General Pharmaceutical Council

Council meeting 12 March 2020

Meeting papers and agenda

Public

Contents

General Pharmaceutical Council

Agenda

Council meeting

12 March 2020
13:30 to 16.00 **approx.**
Council Room 1, 25 Canada Square, London E14 5LQ

Public business

1.	**Attendance and introductory remarks**	Nigel Clarke
2.	**Declarations of interest** *Public items*	All
3.	**Minutes of last meeting** *Public session on 13 February 2020*	Nigel Clarke
4.	**Actions and matters arising**	Nigel Clarke
5.	**Workshop summary – 13 February 2020** *For noting*	Nigel Clarke
6.	**Evidence of English language skills – draft consultation** *For approval*	*20.03.C.01* Martha Pawluczyk
7.	**Policy on emergency registration arrangements** *For approval*	*20.03.C.02* Mark Voce
8.	**Terms of Reference for the Audit and Risk Committee and the Finance and Planning Committee** *For approval*	*20.03.C.03* Nigel Clarke
9.	**Deputising arrangements for the Chair 2020-21** *For approval*	*20.03.C.04* Janet Collins
10.	**Procedure for dealing with complaints against members of statutory committees** *For approval*	*20.03.C.05* Paul Cummins

11.	**Update on the 'Report of the Independent Inquiry into the issues raised by Paterson'**	*20.03.C.06*
	For noting	Duncan Rudkin

12.	**Audit and Risk Committee Minutes**	*20.03.C.07*
	Unconfirmed minutes of the meeting held on 5 February 2020	Digby Emson
	For noting	

13.	**Any other business**	Nigel Clarke

Confidential business

14.	**Declarations of interest**	All
	Confidential items	

15.	**Minutes of last meeting**	Nigel Clarke
	Confidential session on 13 February 2020	

16.	**Confidential actions and matters arising**	Nigel Clarke

17.	**Committee memberships 2020-21**	*20.03.C.08*
		Duncan Rudkin

18.	**Audit and Risk Committee minutes (unconfirmed)**	*20.03.C.09*
	Unconfirmed minutes of the confidential session on 5 February 2020	Digby Emson
	For noting	

19.	**Any other confidential business**	

Date of next meeting

Thursday, 23 April 2020

Minutes

Minutes of the Council meeting held on Thursday 13 February 2020 at 25 Canada Square, London at 13:00

TO BE CONFIRMED 12 March 2020

Minutes of the public session

Present

Nigel Clarke (Chair)

Digby Emson

Mark Hammond

Penny Hopkins

Ann Jacklin

Jo Kember

Alan Kershaw

Elizabeth Mailey

Rima Makarem

Evelyn McPhail

Arun Midha

Aamer Safdar

Jayne Salt

Apologies

Neil Buckley

In attendance

Duncan Rudkin (Chief Executive and Registrar)

Carole Auchterlonie (Director of Fitness to Practise)

Claire Bryce-Smith (Director of Insight, Intelligence and Inspection)

Laura McClintock (Chief of Staff)

Francesca Okosi (Director of People)

Mark Voce (Director of Education and Standards)

Jonathan Bennetts (Associate Director of Finance and Procurement)

Rachael Oliver (Head of Communications)

Julian Graville (Head of Inspection)

My Phan (Head of Data and Insight)

Paul Cummins (Head of Adjudication)

Carol Anderson (Head of Human Resources)

Melissa Nurse-Barrow (Associates and Partners Manager)

Janet Collins (Governance Manager)

88.   Attendance and introductory remarks

88.1   The Chair welcomed those present to the meeting. Apologies had been received from Neil Buckley

89. Declarations of interest

89.1   The Chair reminded members to make any declarations of interest before each item.

90. Minutes of the last meeting

90.1   **The minutes of the public session held on 5 December 2019 were confirmed as a fair and accurate record of the meeting and signed by the Chair.**

91. Actions and matters arising

91.1   The actions due by this meeting were covered on the agenda and there were no matters arising.

91. Workshop summary – 5 December 2019

91.1   Council noted the discussions from the December workshop.

92. Evaluation of threshold criteria for referring cases to the Investigating Committee (IC)

92.1   Carole Auchterlonie (Director of Fitness to Practise) presented an evaluation of the revised threshold criteria, which had been in operation since February 2018. The revised criteria applied to conduct, performance and health cases and also included a requirement that it should be in the public interest to refer a case to the IC.

92.2   The evaluation covered the quality of decision making, the consistency of application, the impact and reflections from decision makers. The review was positive in relation to the quality of decision making, although it found that there was room for improvement in the way that decisions were recorded.

92.3   The review concluded that the use of the criteria was leading to appropriate outcomes and gave some reassurance that staff understood the purpose of the criteria and how to apply them. However, lack of detail in the recording of reasons

meant that it was not possible to assess the effectiveness of the criteria as a decision-making tool.

92.4 It was important to emphasise that the removal of patient harm as an automatic reason for referral did not imply any increased risk to patients. The intention was to allow for a more rounded view of the circumstances which had led to harm and not lead to cases being referred when, although a patient may have suffered harm, there was no indication that the registrant's fitness to practise was impaired.

92.5 There was some discussion about whether there was consistency between the approaches taken in fitness to practise and inspection in terms of proportionality. This needed to be the subject of a fuller debate.

92.6 In relation to the 'public interest test', it was noted that there was not a specific guidance document to which staff could refer. Rather, the test was applied using discussion and examples.

92.7 In cases relating to a registrant's mental health, factors taken into account when considering whether the registrant was able to practise 'safely and effectively' included medical evidence, the registrant's insight and the support which was in place. However, the team was looking at the management of health cases generally as part of the FtP review.

