work to strengthen pharmacy governance, discussed further under Standard 6 below.

We will monitor progress of these significant pieces of work over the coming years.

[1] Guide to Information - August 2022

2.2 We have seen the GPhC applying learning appropriately this year – for example in taking action to tackle issues around online pharmacies based on intelligence from its inspection work and analysis of its fitness to practise data.

Conclusion

The GPhC has not changed any processes relevant to this Standard this year. It is clear about its purpose, and we continue to see examples of it applying learning from one function to another. We are satisfied that this Standard is met.

3 The regulator understands the diversity of its registrants and their patients and service users and of others who interact with the regulator and ensures that its processes do not impose inappropriate barriers or otherwise disadvantage people with protected characteristics.

3.1 The GPhC has made good progress delivering its five-year Equality Diversity and Inclusion (EDI) strategy 2021-2026.[2] Examples of the work it completed this year include:

- launching new equality guidance for pharmacies which is designed to help tackle discrimination and is designed to support pharmacy owners to fulfil their legal and regulatory duties in relation to equality
- updating its hearings and outcomes guidance for fitness to practise committees to address how decision- makers should consider concerns about discrimination, and how to take account of cultural factors when deciding on an outcome
- holding a roundtable event with stakeholders about racism in pharmacy and publishing a report summarising the discussions and setting out next steps for action.

The GPhC also:

- began to accredit universities to its new initial education and training standards (due to be fully implemented by 2026), which includes strengthened requirements on EDI
- started work on minimising discrimination and bias in fitness to practise decision-making, including looking at how to handle allegations of discrimination in concerns raised about pharmacy professionals. This includes a project on anonymised decision-making at the Investigating Committee. The GPhC expects to analyse and review its findings from January 2024.

[2]Launched in November 2021: https://www.pharmacyregulation.org/sites/default/files/document/gphc-equality-diversity-inclusion-strategy-november-2021.pdf

EDI data

3.2 The GPhC holds a reasonable amount of data on the diversity of its registrants. There are some protected characteristics – such as sexual orientation – for which it holds relatively low levels of data, but we have seen some improvement this year. Part of the GPhC's EDI strategy is aimed at improving the diversity data it collects and the ways it is used; it plans to routinely publish data on pharmacists and pharmacy technicians annually.

3.3 The GPhC also published an article about the work it has carried out to improve the diversity of Council in recent years.[3] By 2022, just under 65% of Council members were female and 36% were from ethnic minority backgrounds, compared to 43% and 15% respectively in 2018/19. The article includes a list of practical actions the GPhC took, which other regulators may find helpful.

Conclusion

The volume and breadth of the GPhC's work in this area this year has been impressive, and it is encouraging that the GPhC recognises and acknowledges that there are a range of issues it still needs to address. We are satisfied that this Standard is met.

4 The regulator reports on its performance and addresses concerns identified about it and considers the implications for it of findings of public inquiries and other relevant reports about healthcare regulatory issues.

4.1 The GPhC regularly reports on its performance in a variety of ways, including its annual report and through operational updates at its Council meetings. The GPhC has also been working on some changes to the way that its operational performance is reported to Council and has implemented a Board Assurance Framework model.

4.2 The GPhC proactively seeks feedback about its performance, identifies learning and acts on feedback received. For example, it implemented lessons learned from its review of the problems that arose with the June 2022 registration assessment, discussed further under Standard 9 below.

4.3 In December 2022, following publication of our *Safer care for all* report, the GPhC outlined the key actions it will be working towards including:

[3] GPhC case study: Improving diversity in senior pharmacy professional leadership (pharmacyregulation.org)

- examining differential attainment of graduates from certain backgrounds and working with universities with a pattern of lower pass rates in the GPhC registration assessment
- working with employers to help them understand when cases should be referred
- taking action where concerns are raised about discriminatory behaviour by pharmacy professionals, supporting people to make non-discriminatory regulatory decisions, seeking to remove unconscious bias in decision-making and supporting people who share particular protected characteristics such as mental health problems through the process.

Conclusion

There are clear examples of the GPhC taking action to address concerns identified about it and it continues to monitor and act on reports about healthcare regulatory issues, including our *Safer care for all* report. We are satisfied that this Standard is met.

5 The regulator consults and works with all relevant stakeholders across all its functions to identify and manage risks to the public in respect of its registrants.

5.1 We have seen evidence that the GPhC takes a transparent approach to consultation, including reporting the feedback received and actions to be taken, and engages a broad range of stakeholders. This year, the GPhC held consultations on:

- proposed changes to fees
- equality guidance for premises
- hearings and outcomes guidance.

5.2 From mid-January 2023 the GPhC also carried out targeted pre-consultation engagement with the pharmacy and health sector, and patients and the public, to discuss the requirements and expectations around the roles of Chief Pharmacists, Responsible Pharmacists and Superintendent Pharmacists. The GPhC plans to hold a full public consultation later in the year.

5.3 The GPhC continued to work with professional bodies, education providers, advisory groups and others on a range of issues. We received largely positive feedback from stakeholders about the engagement they had with the GPhC.

What we heard from stakeholders

"Our experience has been generally positive and we are regularly provided with an opportunity to interface with them and to attend meetings. Regular communication has continued throughout 22/23 with GPhC representatives in Wales, with monthly meetings

arranged and attended. This allows for early discussion of potential issues and communication to the contractor network."

"The GPhC continued to contribute its expertise in education and training quality strategy, as well as wider work on capturing learner insights through the National Education and Training Survey. They have provided constructive suggestions, and shared information. The GPhC continues to deliver its key function of promoting professional standards and maintaining public confidence in the professions. The GPhC does this with the involvement of stakeholders from across the system and with regard to the wider context and the drivers for educational reform."

"Overall, the GPhC has been open in hearing [our] views and my colleagues have good working relationships with individuals within the GPhC. On behalf of our members, we appreciate their willingness to engage. On occasion this has led to the GPhC following through on [our] suggestions."

"The GPhC is currently much more approachable, willing to listen to concerns and issues raised, and take steps to address issues where possible."

"There is a monthly opportunity to meet with the Scottish Director of the GPhC, and this provides a welcome opportunity to discuss areas of shared interest. This regular contact is incredibly helpful with a two-way dialogue on hot topics and key regulatory issues."

Conclusion

Overall, the feedback we have received suggests that the GPhC has worked hard to develop relationships with its stakeholders and build collaborative working arrangements. Its stakeholders have provided clear examples of the GPhC working collaboratively with them and listening and responding when concerns are raised. We are satisfied that this Standard is met.

Guidance and Standards

6 The regulator maintains up-to-date standards for registrants which are kept under review and prioritise patient and service user centred care and safety.

6.1 The GPhC used a Council workshop in April 2023 to examine whether its current standards for registered pharmacists and pharmacies – which were last revised in 2018 – were still fit for purpose. It considered evidence from various sources

including pharmacy inspections, fitness to practise, and anecdotal sector knowledge, and reviewed whether the existing standards were sufficiently up to date and effective in three real-life contexts. The GPhC concluded that it was able to adapt its standards and guidance to meet emerging issues should the need arise. We have seen no evidence to suggest the current standards are out of date, and the GPhC has taken steps to assure itself they remain fit for purpose.