92.8 **Council noted the evaluation of the revised threshold criteria.**

93. Communications and engagement update

93.1 Rachael Oliver (RO) introduced **20.02.C.01**, the quarterly report on communications and engagement with stakeholders. This quarter's report focussed on the consultation on the draft 2020 Fees Rules and the publication of:

- guidance for pharmacist prescribers;
- the findings of the survey of registered pharmacy professionals;
- guidance for patients using pharmacy services.

93.2 There had been significant interest from the national media in relation to the supply of opioids. Duncan Rudkin had been interviewed for a Horizon programme on the subject and outlined the action the GPhC was taking in this area.

94.2 Members noted that communications in this area were being well handled and that it would continue to be important to take all opportunities to communicate on this subject.

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

95. Finance update, annual plan progress report and performance monitoring reports for Q3

95.1 Duncan Rudkin (DR) introduced **20.02.C.02** which provided reports to Council on three areas of the organisation's performance in quarter three (October-December)

of 2019/20; namely financial performance, progress against the annual plan and operational performance.

Finance update

95.2   The Q3 finance update was important as it provided an indication of the likely position at the end of the financial year. The deficit continued to fall and the current forecast was for a deficit of approximately £120k by the end of the financial year. 97% of the efficiency savings built into the budget had been identified and the remaining 3% were expected by the end of the year.

95.3   The Council was pleased to note the performance shown in the finance update and acknowledged the work undertaken to reach the current position.

Annual plan progress

95.4   Progress in the five strategic priority areas continued, with an improvement in 'operating as a professional, lean organisation' which was due to the progress being made with the EDI strategy against its revised timeline. 'Building our data and insight capability' remained amber as the plans needed to be clarified once the budget and business plan were agreed.

Operational performance

95.5   The Council discussed the various areas of the performance monitoring report.

95.6   **Council noted:**

i)   **the key areas of performance highlighted in the cover paper;**

ii)   **the finance update provided at Appendix 1;**

iii)   **the report on progress against the 2019/20 annual plan at Appendix 2; and**

iv)   **the operational performance information provided at Appendix 3.**

96. GPhC Strategic plan 2020-25 and Annual plan 2020/21

96.1   DR introduced **20.02.C.03**, which set out the five-year strategic plan and the annual plan for 2020/21. The foreword for the strategic plan was not yet finalised and suggestions from members were welcome.

96.2   The ten-year vision had been agreed by Council in December 2019. The development of the first five-year strategic plan was designed to support the delivery of the vision, acting as a roadmap of work and summary outcomes. The annual plan 2020/21 set out the next level of detail for the priority work programmes for the coming year.

96.3   The Council discussed both plans, and made several suggested changes to wording.

96.4   **With those amendments, Council approved the Strategic plan 2020-25 and the Annual plan 2020/21.**

97. Budget 2020/21

97.1 Jonathan Bennetts (JB) presented **20.02.C.04**, which set out the proposed budget for 2020/21. He thanked his colleagues, particularly Vanessa Clarke and Iqbal Hussain, for their hard work in preparing it.

97.2 The proposal was for a break-even budget with both income and expenditure set at £24.35m. Members welcomed the break-even position and recognised the work which had gone into achieving it and dealing with the deficit.

97.3 The figures were based on projected growth of 1.7% in pharmacist registrations and 1% in pharmacy technician registrations; and a decline of 0.9% in registered premises. The paper also included the sensitivities if registrant numbers were to fall.

97.4 Expenditure had been considered under four main headings:

- Mandatory (statutory responsibilities);
- Business as usual (day to day activities);
- Continuous improvement (improving service delivery);
- Strategic projects (one off medium to large scale activities).

97.5 Initial proposals would have resulted in a deficit of £0.7m for 2020/21 but improved prioritisation and challenge had allowed that to be revised down to a breakeven position.

97.6 The paper also covered capital expenditure, risks and opportunities and reserves.

97.7 The Council approved the budget for 2020/21.

98. Procedure for dealing with complaints against statutory committee members

98.1 After a brief discussion, this paper (**20.02.C.05**) was withdrawn for some amendments and moved to the March agenda.

99. Any other public business

99.1 One of the members raised an issue about the size of the Council papers for this meeting and questioned whether it would have been better to have had a meeting in January. The same member also questioned the timing of Council papers and raised issues with both postal and electronic delivery.

99.2 The timing of the publication of the PSA annual review (which formed a significant part of the papers) was not within the GPhC's gift and, beyond the budget and business plan, which were always considered in February ahead of the new financial year, other papers had been kept to a minimum.

99.3   There was some discussion about electronic alternatives to Council papers including a members' portal and various apps which could be used. This work was underway but had to form part of the overall IT strategy which was currently under discussion.

99.4   There being no further public business, the meeting closed at 15.20.

Date of the next meeting:

Thursday 12 March 2020

These minutes are confirmed as a true and accurate record of the meeting.

Nigel Clarke, Chair of Council

12 March 2020

Council action log

Meeting date	Ref.	Action	Owner	Due	Status	Comments/update

There are no outstanding actions as of 5 March 2020

Council workshop summary

Meeting paper for Council on 12 March 2020

Public

Purpose

To provide an outline of the discussions at the Council workshop on 13 February 2020.

Recommendations

The Council is asked to note the discussions from the February 2020 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 Council does not make decisions in the workshops. They are informal discussion sessions to assist the development of the Council's views. A summary of the workshop discussions is 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.   Summary of the February workshop

Chief Executive's update

2.1   Duncan Rudkin (Chief Executive) provided Council members with an update on COVID-19 (the novel coronavirus outbreak), proposed reforms to regulators' governance and operational frameworks and the Medicines and Medical Devices Bill which had featured in the recent Queen's Speech.

COVID-19

2.2   NHS England was preparing guidance for healthcare professionals and services operating largely in the community (particularly dentistry, optical services and pharmacy) in the event that it was needed. Similar guidance was being prepared in Scotland and Wales and the

GPhC was keeping in contact with the devolved administrations and the other regulators. Staff were in contact with the GPhC Inspector who covered pharmacies in Brighton in relation to a pharmacy in a medical centre which had been closed for a deep clean.

Governance

2.3 Proposed changes to governance included a move to Unitary boards instead of Councils, the freedom for the regulators to change their own processes through Rules and the repeal of prescriptive legislation with a view to replacing it with a more consistent legislative framework.

Medicines and Medical Devices Bill

2.4 The Bill had been announced in the Queen's speech. Its origin lay in the need to avoid legislative gaps after the end of the Brexit transition period in December 2020 and it would provide enabling powers to allow the UK government to continue to make or amend medicines regulations. However, the scope would be wider than changes required by departure from the EU.

Public Inquiries update

2.5 Laura McClintock (LM) updated the Council on the current approach to implementing the findings of public inquiries, which now featured in a PSA standard on regulatory performance. LM made particular reference to the recent publication of the Paterson report which, while it did not contain recommendations specific to pharmacy, did cover a number of themes of which the GPhC needed to be mindful. These included collaboration across the regulatory system to keep patients safe, patient awareness of complaint options and healthcare professionals working while under investigation.

2.6 Council was also updated on the Gosport Report, the Williams Review and the Cumberlege Review into how the healthcare system responded to reports from patients about side effects of treatments including sodium valproate.

Achieving excellence in pharmaceutical care – a strategy for Scotland

2.7 Rose Marie Parr, Chief Pharmaceutical Officer for Scotland, joined the workshop to present on the above strategy.

2.8 She spoke about health inequalities in Scotland and the role that pharmacy sought to play in delivering healthcare to the population. She focussed on the role that community pharmacy could play, integrating pharmacists and pharmacy technicians into GP practices, service integration, the development of portfolio careers in pharmacy and the safer use of medicines, particularly for patients with co-morbidities and long-term conditions.

Community pharmacy – a changing sector

2.9 Leyla Hannbeck, Chief Executive of the Association of Independent Multiple Pharmacies, presented on the key challenges and the focus areas for community pharmacy.

2.10 These were:

- the increasingly clinical role of pharmacists;
- workforce issues;
- medicines shortages;

- supervision;

- automation, including hub and spoke;

- mergers and closures; and

- new medicines.

2.11 The AIMp would be launching a survey of its members in the near future to find out more about the challenges they were facing.

3. Recommendations

The Council is asked to note the discussions from the February 2020 workshop.

Janet Collins, Governance Manager
General Pharmaceutical Council

20 February 2020

Evidence of English language skills consultation 2020

Meeting paper for Council on 12 March 2020

Public

Purpose

To provide the Council with the proposed consultation on revised evidence of English language skills.

Recommendations

1. The Council is asked to approve the consultation on revised evidence of English language skills. Introduction

1.1   One of the key ways in which we protect the public is by making sure that only pharmacists and pharmacy technicians with the knowledge and skills to practise safely and effectively can register and work in Great Britain.

1.2   This includes making sure that pharmacists and pharmacy technicians can communicate effectively in English. Patients and the public rightly expect that healthcare professionals involved in their care can clearly communicate with them. Allowing healthcare professionals without the necessary knowledge of English to practise in Great Britain could also put patient safety at risk.

1.3   The GPhC has required evidence of English language ability from all applicants since the introduction of The Health Care and Associated Professions (Knowledge of English) Order 2015 (the Knowledge of English Order). The Knowledge of English Order made the following changes to the Pharmacy Order 2010:

- introduced a legal requirement for all registrants and applicants to have the necessary knowledge of English for safe and effective practice as a condition of registration with us;

- introduced a new ground for fitness to practise proceedings of not having the necessary knowledge of English; and

- placed a statutory duty on us to consult and publish guidance on the evidence, information or documents to be provided by an applicant to show that they have the necessary knowledge of English. We are also required to consult if we wish to make any changes to the published guidance.

1.4   We consulted on guidance on acceptable evidence of English language skills in September 2015. We currently accept the following evidence:

- a recent1 pass of the academic version of International English Language testing System (IELTS) test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test; or

- a recent pharmacy qualification that has been taught and examined in English in a majority English speaking country (other than the UK) (for example Ireland, United States of America, Australia, or New Zealand); or

- recent practice for at least two years as a pharmacy professional in a majority English speaking country.

1.5   In this consultation we are proposing to revise our guidance to include a recent pass of the Pharmacy Occupational English Language Test (OET) as evidence of English language competence as an alternative to the International English Language testing System (IELTS) test.

1.6   The OET is a test specifically for healthcare professionals. There are 12 different versions of the OET, to test health practitioners from the following 12 professions: nursing, medicine, dentistry, occupational therapy, optometry, physiotherapy, pharmacy, radiotherapy, speech pathology, podiatry, dietetics and veterinary science.

1.7   The NMC and GMC already accept the OET as evidence of an applicant's English language competence as an alternative test to the IELTS test. Accepting the Pharmacy OET will give applicants another option for how they can demonstrate their competence in English, through a test that uses scenarios based on pharmacy practice.

1.8   The Council is asked to approve the consultation on revised evidence of English language skills.

2.   Equality and diversity implications

2.1   We completed an equality assessment when we originally consulted on guidance on evidence of English language skills. In this consultation we are proposing to revise this guidance to include a recent pass of the Pharmacy Occupational English Language Test (OET) as evidence of English language competence as an alternative to the IELTS. This would give applicants for registration another option for how they can demonstrate their competence in English, through a test that uses scenarios based on pharmacy practice.

2.2   In the consultation we have asked questions about the impact, both positive and negative, of our proposals on certain individuals or groups who share any of the protected characteristics or on any other individuals or groups (not related to protected characteristics) for example, patients, pharmacy owners or pharmacy staff.