6.2 One stakeholder raised concerns regarding pharmacy automation and the use of so-called artificial intelligence by certain pharmacy owners, specifically around the growing use of 'advance clinical checking'[4] of dispensing of repeat medication. In response, the GPhC explained that these issues are not just a matter for the regulator but are under the remit of many organisations and linked to several key pieces of work underway both within the GPhC and externally by others, including the Department of Health and Social Care. The GPhC said it continues to engage with a wide variety of stakeholders in relation to such issues and is looking at the sector coming together to "work on developing quality/industry kitemark-type standards to help fill a gap in the more operational space of the running of online pharmacies - an area of service provision subject to a fast pace of change and growth, but one which is also immature and not without some quality concerns."

6.3 New legislative orders, which commenced on 1 December 2022, gave the GPhC powers to outline in rules the essential roles and responsibilities of Responsible Pharmacists and to set professional standards for Responsible Pharmacists, Superintendent Pharmacists and Chief Pharmacists. The GPhC has carried out pre-consultation work to discuss the requirements and expectations around these roles and will be taking this work forward starting with a formal consultation later in the year.

Conclusion

We are satisfied that the GPhC is keeping its standards under review and that it is taking emerging risks into account as part of this work. We encourage the GPhC to work constructively with stakeholders on the risks and opportunities raised by pharmacy automation and will be monitoring progress. We will also continue to monitor how the GPhC works to develop rules and standards for Responsible Pharmacists, Superintendent Pharmacists and Chief Pharmacists. We are satisfied that this Standard is met.

[4] The performance of a single initial clinical check on an NHS repeat prescription to cover multiple repeat supplies issued on future dates.

7 The regulator provides guidance to help registrants apply the standards and ensures this guidance is up to date, addresses emerging areas of risk, and prioritises patient and service user centred care and safety.

7.1 The GPhC publishes a range of guidance and resources for registrants. It continues to review and revise its existing guidance to ensure it is up to date and fit for purpose. This year, it published:

- new equalities guidance for pharmacies[5]
- new guidance on standards for education and training of pharmacist independent prescribing[6]
- guidance on the initial assessment of incoming concerns in fitness to practise cases cases[7]
- guiding criteria to inform its approach to the regulation of pharmacy technicians.

7.2 The GPhC has continued to use its website, e-newsletter and social media channels to provide information and guidance for registrants on a range of issues, such as risks relating to online services.[8] It has also published examples of notable practice on its inspections website, such as encouraging team members to act openly and honestly in accordance with the duty of candour.[9]

Conclusion

The GPhC continues to provide registrants with guidance on emerging areas of risk, such as online pharmacy services. We are satisfied that this Standard is met.

Education and Training

8 The regulator maintains up-to-date standards for education and training which are kept under review, and prioritise patient and service user centred care and safety.

8.1 As we reported in our 2021/22 performance review, the GPhC launched its new *Standards for the initial education and training of pharmacists* in January 2021,

[5] https://www.pharmacyregulation.org/news/gphc-publishes-new-equality-guidance-pharmacies
[6] https://www.pharmacyregulation.org/news/gphc-council-agrees-new-guidance-entry-independent-prescribing-courses
[7] https://www.pharmacyregulation.org/news/gphc-publishes-guidance-initial-assessment-incoming-concerns
[8] https://www.pharmacyregulation.org/news/gphc-issues-advice-pharmacists-and-owners-about-risks-relating-online-services
[9] https://inspections.pharmacyregulation.org/knowledge-hub

and also introduced an interim set of learning outcomes for the new pharmacist Foundation Training Year in July 2021. The GPhC is working with stakeholders from across the UK[10] to support the phased implementation of the new Standards which will come into full effect in 2025-26, including hosting regular meetings of an Advisory Group of stakeholders.

What we heard from stakeholders

"[We] have provided representatives to all Advisory Group meetings and welcomed the opportunity to feed collaboratively into discussions exploring key elements of reform."

"The GPhC has recognised the challenges faced by Schools of Pharmacy in implementing the new standards in the required timeframe, with the GPhC Initial Education and Training of Pharmacists Advisory Group acting as a forum for stakeholders to raise concerns. The GPhC has shown a willingness to involve all stakeholders in discussions and recognises it needs to improve communication with stakeholders. It is willing to listen to concerns of stakeholders and take proportionate action to alleviate concerns where this is possible."

8.2 In May 2022, GPhC Council agreed changes to the *Standards for the education and training of pharmacist independent prescribers* following a public consultation. The principal change was to amend the requirements for entry to an accredited independent prescribing course, taking effect from 1 October 2022. The GPhC produced guidance to support education providers as they design courses to meet the new standards.

Conclusion

The GPhC continues to implement reforms to the education and training of pharmacists. It is working closely with stakeholders to make sure areas of risk are identified and addressed. We are satisfied that this Standard is met.

[10] Although the GPhC does not regulate pharmacists in Northern Ireland, it works with the PSNI in the area of education and training. The PSNI adopts the GPhC's education and training standards and the two regulators carry out joint accreditation visits in Northern Ireland.

9 The regulator has a proportionate and transparent mechanism for assuring itself that the educational providers and programmes it oversees are delivering students and trainees that meet the regulator's requirements for registration, and takes action where its assurance activities identify concerns either about training or wider patient safety concerns.

9.1 As we noted in our report last year, we were concerned by the delays and other problems faced by candidates at six test centres at the June 2022 registration assessment. We were satisfied with the immediate steps the GPhC took to deal with the delays and prevent similar problems. Since then, the GPhC has introduced a number of further measures, and successfully completed the November 2022 and June 2023 sittings without similar issues occurring.

9.2 After each sitting of the registration assessment, the GPhC publishes an analysis of candidate performance by various categories, including schools of pharmacy and protected characteristics. The GPhC uses this analysis to identify concerns about education and training. This year's data show ongoing concerns in two separate areas. The GPhC is taking the following action and we will be monitoring this activity:

- There continues to be differential attainment based on ethnicity, sector of training (hospital versus community) and age. As part of its work to address this, the GPhC's new *Standards of education and training for pharmacists* include stronger EDI requirements and EDI has been made a focus of interim accreditation visits. The GPhC is also exploring what else it can do to further understand differential attainment and the causal or contributing factors.
- The GPhC has noted that three schools of pharmacy have had lower pass rates than other institutions. The GPhC has asked them to provide action plans and indicated that it aims to see improvements from all three in relation to pass rates. All three schools of pharmacy are also seeking reaccreditation to the new initial education and training standards. Once the accreditation has taken place the GPhC will prepare a report setting out any recommendations or conditions on the school's accreditation.

9.3 The GPhC has continued to reaccredit MPharm degrees to its new *Standards for the initial education and training of pharmacists*. The process for reaccreditation to the revised standards began on 1 October 2021, with higher education institutions receiving a reaccreditation event in a staggered arrangement between the 2021/22 and 2023/24 academic years. Schools of Pharmacy that have been through the new process have provided us with generally positive feedback, although we did receive some concerns about the consistency and amount of paperwork involved in accreditation visits. Stakeholders have said that the GPhC has shown a willingness to listen to concerns and take proportionate action as appropriate.

What we heard from stakeholders

"The new accreditation process is generally viewed as being more relaxed with a more engaging and discursive tone, adopting a collaborative and collegiate approach with more relevant questioning, and being supportive and constructive and much less confrontational than the previous accreditation process."