2.3   Analysis of responses to these questions will be included as part of the consultation analysis report which, will be published on the GPhC website after the consultation has closed.

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[1]When we refer to 'recent' we mean evidence relating to English language competence that is less than 2 years old at the point of making an application to the GPhC.

3. Communications

3.1 It is important that we communicate our proposal in a transparent and open way, seeking views from all who may be affected by the proposed change.

3.2 The consultation will be published on the GPhC's website. It will also be sent to a range of stakeholders and communicated to the pharmacy media. The consultation will run for 6 weeks as opposed to 12 weeks and people will be able to respond online, by email or by post. A shorter timescale is appropriate as the consultation proposes a minor amendment to the evidence of English language skills and the change will only impact a small number of applicants. We will consider the precise timing of the consultation in light of the developing implications of the coronavirus outbreak.

4. Resource implications

4.1 The launch and conduct of the consultation can be covered within existing resources.

5. Risk implications

5.1 Failure to consult appropriately on the revised guidance on evidence of English language skills would mean that the GPhC would not be complying with its statutory duties.

6. Monitoring and review

6.1 The consultation responses will be analysed and a draft consultation report prepared for Council's meeting in July 2020. The final draft of the revised guidance on evidence of English language skills as a result of the consultation, will be presented at the same meeting.

7. Recommendations

The Council is asked to approve the consultation on revised evidence of English language skills.

Mark Voce, Director of Education and Standards
General Pharmaceutical Council

Mark.Voce@pharmacyregulation.org

Tel: 020 3713 7838
 03 March 2020

General Pharmaceutical Council

Draft consultation on English language guidance

The deadline for responding to this consultation is Click here to enter a date.

General Pharmaceutical Council

About the GPhC

Who we are

We regulate pharmacists, pharmacy technicians and pharmacies in Great Britain.

We work to assure and improve standards of care for people using pharmacy services.

What we do

Our role is to protect the public and give them assurance that they will receive safe and effective care when using pharmacy services.

We set standards for pharmacy professionals and pharmacies to enter and remain on our register.

We ask pharmacy professionals and pharmacies for evidence that they are continuing to meet our standards, and this includes inspecting pharmacies.

We act to protect the public and to uphold public confidence in pharmacy if there are concerns about a pharmacy professional or pharmacy on our register.

Through our work we help to promote professionalism, support continuous improvement and assure the quality and safety of pharmacy.

Foreword

One of the key ways in which we protect the public is by making sure that only pharmacists and pharmacy technicians with the knowledge and skills to practise safely and effectively can register and work in Great Britain.

This includes making sure that pharmacists and pharmacy technicians can communicate effectively in English. Patients and the public rightly expect that healthcare professionals involved in their care can clearly communicate with them. Allowing healthcare professionals without the necessary knowledge of English to practise in Great Britain could also put patient safety at risk.

We require everyone applying to register as a pharmacist or pharmacy technician to provide evidence, information or documents to show they have the necessary knowledge of English for the safe and effective practice of pharmacy before they can register.

The evidence provided by the applicant must be recent, objective, independent and robust. We also need to be able to easily check the evidence. We currently accept several different forms of evidence and keep under review any other forms of evidence that might meet our criteria.

In this consultation we are proposing to revise our Guidance on evidence of English language skills to include a recent pass of the Pharmacy Occupational English Language Test (OET) as evidence of English language competence as an alternative to the International English Language Testing System (IELTS). This would give applicants for registration another option for how they can demonstrate their competence in English, through a test that uses scenarios based on pharmacy practice.

We want to hear your feedback on our proposals, including whether you think these changes would enable us to continue to make sure that pharmacy professionals have the English language skills they need to practise effectively and keep patients safe. We look forward to hearing your views.

Duncan Rudkin
Chief Executive

The consultation process

The consultation will run for <mark>XX</mark> weeks and will close on <mark>XXX 20XX</mark>. During this time, we welcome feedback from individuals and organisations. We will send this document to a range of stakeholders, including OSPAP providers, organisations representing pharmacy owners and other employers (such as CCA, NPA, AIMP, NHS in three countries), organisations representing pharmacy professionals (RPS, APTUK, PDA), patient representative groups and others with an interest in this area.

After the consultation, we will publish a report summarising what we heard.

Our report on this consultation

Once the consultation period ends, we will analyse the responses we receive and consider any changes that are needed.

Our governing Council will receive the analysis at a meeting in XXX 20XX and will consider the responses when approving the revised guidance on evidence of English language skills.

We will publish our analysis of the responses and an explanation of the decisions we take. You will be able to see this on our website **www.pharmacyregualtion.org**

Why we consult

We are required to consult before we set any standards or requirements under the Pharmacy Order 2010. We will also consult where necessary to make sure we exercise our statutory functions effectively and proportionately to meet our overarching objective of protecting the public.

Responding to the consultation

How we use your information

We will use your response to help us develop our work. We ask you to give us some background information about you and, if you respond on behalf of an organisation, your organisation. We use this to help us analyse the possible impact of our plans on different groups. We are committed to promoting equality, valuing diversity and being inclusive in all our work as a health professions regulator, and to making sure we meet our equality duties. There is an equality monitoring form at the end of the survey. You do not have to fill it in, but if you do, it will give us useful information to check that this happens.

How we share your information

If you respond as a private individual, we will not use your name or publish your individual response. If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to. If you want any part of your response to

stay confidential, you should explain why you believe the information you have given is confidential.

We may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it but we cannot guarantee that confidentiality can be maintained in all circumstances.

If you email a response to the consultation and this is covered by an automatic confidentiality disclaimer generated by your IT system this will not, in itself, be binding on the GPhC.

Your rights

Under data protection law, you may ask for a copy of your response to this consultation or other information we hold about you, and you may also ask us to delete your response. For more information about your rights and who to contact please read our privacy policy on our website.