Conclusion

The GPhC has transparent and proportionate processes for approving and quality assuring education programmes. The GPhC has also taken a number of steps to reduce the risk of delays and other problems at its registration assessments. We are satisfied that this Standard is met.

Registration

10 The regulator maintains and publishes an accurate register of those who meet its requirements including any restrictions on their practice.

10.1 The GPhC did not make any changes to the way it maintains or publishes its register this year. It has kept its temporary register open for another two years following a request by government to the regulators.

10.2 We checked the register entries for cases where there had been a fitness to practise hearing between July 2022 and June 2023. All entries were as expected and we identified no concerns.

10.3 One stakeholder raised concerns around the level of detail and information on the GPhC's register.

What we heard from stakeholders

"The GPhC appears to lack sufficient data and clarity to be able to reliably tell how many of the pharmacies on its register are also offering prescribing services, and how many are offering these prescribing services online... There is more to be done to capture the data on those pharmacies that provide prescribing services so that appropriate and proportionate inspection and regulation can be put in place."

10.4 The GPhC responded to this concern by explaining that its current Strategic Plan includes 'reviewing what we register, the basis of registration and the information we collect and use at registration and renewal… for 2023-25. This will be a significant part of adopting a regulatory approach that is increasingly informed by intelligence and exploring what a more strategic approach to pharmacy regulation could look like.' We have not seen evidence that not holding this data is a risk to public protection, however we will monitor any emerging risks and look to see what steps the GPhC plans to take in this area.

Conclusion

We have seen evidence that the GPhC maintains and publishes an accurate register of those who meet its requirements including any restrictions on their practice. We are satisfied that this Standard is met.

11 The process for registration, including appeals, operates proportionately, fairly and efficiently, with decisions clearly explained.

11.1 The GPhC has not made any substantial changes to its registration processes for pharmacy professionals or pharmacy premises.

11.2 The GPhC continues to process applications for registration efficiently; the median time taken remains less than one week for both UK and international graduates.

Conclusion

We have no concerns about the GPhC's registration processes and are satisfied that this Standard is met.

12 Risk of harm to the public and of damage to public confidence in the profession related to non-registrants using a protected title or undertaking a protected act is managed in a proportionate and risk-based manner.

12.1 The GPhC process for managing protection of title cases is unchanged since last year. Its website continues to provide information about its protection and misuse of title function, including the designated titles that are protected by law, and how people can raise a complaint.

12.2 The GPhC takes action to manage risks resulting from non-registrants using a protected title. It received a total of 22 potential illegal practice or use of restricted title cases between July 2022 and June 2023 with the median time taken to close these concerns being 25 weeks. The GPhC is dealing with these cases in a timely manner.

Conclusion

We are satisfied that this Standard is met.

13 The regulator has proportionate requirements to satisfy itself that registrants continue to be fit to practise.

13.1 The GPhC re-introduced full revalidation requirements for pharmacy professionals in October 2022 following a reduced revalidation process in response to the pandemic. The GPhC intends to review its revalidation standards and requirements on an annual basis and make any subsequent updates from 1 January 2024. The GPhC also plans to evaluate the effectiveness of its revalidation process as part of its work on post-registration assurance of practice.

13.2 The GPhC introduced a more risk-based approach to its routine pharmacy inspections in June 2022, following a full public consultation in 2018 and refinements made during the pandemic. Alongside this new approach, the GPhC continued to carry out other types of routine inspections, including re-inspections of pharmacies that have failed one or more standards after six months, and routine inspections of new pharmacies joining the register.

13.3 We received feedback from one stakeholder who raised concerns around this new risk-based approach and whether risks are being properly addressed. The GPhC has told us that it is engaging with these concerns and exploring how it can address them, both in the short and long term.

Conclusion

While we note the concerns raised by one stakeholder about the GPhC's new approach to routine pharmacy inspections, there is evidence that the GPhC is being responsive and is managing emerging risks proportionately. We will monitor the new premises inspection process and report any further developments in our next review.

Fitness to practise

In previous years we have reported on our concerns about the GPhC's performance against our fitness to practise Standards. We identified concerns in relation to timeliness, transparency and clarity of the initial assessment and investigation process, decision-making, and ensuring parties were supported to participate in the process. We also identified concerns about the way risk assessments were documented.

As part of our performance review this year, we reviewed a sample of 27 cases closed by the GPhC between 1 August 2022 and 11 January 2023 (17 closed at initial assessment

and 10 closed at investigation). The purpose of our audit was to assess whether the GPhC had addressed our previous concerns.

Details of our audit findings are set out against the relevant Standards.

14 The regulator enables anyone to raise a concern about a registrant.

14.1 The number of fitness to practise complaints received by the GPhC increased by over a third this year – from 3,080 in 2021/22 to 4,178 in 2022/23 – driven by a sharp increase in concerns raised by members of the public. The GPhC told us that was linked to increased pressures on frontline pharmacies coupled with limited resources and pharmacist shortages, as well as instances of supply chain disruption.

14.2 Regarding particular types of concern, the GPhC outlined that it is seeing an increase across a number of categories. The GPhC is doing more work to improve the data it holds on referrals and has begun working towards better understanding the reasons behind the increase. We will continue to monitor any developments.

14.3 During the course of our audit work this year (discussed further under Standards 15, 16 and 18) we found no evidence to suggest there were any barriers to people raising concerns with the GPhC.

Conclusion

We are satisfied that this Standard is met.

15 The regulator's process for examining and investigating cases is fair, proportionate, deals with cases as quickly as is consistent with a fair resolution of the case and ensures that appropriate evidence is available to support decision-makers to reach a fair decision that protects the public at each stage of the process.

15.1 The GPhC last met our Standard on fitness to practise timeliness in 2017/18. The GPhC has taken various measures to try and improve its performance in recent years, and launched a five-year fitness to practise strategy in July 2021.[11] Actions taken by the GPhC this year included:

[11] *Managing concerns about pharmacy professionals: Our strategy for change 2021-26*

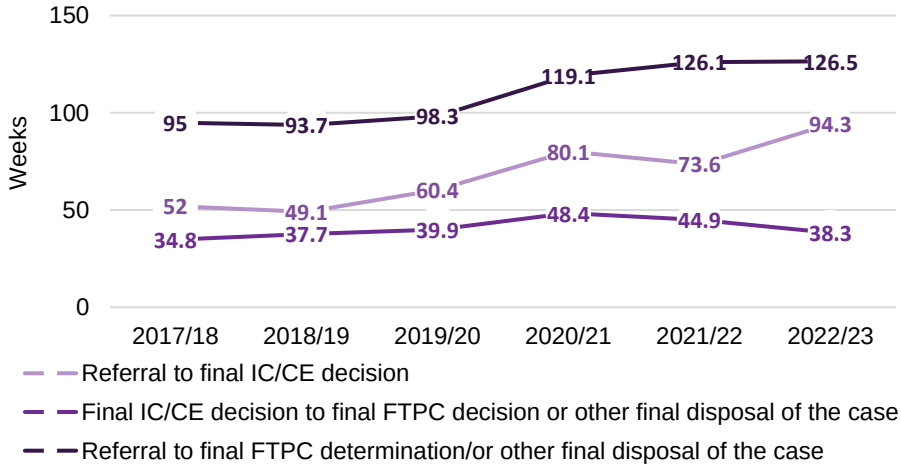
- recruiting additional case officers and using additional administrative support to enable case officers to focus on progressing cases;
- using external panel law firms to manage / investigate cases to free up capacity in the team to deal with more complex cases; and
- carrying out internal audits on its fitness to practise processes and decision-making frameworks.

15.2 The GPhC monitors delivery of its Strategy through updates to Council and reports on operational performance through its quarterly Board Assurance Reports. The GPhC has also recently set up an FP Standards Board, chaired by its Chief Executive, to try to improve performance in this area. However, it is too early for us to assess the impact of this development.

Timeliness of fitness to practise investigations

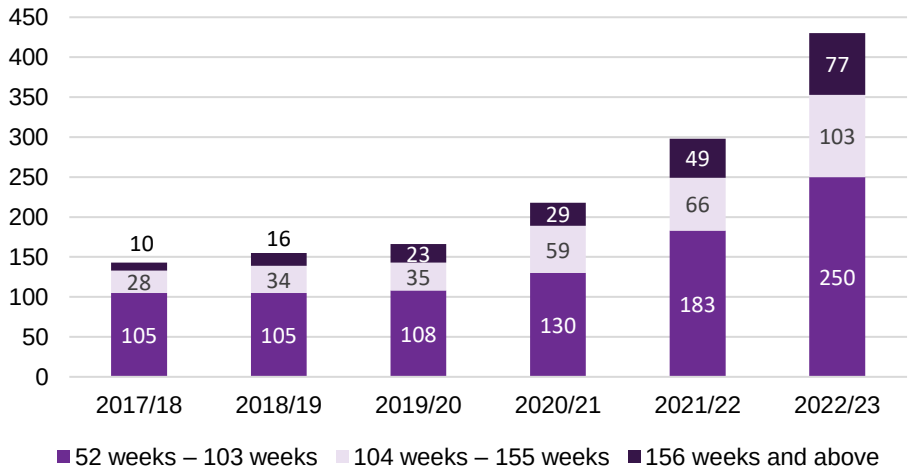
15.3 As Figure 1 shows, the GPhC's performance against our key timeliness measures was mixed this year. There was a significant deterioration in timeliness from referral to final Investigating Committee (IC) decision, an improvement in timeliness from final IC decision to final fitness to practise committee (FTPC) decision or disposal of the case, and no material change in timeliness from referral to final FTPC decision or disposal of the case.

Fig 1. Median timeframes of key timeliness measures



15.4 As Figure 2 shows, the number of open cases over 52 weeks has again steadily increased, most notably with cases that are between 52 and 103 weeks old. A growing older caseload is likely to have an impact on the GPhC's ability to reduce its end-to-end timeframes in the short to medium term.

Fig 2. Number of open cases over 52 weeks old



What we heard from stakeholders

"I remain very concerned by the speed at which the GPhC progresses its fitness to practise cases…"

'The process of managing case progression, even cases in the early stages, in a timely and consistent manner is an ongoing issue and this has considerable impact on the mental well-being of our members."

15.5 The GPhC has told us that it recognises 'more work is required to ensure that cases are being progressed more quickly and the focus now is on tackling the main drivers of delays that are within our control. As part of the Fitness to Practise End-to-End Process Review Project, we are also completing a number of change initiatives to further improve stakeholder experience including the re-allocation of cases during unplanned long term sickness absence or case officers leaving, to make sure there is no delay or impact on the progression of cases. We have also increased the capacity of our case management system (CRM) to store data to populate templates which we think will make the process of information sharing more streamlined and quicker. We have introduced new software to help parties review evidence and sign witness statements electronically.'

15.6 We recognise the GPhC's commitment to improving the timeliness of its fitness to practise process. However, the work has had little impact in this review period and the number of open old cases has increased again. The GPhC is still taking too long to deal with fitness to practise cases and so has not met Standard 15.

15.7 This is the fifth year in a row the GPhC has not met our fitness to practise Standard for timeliness, so we have taken action under our escalation policy.[12] We have written to the Secretary of State for Health and Social Care and the Health and Social Care Committee to raise our concerns, and we will continue to closely monitor the GPhC's progress.

Transparency and clarity of the process

15.8 The purpose of our audit, in relation to this Standard, was to assess whether the GPhC had addressed our previous concerns about the transparency and clarity of the initial assessment and investigation process, and to monitor its use of voluntary agreements.

15.9 We found that the initial assessment process was clear and transparent. Concerns were recorded accurately and progressed to the relevant decision-making forums to determine whether the case should be closed at initial assessment stage or referred on to investigation. Where appropriate, the GPhC undertook initial enquiries to determine the most appropriate course of action. Record-keeping was generally of good quality, and we were able to see how decisions were made. We saw good examples of case officers and Inspectors working closely together on intelligence referrals where the Inspector's analysis and follow-up activity informed the response to the person raising the concern.

15.10 We reviewed nine cases in total across both initial assessment (five cases) and investigations (four cases) where the GPhC decided to close the case with 'informal guidance.'[13]

15.11 We saw improvements in the GPhC's informal guidance process, including updated internal guidance and revised letter templates. However, we found examples of the GPhC sending closure letters that did not accurately reflect the agreed reason for closure. It is important that all parties understand the nature of each closure decision and the GPhC fully explains the consequences of the outcome where appropriate.

15.12 As part of our audit we reviewed one case closed with a voluntary agreement between the GPhC and the registrant (and with no further action). We had no concerns in the handling of this particular case, and the GPhC appears to be using the process in a limited and proportionate way.[14]

[12] Escalation of performance review concerns – process document

[13] We note that from January 2023, the GPhC no longer issues 'informal guidance' at the initial assessment stage but rather 'reminders.' We did not review any cases that were closed with 'reminders' as this began to occur outside of the audit review period

[14] In each of the three recent years where we audited the GPhC (2018/19, 2020/21 and 2022/23), only one case in each year had been disposed of in this way. We audited all three cases.

Conclusion

The GPhC is working to implement its five-year fitness to practise strategy, and we are pleased that it has addressed our previous concerns around the transparency and clarity of its assessment and investigation processes. However, we have not seen evidence that timeliness has improved this year, and it continues to be a source of concern to stakeholders. The data also shows that the GPhC has an increasing number of older cases, despite its efforts to clear the backlog of its oldest caseloads. We therefore conclude that this Standard is not met. We have taken action under our escalation policy and will closely monitor the progress of the GPhC's work to improve its timeliness in fitness to practise.

16 The regulator ensures that all decisions are made in accordance with its processes, are proportionate, consistent and fair, take account of the statutory objectives, the regulator's standards and the relevant case law and prioritise patient and service user safety.

16.1 The GPhC last met our Standard on fitness to practise decision-making in 2017/18. Last year, we reported that the GPhC had introduced a number of measures to improve the quality of its decision-making in fitness to practise cases, including new guidance for staff and a new Investigation Planning and Report Form. However, it was too soon for these changes to have made an impact, and we had not seen tangible evidence that our previous concerns about decision-making at the triage / initial assessment and investigation stages of the process had been fully addressed.

16.2 As part of our audit this year we reviewed the impact of these improvements and whether the GPhC's decision-making at both initial assessment and investigations had improved.