How to respond

You can respond to this consultation by going to **www.pharmacyregulation.org/XXX** and filling in the online questionnaire there.

We encourage respondents to use the online questionnaire. However, if you want to send a response by email, please write your response to the consultation questions and send it to us at **consultations@pharmacyregulation.org**.

Other formats

Please contact us at **communications@pharmacyregulation.org** if you would like a copy of the consultation survey in another format (for example, in larger type or in a different language).

Comments on the consultation process itself

If you have concerns or comments about the consultation process itself, please send them to:

feedback@pharmacyregulation.org

or post them to us at:

Governance Team

General Pharmaceutical Council

25 Canada Square

London E14 5LQ

Please do not send consultation responses to this address.

Details of proposals and context

The GPhC has required evidence of English language ability from applicants since the introduction of The Health Care and Associated Professions (Knowledge of English) Order 2015 (the Knowledge of English Order). The Knowledge of English Order made the following changes to the Pharmacy Order 2010:

- introduced a legal requirement for all registrants and applicants to have the necessary knowledge of English for safe and effective practice as a condition of registration with us.

- introduced a new ground for fitness to practise proceedings of not having the necessary knowledge of English and

- placed a statutory duty on us to consult and publish guidance on the evidence, information or documents to be provided by an applicant to show that they have the necessary knowledge of English. We are also required to consult if we wish to make any changes to the published guidance.

The GPhC first consulted on guidance on evidence of English language skills in September 2015. This guidance was approved by Council at its meeting in September 2016 in preparation for a new law coming into force on 21 November 2016. The Guidance has therefore been applied to all new applicants joining or returning to the register from 21 November 2016 onwards.

The evidence we currently accept

The evidence we currently accept must:

- Be recent[2], objective, independent and robust

- Clearly demonstrate that the applicant can read write and communicate with patients, pharmacy services users, relatives and healthcare professionals in English and

- Be readily verifiable by us.

We currently accept 3 types of evidence.

1. A recent pass of the academic version of the international English Language testing System (IELTS) test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test.

2. A recent pharmacy qualification that has been taught and examined in English from a majority English speaking country i.e. Ireland, United States of America, Australia and New Zealand. The entire course must have been taught and examined in English and at least 75% of any in-service training including clinical interaction, contact with patients, carers and other healthcare professionals   as part of that course must have been conducted in English.

3. Recent practice for at least two years as a pharmacy professional in a majority English speaking country. The applicant is required to provide a detailed written reference from their employer with evidence to demonstrate their ability in the four areas of reading, writing, listening and speaking in English.

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[2] When we refer to 'recent' we mean evidence relating to English language competence that is less than 2 years old at the point of making an application to the GPhC.

Therefore, at present where an applicant can only provide evidence of their English language skills by passing an English language test, they are required to pass the academic version of the IELTS test. This is the only English language test we currently accept.

Concerns about language competence

In our current guidance where we receive an allegation or have concerns that a registrant may not have the necessary knowledge of English, the Registrar, Investigating Committee or Fitness to Practise Committee can require the registrant to undertake the academic level IELTS test and achieve the required score of at least 7 with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test.

An alternative English language test to the IELTS

In this consultation we are proposing to revise our Guidance on evidence of English language skills to include a recent pass of the Pharmacy Occupational English Language Test (OET) as evidence of English language competence. We would continue to accept a recent pass of the International English Language Testing System (IELTS) as evidence.

Overview of the Occupational English Language Test (OET)

The OET is the only English language test specifically for healthcare professionals. There are 12 different versions of the OET, to test health practitioners from the following 12 professions: nursing, medicine, dentistry, occupational therapy, optometry, physiotherapy, pharmacy, radiotherapy, speech pathology, podiatry, dietetics and veterinary science. The NMC and GMC already accept the OET as evidence of an applicant's English language competence as an alternative test to the IELTS test.

The OET like IELTS is part-owned by Cambridge Assessment English. The OET for Pharmacy is applicable to both pharmacists and pharmacy technicians and is accepted by pharmacy regulators such as the Pharmacy Board of Australia and the Pharmaceutical Society of Ireland.

The OET differs from IELTS in that it assesses language skills using real healthcare communication scenarios that candidates are likely to meet in the workplace.

The OET meets our criteria in that the test:

- Is objective, independent and robust.

The test materials are developed by expert test writers in collaboration with subject matter experts, including practising pharmacy professionals and academics from pharmacy schools and training programs. The OET is delivered at more than 145 test venues in 44 countries using secure test facilities and trained staff. Additional features include robust candidate identity and malpractice checks and tests assessed centrally.

- Tests candidates' ability to read, write, listen and speak in English.

The Writing and Speaking sub-tests are specific to pharmacy while the Reading and Listening tests cover general health-related subjects.

- Is readily verifiable by us.

The OET programme provides a secure results verification portal for recognising organisations to check the authenticity of an applicant's OET results online in a quick, secure and reliable way.

The Structure and Content of the OET

OET was developed with a focus on the ability to communicate in the workplace.

For example, a candidate taking the Pharmacy speaking test might be required to reassure an anxious patient or explain a technical process in lay person's terms.

There is a separate sub-test for each skill area assessed by OET: Listening, Reading, Writing and Speaking.

Test format overview Sub-test (duration)	Content	Shows candidates can:
Listening (40 minutes)	3 parts Common to all 12 professions	Follow and understand a range of health-related spoken materials such as patient consultations and workplace communication.

Test format overview Sub-test (duration)	Content	Shows candidates can:
Reading (60 minutes)	3 parts Common to all 12 professions	Read and understand different types of text on health-related subjects.
Writing (45 minutes)	1 task Specific to each profession	Write a letter in a clear and accurate way which is relevant for the reader.
Reading time: 5 minutes **Writing time: 40 minutes**		
Speaking (20 minutes)	2 tasks Specific to each profession	Effectively communicate in a real-life context using role-plays.