Initial assessment and investigation decisions

16.3 We reviewed 17 cases closed at the initial assessment stage and 10 cases closed at investigations. We found the large majority of decisions to be reasonable, with clear, accurate and detailed reasons recorded and with the relevant test considered and applied. We were satisfied that, in all but four cases, the decisions to close the cases were sufficient to protect the public and maintain public confidence.

16.4 We disagreed with the decisions to close in four cases. The GPhC accepted our view in two cases and confirmed it will take learning from the feedback we provided. In relation to the remaining two cases, the GPhC provided us with further information about the decisions to close. While we do not agree with the GPhC's position entirely we are satisfied that the GPhC has improved sufficiently in its decision-making at both initial assessment and investigation stages. We also take some assurance from an external audit commissioned by the GPhC which found

significant improvement in the decision-making and reasoning provided for closure decisions before the Investigating Committee stage.

Fitness to Practise Committee (FTPC) decisions

16.5 Unlike the earlier stages of the GPhC's fitness to practise process, we have not had any concerns about decisions made by its FTPC in recent years. We have sent a very small number of learning points to the GPhC in relation to these decisions this year, and have not appealed any of its decisions. We therefore have no significant concerns about the GPhC's decision-making at final hearings.

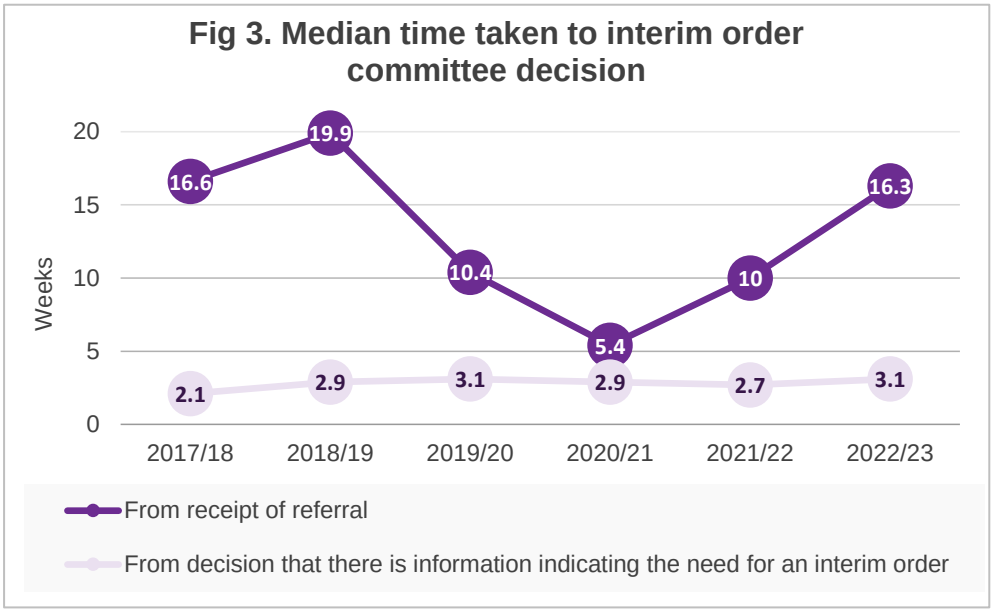
Conclusion

Our audit has provided us with assurance that the GPhC's work to improve its decision-making at both initial assessment and investigation stages has addressed our previous concerns. We have seen that the new initial assessment guidance has been implemented well and the GPhC has enhanced both its decision-making and scrutiny of decision-making at the investigation stages using the new reporting form. We also have no concerns about decisions made at final hearing. We are therefore satisfied that this Standard is met.

17 The regulator identifies and prioritises all cases which suggest a serious risk to the safety of patients or service users and seeks interim orders where appropriate.

Timeliness of interim orders

17.1 As Figure 3 shows, there has been a sharp increase in the time taken between the GPhC receiving a fitness to practise referral and making an interim order committee decision. This measure helps us understand how quickly the most serious cases are being progressed. The GPhC's performance against this measure is in the mid-range of all the regulators this year, and given the increase in the past two years, we will monitor the data closely. The GPhC continues to apply promptly for interim orders once it receives information indicating the need for one.



Risk assessments

17.2 In previous years we have reported our concerns about how the GPhC identified and documented risks at its triage / initial assessment and investigation stages. Although this Standard was not the subject of our audit this year, our case review provided insight into the way the GPhC identifies and prioritises its most serious cases.

17.3 In all the cases we reviewed, risk assessment forms and/or case management system fields had been completed. Where new information had been received, we also saw risk assessments being updated as expected. We could understand how risk ratings had been arrived at in most cases, although there were a small number of cases where the risk assessments did not include all the risk factors we would have expected as per the GPhC's initial assessment guidance. However, we did not see any examples of cases being given an inappropriate risk rating.

Conclusion

We have seen evidence that the GPhC identifies and prioritises cases which suggest a serious risk to the safety of patients or service users and seeks interim orders where appropriate. Although we have noted the increase in the median time taken from receipt of referral to interim order, the GPhC acts quickly once it identifies a need for an interim order. Our audit provided us with assurance that the GPhC carries out risk assessments effectively and we are satisfied that this Standard is met.

18 All parties to a complaint are supported to participate effectively in the process.

18.1 The GPhC last met our Standard on support to fitness to practise parties in 2017/18. In 2018/19, we conducted an audit on this Standard and reported on a number of concerns, which included: parties not being kept updated on their cases; processes not being clearly explained; outcomes not always being sent; and parties given short response deadlines.

18.2 The GPhC has made various improvements to its processes since then, including staff training, new templates and quality assurance work. However, since 2018/19 we had not seen evidence that the GPhC's work in this area had resolved our previous concerns. As part of this year's audit, we assessed the support provided by the GPhC to parties at the triage / initial assessment and investigations stages of its fitness to practise process.

18.3 In most cases, we had no concerns about the customer service provided to the parties: the process was routinely explained to registrants and complainants at the outset; they were kept regularly updated throughout the investigation and they were promptly notified of the outcome. We saw good examples of tailored and compassionate communication, notably to complainants with supportive tone of voice. In closure letters to parties, the GPhC also provided a link to a customer satisfaction survey to provide feedback about their experience of the fitness to practise process.

18.4 In the majority of the cases we were also satisfied with the level of record-keeping, although, in cases investigated by external law firms, there were examples where not all correspondence to parties was saved on the GPhC case file. The approach to informing all parties of the closure decision also appeared to be inconsistent and varied from case to case. The GPhC has told us that it is looking to improve how it stores correspondence sent by external law firms.

What we heard from stakeholders

"We have an ongoing issue around lack of reply to emails especially around chase-ups on case progression… The wording and quality of communication has significant impact on our members and there is definite scope for significant improvement. We have noted some improvement in some outcome letters but there can still be significant variance in the quality of these."

18.5 The GPhC told us that it has received positive feedback from stakeholders through its customer survey feedback on the work it has completed to date. However, the GPhC recognises that more work is required to ensure that cases are being progressed more quickly and the focus now is on tackling the main drivers of delays that are within its control.

Conclusion

Although we did receive some negative feedback from stakeholders our audit overall has provided us with evidence that the GPhC has improved the support it provides to fitness to practise parties, and that the issues we identified in our last audit have largely been resolved. We encourage the GPhC to reflect on the comments we have received from stakeholders, and to use the feedback it collects itself, to drive further improvement. On balance, we are satisfied that this Standard is met.

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General Pharmaceutical Council

Risk Management policy

Meeting paper for Council on 12 October 2023

Public

Purpose

To summarise proposed changes to the Risk Management policy and Risk Appetite Statement for Council's decision.

Recommendations

The Council is asked to approve the updated version of the Risk Management policy, complete with the revised Risk Appetite Statement (Appendix 1 to the policy) and new risk matrix (Appendix 2 to the policy) and new risk significance indicators (Appendix 3 to the policy).

1. Introduction

1.1 This paper sets out the changes in the latest iteration of the Risk Management Policy which can be seen at **Appendix 1** (with changes tracked).

2. Key considerations

Changes to policy

2.1 There have been four key changes to the Risk Management policy since Council last approved it in May 2022. These are:

(a) An updated Risk Appetite Statement following sessions with Council in April and May 2023 (Appendix 1 to the policy). The key change here is a lengthened section on equality, diversity and inclusion which specifically references our positive action approach;

(b) A revised risk matrix already seen by SLG, ARC and Council at earlier sessions (Appendix 2 to the policy);

(c) A new set of risk significance indicators (short statements to indicate how we will rate significance for different types of risk) at Appendix 3 to the policy; and

(d) More detail in the section on ICO referrals in the main body of the policy, following advice in the May 2023 internal audit into GDPR compliance.

Review period

2.2 The review period for the Risk Management policy is every twelve months. It is suggested that this is changed to every two years, with the next review being a substantive review and re-draft of the policy.

3. Equality and diversity implications

3.1 There are no direct equality, diversity and inclusion implications, associated with the policy though the organisation's risk profile includes two documents relating to equality and diversity, and the risk appetite statement references Council's attitude towards risk in this area.

4. Communications

4.1 We will communicate the updated version of this document through Sharepoint.

5. Resource implications

5.1 Risk management is usually resourced within existing budget.

6. Risk implications

6.1 Risk implications are inherent. This policy addresses the organisation's approach to risk management.

7. Recommendations

The Council is asked to approve the updated version of the Risk Management policy, complete with the revised Risk Appetite Statement (Appendix 1 to the policy) and new risk matrix (Appendix 2 to the policy) and new risk significance indicators (Appendix 3 to the policy).

Rob Jones, Head of Risk Management and Audit6
General Pharmaceutical Council

05/10/2023

General Pharmaceutical Council

Risk Management Policy

GPhC0054 Version 1.2

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

Policy details

Policy reference	GPhC0054
Version	1.2
Policy author	Rob Jones, Head of Risk Management and Audit
Approved for issue by	[Approved by], [Approved date]
Effective from	22 April 2021
Next review	12 May 2023

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
1.0		Changes made to add reference to manual processes and disruption when developing systems and bullying in the risk appetite statement.	Rob Jones
1.1		Changes made following advisory audit.	Rob Jones

Version	Approved date	Description of change	Amendments by
		Audit and Risk Manager changed to Head of Risk Management and Audit	
1.2		Changes made to reference strategic delivery and corporate risk registers. Review cycle for Council changed to quarterly from six monthly, as part of BAF. External horizon scanning added to SLG responsibilities. Changes to risk appetite statement. Addition of risk significance indicator and revisions to risk scoring matrix. Addition of specifics relating to data protection as recommended in GDPR audit.	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 ultimately 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 are driven by external events or by 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 delivery risk register** – the risk register logging and detailing risks to the organisation's strategic delivery.~~ng 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.

~~5.7~~5.8 **Data Protection Impact Assessment** - a process of systematically and comprehensively identifying data protection risks of a project, process or system. These risks can then be analysed to minimise or address the risk.

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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 quarterly as part of the Board Assurance Framework~~twice year~~. 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 regard to 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 delivery 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. Head of Risk Management and Audit

6.8 The day-to-day oversight of and reporting on risk management is dealt with by the Head of Risk Management and Audit, 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 3);
- to ensure the strategic delivery and corporate ~~operational~~ risk registers are updated at least quarterly;
- to review the strategic delivery 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 undertake six monthly external horizon scanning;
- to work with the Chief Executive, Director of Finance, and Head of Risk Management and Audit 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 Head of Risk Management and Audit 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 Head of Risk Management and Audit 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 Head of Risk Management and Audit.

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.

~~7.7~~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

~~7.8~~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.

~~7.9~~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.

~~7.10~~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.

~~7.11~~7.13 In cases here data protection risks have been identified, then these will be managed through the organisation's Data Protection Impact Assessment procedure, taking advice from the Data Protection Officer as appropriate~~.~~

~~7.12~~7.14 For further guidance on how to assess the risk against Council's stated risk appetite, please contact the Head of Risk Management and Audit.

iii. Risk management plan

~~7.13~~7.15 **Identification and Assessment of Risk**

~~7.14~~7.16 The GPhC has two main risk registers, which record and track risks faced by the GPhC. These are the strategic delivery 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.

~~7.15~~7.17 The strategic delivery 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 Delivery Risk Register at the earliest opportunity so that full consideration of the matter and the proposed scoring can be undertaken.

~~7.16~~7.18 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.

~~7.17~~7.19 The risk score is applied using a formula: x (likelihood) multiplied by y (significance). The controls and mitigation already in place are then added.

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

~~7.18~~7.21 The likelihood calculator in Appendix 2 and the risk significance indicator at Appendix 3, should be used to ensure the scoring is done in a consistent manner. Whilst the exact nature of the risk may not be directly referenced, it should act as a rough measure.

~~7.19~~7.22 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').

~~7.20~~7.23 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.

~~7.21~~7.24 **Monitoring and control of identified risks**

~~7.22~~7.25 Having assessed the risk and identified controls and any additional mitigating actions, the risk is then managed on a day-to-day basis. The Head of Risk Management and Audit 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.

8.

8.1 **Departmental risk registers**

8.2 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 Head of Risk Management and Audit that the register has been created so that it can be logged within the Register of Risk Registers (Appendix 3).

8.3 **Review process and escalation**

8.4 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.

8.5 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.

8.6 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.

8.7 A flow chart for the GPhC's risk life cycle process is set out at Appendix 4.

8.8 **Internal Audit**

8.9 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.

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

9. Training requirements

9.1 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.

10. Monitoring and compliance

10.1 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 delivery risk register and key corporate risks ~~twice yearly~~quarterly as part of the Board Assurance Framework;
- ARC will review the strategic delivery risk register and corporate ~~operational~~ risk register at each meeting, alternating its primary focus;
- SLG will review the strategic delivery 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.

11. References

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

~~11.2 The Register of Risk Registers, referenced at paragraphs 6.8 and 7.25, can be seen here (WORK IN PROGRESS).~~

12. Associated documentation

12.1 Incident Management Policy

12.2 Strategic Delivery Risk Register

12.3 Corporate ~~Operational~~ Risk Register

12.4 Register of Risk Registers

12.5 Data Protection Policy

~~12.4~~12.6 Data Protection Impact Assessment procedure

13. Appendices

13.1 Appendix 1 is the risk appetite statement.

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

13.3 Appendix 3 is the risk significance indicator.

13.4 Appendix 4 is the template for the register of risk registers.

13.5 Appendix 5 is a flow chart for the risk life cycle 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 and the public 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 review whether the risk appetite level is indeed 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 9
Medium	Preference for safe options that have a low degree of risk, but prepared to explore more progressive solutions.	9 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).**

In addition, any risk with a current risk score of '5' must be kept under review even where the 'likelihood' reaches '1'.