For further details of the structure of the OET please see Annex 1

How the OET Results compare to the IELTS scores we accept

For an IELTS test certificate to be acceptable as evidence of an applicant's English language competence it must evidence a recent pass of the academic version of the IELTS test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test.

There is no overall grade for OET. In the OET candidates receive a separate grade for each sub skill of language proficiency – Listening, Reading, Writing and Speaking. Grades are scored on a numerical scale 0 – 500 alongside an alphabetic score range from A (highest) to E (lowest).

Below are the OET Scores compared to IELTS scores and level descriptors for each grade[3].

IELTS	Numerical score	Alphabetical score	Band descriptor
8.0 - 9.0	450 – 500	A	Can communicate very fluently and effectively with patients and health professionals using appropriate register, tone and lexis. Shows complete understanding of any kind of written or spoken language.
7.0 – 7.5	350 - 440	B	Can communicate effectively with patients and health professionals using appropriate register, tone and lexis, with only occasional inaccuracies and hesitations. Shows good understanding in a range of clinical contexts.

[3] Lim,G. The OET and IELTS: A Benchmarking Report. Cambridge Assessment English, UK 2016(2016, updated October 2017).

IELTS	Numerical score	Alphabetical score	Band descriptor
6.5	300 - 340	C+	Can maintain the interaction in a relevant healthcare environment despite occasional errors and lapses, and follow standard spoken language normally encountered in his/ her field of specialisation.
5.5 – 6.0	200- 290	C	
Less than 5.5	100 – 190	D	Can maintain some interaction and understand straightforward factual information in his/ her field of specialisation but may ask for clarification. Frequent errors, inaccuracies and mis- or overuse of technical language can cause strain in communication.
	0 – 90	E	Can manage simple interaction on familiar topics and understand the main point in short, simple messages, provided he/ she can ask for clarification. High density of errors and mis- or overuse of technical language can cause significant strain and breakdown in communication.

A score of at least a B in each of the four areas of reading, writing, listening and speaking in the Pharmacy OET equates to a score of at least 7.0 in the IELTS.

Revision to our guidance on evidence of English language skills

In this consultation we are proposing to revise our Guidance on evidence of English language skills to include a recent pass of the Pharmacy Occupational English Language Test (OET) as evidence of English language competence. We would continue to accept a recent pass of the International English Language Testing System (IELTS) as evidence.

We currently accept a recent pass of the academic version of IELTS with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test. In the case of the OET we are proposing that we would accept a recent pass of the Pharmacy version of the test with at least a score of B in each of the four areas of reading, writing, listening and speaking at one sitting of the Pharmacy OET.

This would mean that in the case of non-EEA qualified pharmacist applicants the Pharmacy OET would be accepted as an alternative to IELTS for eligibility to start the Overseas Pharmacists' Assessment Programme and registration purposes. Applicants must score at least B in each of the four areas of reading, writing, listening and speaking at one sitting of the test.

In the case of EEA qualified pharmacists and pharmacy technicians and non-EEA qualified pharmacy technicians the Pharmacy OET would be accepted as an alternative to IELTS for registration purposes. Applicants must score at least B in each of the four areas of reading, writing, listening and speaking at one sitting of the test.

Where we receive an allegation or have concerns that a registrant may not have the necessary knowledge of English, the Registrar, Investigating Committee or Fitness to Practise Committee can require the registrant to pass either the academic version of the IELTS or the Pharmacy OET and provide evidence of having achieved the accepted pass scores at one sitting of the test.

A draft of the revised guidance on evidence of English language skills can be found at XXXX

Annex 1 - Details of each sub-test of the OET

Listening sub-test

The Listening sub-test consists of three parts:

Part A Consultations: Part A consists of an audio-recorded, simulated professional-to-patient consultation with gap-fill (short answer) questions, covering a partial case history.

Part B Workplace Communication: Part B consists of an audio-recorded exchange, professional-to-professional interaction with multiple-choice questions.

Part C Short talk/interview: Part C consists of an audio-recorded short talk or interview on a healthcare topic with multiple-choice questions.

The audio recordings include a wide-range of English-speaking accents, including Australian, New Zealand, British, Irish and North American voices

Reading sub-test

The reading sub-test consists of three parts:

Part A Workplace Texts: is a summary reading task on workplace text, requiring candidates to skim and scan 4 short texts (a total of about 650 words) related to a single health-related topic and to answer matching, gap-fill and short answer questions types. Candidates are required to write responses for 25-35 gaps in total, within a (strictly monitored) time limit of 15 minutes. This expeditious reading task is designed to test the candidate's ability to source information from multiple texts, to synthesise information in a meaningful way and to assess skimming and scanning ability under a time limit.

Part B & C Workplace Texts: candidates are required to read two passages (600-800 words each) on general health topics and answer multiple choice questions for each text (a total of 16-20 questions) within a time limit of 45 minutes. Part B & C are designed to assess candidates' ability to read, in greater detail, general and specific information for comprehension.

Writing sub-test

The Writing sub-test involves a task in which candidates, via interaction with a set of clinical case notes, produce a letter (usually of referral) to another professional. The letter must record treatment offered to date and the issues to be addressed by the other professional, following instructions given within the test. The letter must take account of the stimulus material presented in the case notes.

The body of the letter must consist of approximately 180-200 words and be set out in an appropriate format (duration - 45 minutes).

Speaking sub-test

The OET Speaking sub-test is a test of the candidate's oral use of English language to communicate in a simulated health-related consultation.

The simulated consultation is between a patient and a health practitioner, with the candidate taking the role of the pharmacist or pharmacist technician and the interlocutor taking the role of

the patient or patient's relative or carer. The candidate and the interlocutor interact face-to face. It consists of two simulated consultations in the form of two role-plays.

Response to the consultation on revised Guidance on evidence of English language skills

We welcome your views on the following questions. Please go to **www.pharmacyregulation.org/xx** to fill in the online survey.

Background questions

First, we would like to ask you for some background information. This will help us to understand the views of specific groups, individuals and organisations and will allow us to better respond to those views.

Are you responding:

as an individual

on behalf of an organisation

Section A: Responding as an individual

Please tell us your:

first name:

surname:

email:

Where do you live?

England

Scotland

Wales

Northern Ireland

Other

If you selected 'other', please say where:

Are you responding as:

a pharmacist?

a pharmacy technician?

a member of the public?

other?

If you selected 'other', please explain:

Free text box

Sector

Please choose the option below which best describes the area you mainly work in.

Community pharmacy (including online)

Hospital pharmacy

Prison pharmacy

GP practice

Care home

Primary care organisation

Pharmaceutical industry

Research, education or training

Other

If you selected 'other', please say what area you mainly work in:

Free text box

Size of community pharmacy

Which of the following best describes the community pharmacy you work in (or own)? *

Independent pharmacy (1 pharmacy)

Independent pharmacy chain (2-5 pharmacies)

Small multiple pharmacy chain (6-25 pharmacies)

Medium multiple pharmacy chain (26-100 pharmacies)

Large multiple pharmacy chain (Over 100 pharmacies)

Online- only pharmacy

Section B: Responding on behalf of an organisation

The questions that follow in this section are standard inclusions but will be finalised following discussion with Data and Insight (Research) team.

Do you want any part of your response to stay confidential? Important: we cannot guarantee that we can maintain confidentiality in all circumstances.

Yes

No

Please explain which parts you would like to keep confidential and why the information you have given is confidential.

Free text box

Please tell us your:

first name:

surname:

job title:

organisation:

address:

email:

Type of organisation

Please choose the option below which best describes your organisation.

Organisation representing patients or the public

Organisation representing pharmacy professionals or the pharmacy sector

Registered pharmacy

NHS organisation or group

Research, education or training organisation

Government department or organisation

Regulatory body

Other

If you selected 'other', please specify say what type of organisation you work for:

Free text

Type of registered pharmacy

Which of the following best describes the registered pharmacy you represent?

Independent community pharmacy (1 pharmacy)

Independent community pharmacy chain (2-5 pharmacies)

Small multiple community pharmacy chain (6-25 pharmacies)

Medium multiple community pharmacy chain (26-100 pharmacies)

Large multiple community pharmacy chain (Over 100 pharmacies)

Online- only pharmacy

Hospital pharmacy

Prison pharmacy

Other

If you selected 'other', please describe your pharmacy:

Free text

Consultation questions

Question 1

We are proposing to accept a pass of the Pharmacy Occupational English Language Test (OET) as evidence of English language competence. This evidence can be used for registration purposes and where we receive an allegation or have concerns that a registrant may not have the necessary knowledge of English. We would continue to accept the International English Language Testing System (IELTS) as evidence.

Do you agree or disagree that the GPhC should accept the Pharmacy OET as evidence of English language competence?

AGREE/DISAGREE/DON'T KNOW

Question 2

What is the reason for your answer?

Question 3

Do you agree or disagree that the GPhC should define an acceptable pass of the Pharmacy OET as a score of at least a B in all four areas of reading, writing, listening and speaking in one sitting of the test?

AGREE/DISAGREE/DON'T KNOW

Question 4

What is the reason for your answer?

Equality and impact questions

Question 5

We want to understand whether our proposals may have a positive or negative impact on any individuals or groups sharing any of the protected characteristics in the Equality Act 2010.

The protected characteristics are:

• age

• disability

• gender reassignment

• marriage and civil partnership

• pregnancy and maternity

• race/ethnicity

• religion or belief

• sex

• sexual orientation

What type of impact do you think our proposals will have on individuals or groups who share any of the protected characteristics?

POSITIVE IMPACT/NEGATIVE IMPACT/POSITIVE OR NEGATIVE IMPACT/NO IMPACT/DON'T KNOW [for each characteristic]

Question 6

We also want to know if our proposals will have any other impact on any other individuals or groups (not related to protected characteristics) – for example, patients, pharmacy owners or pharmacy staff.

Do you think our proposals will have a positive or negative impact on any other individuals or groups?

YES – POSITIVE IMPACT/YES – NEGATIVE IMPACT/ YES – POSITIVE AND NEGATIVE IMPACT/NO IMPACT/DON'T KNOW

Question 7

Please give comments explaining your answers to questions 5 and 6 above. Please describe the individuals or groups concerned and the impact you think our proposals would have.

Receiving updates

We would like to email you to update you on the progress of this consultation as well as about the other work of the GPhC. Please tell us below if you would like to be contacted in the future.

- ☐ I would like to be contacted with updates on the consultation on the guidance to ensure a safe and effective pharmacy team

- ☐ I would like to be contacted with news and information about other consultations from the GPhC

Please give us an email address for updates and communications from the GPhC. Important: you can unsubscribe from our mailing list at any time by clicking on the 'unsubscribe' option within the email.

[   ]

Equality monitoring

At the GPhC, we are committed to promoting equality, valuing diversity and being inclusive in all our work as a health professions regulator, and to making sure we meet our equality duties.

We want to make sure everyone has an opportunity to respond to this consultation on revised Guidance on evidence of English language skills. This equality monitoring form will give us useful information to check that this happens.

Your answers will not be linked to your consultation responses. You do not have to answer these questions if you would prefer not to.

What is your sex?

Please tick one box

- ☐ Male
- ☐ Female
- ☐ Other
- ☐ Prefer not to say

What is your sexual orientation?