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 and public safety
- Regulatory standards and quality
- Health, standards of safety, and wellbeing
- Financial health
- Productivity and efficiency
- 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 and public safety

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 will also treat as priority, the consideration of any changes to the external environment, including social, environmental or technological factors, where there is a linked patient or public safety concern.

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.

Standards of health and 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 approach. 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~~

W~~w~~e 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. This includes being prepared to update our systems to control risks associated with single points of failure when processing regulatory activities, cyber security and other key areas, even where short to mid-term disruption is a potential consequence.

As such, we are more likely to flex in the way we deploy resource than to overspend or overrecruit for positions. Where there is a trade off between patient and public safety, and productivity and efficiency, we will always prioritise patient and public safety.

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 therefore have a low tolerance for bullying and harassment.

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. 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.

We are committed to tackling all forms of discrimination (including racism) in our work and we have adopted a positive action approach. We understand that delivering our strategy and tackling these issues could lead to some conflict. We recognise we may not always get things right given the complexity of these challenges and fast-moving external context, but we are committed to tackling issues positively, with the intention of delivering our equality, diversity and inclusion strategy and doing the right thing.

As outlined in our EDI strategy, we "recognise that EDI issues can generate political controversy, but we are very clear that our approach is not aligned to any particular political viewpoint or ideology. One aspect of diversity we celebrate is the diversity of political views and beliefs within our organisation, as in society at large". Our EDI strategy is grounded squarely in our vision and strategy for pharmacy regulation, our values and our statutory role and functions.

~~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 register template and scoring matrix

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	Time frames and action owner
Risk/Control Owner	Linked strategic objective	Cause	Effect	Likelihood (x)	Significance (y)			Likelihood (x)	Significance (y)				
1.	*We fail to deliver a robust online Registration Assessment within acceptable standards and timeframes* (COR002)												

Likelihood (x)	(Highly likely) 5	5	10	15	20	25
	(Likely) 4	4	8	12	16	20
	(Possible) 3	3	6	9	12	15
	(Unlikely) 2	2	4	6	8*	10*
	(Remote) 1	1	2	3	4*	5*
		1 (Insignificant)	2 (Minor)	3 (Moderate)	4 (Major)	5 (Catastrophic)
		Significance (y)				

Formula: x * y + y = risk score

Highly likely	75% or more chance of happening in next 12 months
Likely	51-74% chance of happening in next 12 months
Possible	31-50 % chance of happening in next 12 months
Unlikely	15-30% change of happening in next 12 months
Remote	Less than 15% chance of happening in next 12 months

*risks falling into these sections are subject to separate 6 monthly review to ensure appropriate steps are being taken to manage the significance of the risk

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

Appendix 3

Risk significance indicator

Risk category	1 (insignificant)	2 (minor)	3 (moderate)	4 (major)	5 (catastrophic)
Patient and public safety	N/A	Short delays in acting on information that may have indicated an issue with patient/public safety (less than two weeks). No exacerbating factors or public criticism.	Moderate delay (more than two weeks, less than a month) in actioning information that could have led to patient safety issue. No exacerbating factors or public criticism.	An individual/premises gains access to the register who is not competent. Or an individual is not removed from the register where a panel has ordered that they should be. Or information that may have led to action being taken is missed. No exacarbating factors. May lead to some industry specific public criticism. May also include a decision by a panel that is considered by the PSA or our own leadership to be both deficient and put the public at **moderate** risk.	Multiple instances of issues with integrity of register or poor quality case management that has led to individuals/premises being left on the register where a panel order their removal. Alternatively, a single incident of register integrity issues/patient safety implications, with exacarbating factors. Or a number of examples of information that may have led to action being taken against individuals/premises being missed. May also include a decision by a panel that is considered by the PSA or our own leadership to be both deficient and put the public at **high** risk. Likely to lead to widespread public criticism.
Regulatory standards and quality	N/A	A single institution requires corrective action following an accreditation visit. Or criticisms are made in industry press or mainstream media, which is not entirely justified, but requires a response.	A single institution is deemed to have fallen below the standards required in educating pharmacy professionals and accreditation is removed. Or criticisms of pharmacy education are made in industry press or mainstream media, which is justified but can be addressed.	Industry specific criticism of key aspects of the standard of pharmacy, with pre registration education or ongoing training identified as at the root cause of the issue. Or more than one institution is deemed to have fallen below the standards required in educating pharmacy professionals and accreditation is removed.	Widespread criticism of the standard of pharmacy, with pre registration education or ongoing training identified as at the root cause of the issue. Exacarbating factors such as patient deaths or public harm linked to issue. Or anticipated changes in the pharmacy sector are not accounted for in the developments of standards which leads to a pharmacy education not being fit for purpose.

Health, standards of safety, and wellbeing	Minor incident requiring first aid.	Single incidents between a low and moderate level. Delay in reporting any health and safety incident.	A higher than accepted number of lower level health and safety incidents are recorded or information comes to light that lower level incidents are not being reported. Or a staff member is threatened whilst carrying out work or in their personal life as a result of their work (but where the threat is not credible).	An avoidable health and safety incident leads to moderate harm to an individual or individuals (i.e. broken limb). Or information comes to light that a moderate health and safety incident has not been reported. Or a member of staff is the victim of physical violence, or harassment, whilst carrying out work or in their personal life as a result of their work. Or wellbeing issues are indicated as a factor in a higher than expected number of staff exit interviews or absences, where rates are at an unacceptably high level.	An avoidable major health and safety issue within the office or during the carrying out of work duties leads to life changing injuries/death of an individual and/or enforcement action by the relevant authority. Or information comes to light that a serious health and safety incident has not been reported and is likely to result in action by enforcement action.
Financial health	Minor inefficiencies where it is clear there is no misdemeanour but where an individual could be construed to have been wasteful. Cost is less than £1000.	Inefficient use of funds. Inefficient contract management where it can be demonstrated that a service could have been procured for a small amount less (between £1000 and £5000). Poor practice in procuring services where there is no significant waste or exacarbating factors, such as bias in the process, will be considered minor.	Industry wide criticism over the GPhC's fee and use of fee in carrying out regulatory duty but where there has been no legal or regulatory misdemeanour. Losses of less than £20k to external fraud. Inefficient contract management where it can be demonstrated that a service could have been procured for a moderate amount less. Failure to follow procurement regulations may be deemed moderate if there are no excarbating factors.	Instances of internal fraud which involves any member of staff. An instance of external fraud that highlights carelessness or poor controls, where losses are between £20k and £100k may also meet this threshold. Inefficient contract management where it can be demonstrated that a service could have been procured for a significant amount less. Failure to follow procurement regulations may be deemed major if there are excarbating factors. A financial crash leading to a considerable fall in investment portfolio which is in line with market benchmarks. May also include criticism at a national press level over the GPhC's fee and use of fee in carrying out regulatory duty but where there has been no legal or regulatory misdemeanour.	Mass instances or extreme instance of internal fraud involving senior staff or financial mismanagement, that either results in criminal action or widespread media coverage. An instance of external fraud that highlights carelessness or poor controls, where losses are above £100k may also meet this threshold. A financial crash leading to a considerable fall in investment portfolio which is significantly out of kilter with market benchmarks.

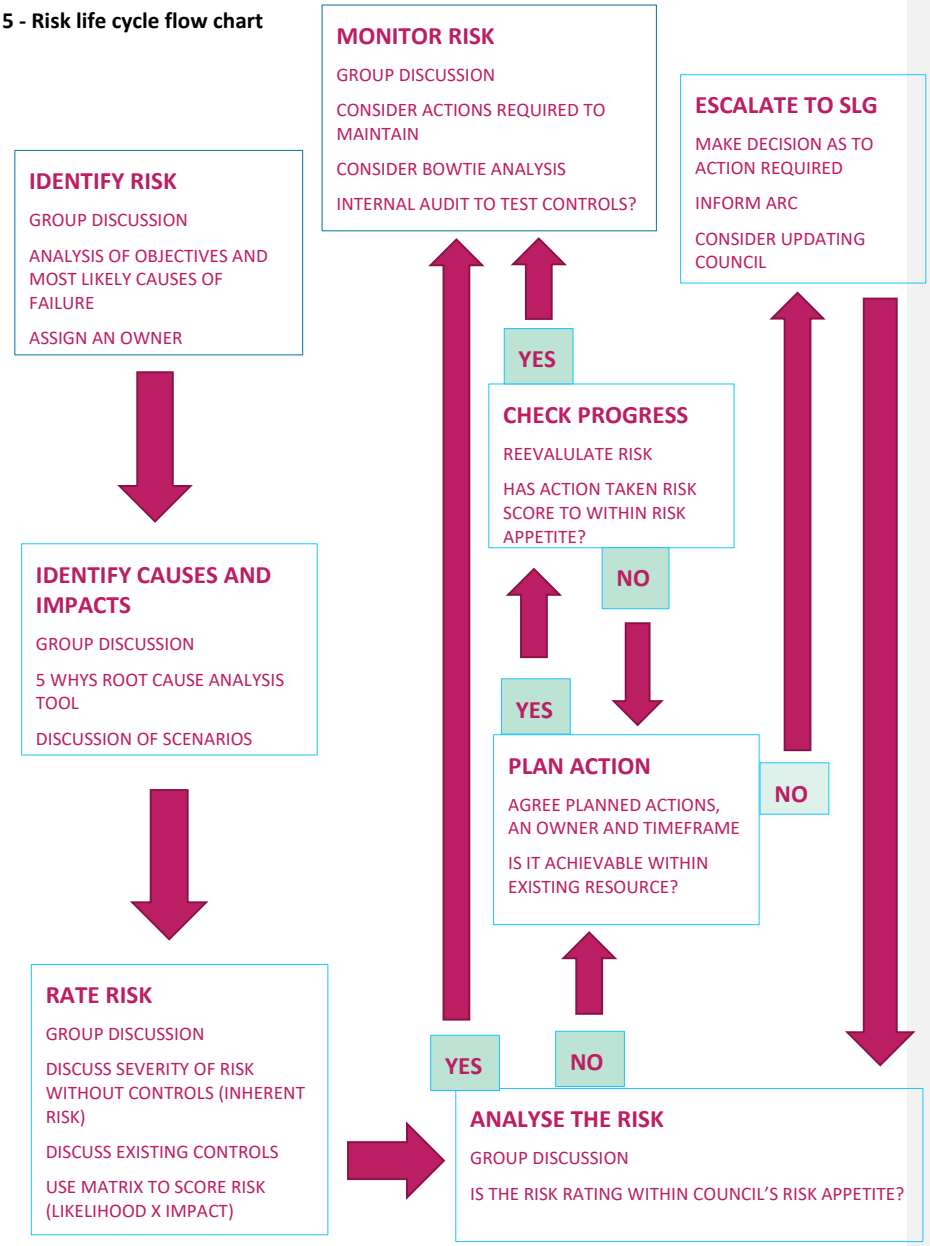
Productivity and efficiency	Slower processing times or planned pauses in non-time critical work.	Short term (less than half a day) disruption to accessing important systems or data. May also include slower processing times for non-time critical work as teams become used to new ways of working, or due to redeployment of staff to more critical work.	Short term (more than half a day, less than two days) loss of access to important systems or data. May involve permanent loss of access to non-critical data or systems. May also include slower processing times for non-critical aspects of key functions as teams become used to new ways of working, or due to redeployment of staff to more critical work.	Medium term (between two days and a week) loss of access to important systems or data. May involve permanent loss of non-critical, but important data. May also include slower processing times for critical aspects of key functions (but not where there are exacarbating factors that lead to public/patient harm).	Long term (more than a week) or permanent loss of access to critical systems or data (the register or CMS). Will also include any widesread disruption to the registration assessment, affecting several centres and where a high number of candidates are impacted.
People resourcing, deployment and development	N/A	Higher than expected turnover in a small section of the organisation for a period of not more than one quarter.	Isolated incidents of bullying or discrimination which are managed in line with procedure. Might also include turnover well over sector averages for a moderate period (a quarter), or a failure to recruit to key posts which impacts upon productivity.	Demonstrable isolated incidents of bullying or discrimination that are not managed promptly or line with best practice. May include criticism by an inquiry or legal body in relation to isolated incidents. Might also include turnover well over sector averages for a sustained period (two quarters) across the organisation, or a failure to recruit to key posts which impacts upon productivity. May also include widespread, justified, perception that the GPhC is not using staff resources efficiently.	Justified public criticism that the organisation has a culture of widespread bullying or discrimination. May include criticism by an inquiry or legal body.
Compliance and legal	N/A	A near miss with regards compliance, that is prevented before an actual breach occurs. Would also include a lower level information security breach that would not lead to harm to the data subject or attract action.	Clear non-compliance with regulations or legislation which is realised and managed internally, but which may not necessarily meet the notification threshold to the ICO. May be reported to other external bodies or third parties, as necessary.	Clear non-compliance with regulations or legislation which leads to a warning or reprimand. There may be lower level industry specific critism. A breach involving an ICO referral where no action is taken. May be the outcome of a higher than expected ICO referrals in a period (more than two in a quarter, or more than three in a 6 month period), even where no action is taken.	Clear non-compliance with regulations or legislation which leads to civil/criminal action, a significant fine or widespread public criticism.

Appendix 4

Register of Risk Registers

	Register	Owner	Last review
Strategic/Corporate Level	Strategic Delivery Risk Register	Council and Chief Executive and Registrar	
	Corporate ~~Operational~~ Risk Register	Chief Executive and Registrar	
Project	Renewal programme risk register	Stuart Heaney	
	Website project risk register	Julia Smith	
	Online Registration Assessment project risk register	Viv Cox	
	Organisational restructure risk register	Gary Sharp	
Operational	Never Event Register	SLG	
	IT Risk Register	Stuart Heaney	
	Hearings risk register	Paul Cummins	
	Rebalancing risk register	Annette Ashley	
	Registration assessment operational risk register	~~Lisa Smith~~Ruth Exelby	

Appendix 5 - Risk life cycle flow chart



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