Please tick one box

- ☐ Heterosexual/straight
- ☐ Gay woman/lesbian

☐ Gay man

☐ Bisexual

☐ Other

☐ Prefer not to say

Does your gender identity match your sex as registered at birth?

Please tick one box

☐ Yes

☐ No

☐ Prefer not to say

Do you consider yourself disabled?

Disability is defined in the Equality Act 2010 as 'physical or mental impairment, which has a substantial and long-term adverse effect on a person's ability to carry out normal day-to-day activities'.

Please tick one box.

☐ Yes

☐ No

☐ Prefer not to say

What is your age group?

Please tick one box

☐ 16 – 24 years

☐ 25 – 34 years

☐ 35 – 44 years

☐ 45 – 54 years

☐ 55 – 64 years

☐ 65+ years

☐ Prefer not to say

What is your race/ethnicity?

Choose the option that best describes your ethnic group/cultural background. Please tick one box.

White

☐ British

☐ Irish

☐ Gypsy or Irish traveller

☐ Other white background (please fill in the box at the end of this section)

Black or Black British

☐ Black Caribbean

☐ Black African

☐ Other black background (please fill in the box at the end of this section)

Mixed

☐ White and black Caribbean

☐ White and black African

☐ White and Asian

☐ Other mixed background (please fill in the box at the end of this section)

Asian or Asian British

☐ Indian

☐ Pakistani

☐ Bangladeshi

☐ Chinese

☐ Other Asian background (please fill in the box at the end of this section)

Arab

☐ Arab

Other

☐ Prefer not to say

☐ Other ethnic group background (please give more information in the box below)

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What is your religion?

Please tick one box

☐ Buddhist

☐ Christian

☐ Hindu

☐ Jewish

☐ Muslim

☐ Sikh

☐ None

☐ Other (please give more information in the box below)

☐ Prefer not to say

Temporary registration arrangements

Meeting paper for Council on 12 March 2020

Public

Purpose

To seek agreement from Council for our updated policy on temporary registration arrangements for pharmacy professionals that could be invoked in the event of an emergency.

Recommendations

The Council is asked to:

agree the updated policy attached at Annex A

1.   Background

1.1   Under the Pharmacy Order 2010, we have powers to register on a temporary basis fit, proper and suitably experienced people to act as pharmacists and pharmacy technicians if an emergency is declared by the Secretary of State. We also have powers to annotate the entries of registrants during an emergency.

1.2   Following the outbreak of the coronavirus (Covid-19), the UK Government and the devolved administrations have set out an action plan and highlighted the stages of response: contain (the current phase), delay, research, and mitigate. The action plan highlights the possibility of healthcare professionals who have retired or recently left their roles returning to them to alleviate pressures and contribute to providing essential services. In light of this, we have undertaken a review of our earlier temporary registration policy which was produced several years ago and out of context from the current situation.

1.3   A draft policy is attached at Annex A. This sets out the legal basis for temporary registration; the approach we will take to identifying the groups of people that we would register temporarily and the application of the policy in practice. The policy sets out that we would focus on those groups of people who had previously demonstrated the required knowledge and skills to practise as a pharmacist or pharmacy technician and who have recent experience of pharmacy practice. As an illustration of the potential numbers, phase one of our proposed approach would mean approximately 2,700 pharmacists and 1,300 pharmacy technicians would become eligible to practise if recent experience was defined as two years.

Phase two would add a further 900 pharmacists and 900 pharmacy technicians using the same timeframe.

1.4   It is important to note that the GPhC has no role or powers in relation to questions around workforce deployment or the contractual basis on which temporarily-registered pharmacists and pharmacy technicians may be asked to work. Likewise, the clinical and organisational governance of the temporary additional workforce are issues to be managed by other authorities, subject to our being mindful of the relevance of the *Standards for Registered Pharmacies,* where relevant in specific contexts.

1.5   Under the Medicines Act 1968, we also have the power to temporarily register premises. At this stage, there are no indications that additional premises may be necessary but we will keep this under review.

2.   Equality and diversity implications

2.1   The approach we are proposing has no specific equality and diversity implications.

3.   Communications

3.1   We have published a joint statement with other regulators setting out our overall approach to emergency situations in the particular context of Covid-19. We will use our communication channels to provide information to registrants, patients and the public and others about temporary registration before, during and after an emergency if one is declared. These communications would need to cover a number of matters, including the application of relevant standards, including indemnity/insurance requirements.

4.   Resource implications

4.1   We do not have any specific fees covering this scenario. In any event, if the powers need to be used, we would expect the costs to be absorbed by the organisation, as part of the GPhC's contribution to the national emergency response.

5.   Risk implications

5.1   Failing to agree a policy on temporary registration would mean we were unable to act immediately on declaration of an emergency by the Secretary of State. The interdependency with the declaration of an emergency at that senior government level inherently recognises a national choice about the balance of risk in an emergency situation.

6.   Monitoring and review

6.1   We are maintaining close contact with the Department for Health and Social Care and with the Devolved Administrations through our Directors for Scotland and Wales. If an emergency is declared, we will monitor the application of the policy throughout its duration.

7.   Recommendations

The Council is asked to:

agree the updated policy attached at Annex A

Mark Voce, Director of Education and Standards
General Pharmaceutical Council

Mark.Voce@pharmacyregulation.org

04 March 2020

Policy on temporary registration arrangements in the event of an emergency involving loss of human life or human illness

Introduction

We have powers to register fit, proper and suitably experienced people to act as pharmacists and pharmacy technicians on a temporary basis if an emergency is declared by the Secretary of State.

We also have powers to annotate the entries of registrants in Part 1 and Part 2 of the register during an emergency. These powers will cease when the emergency ends.

Policy purpose

Under article 34 of the Pharmacy Order 2010, the Registrar may temporarily enter in Part 1 (pharmacists) or Part 2 (pharmacy technicians) of the Register persons or specified groups of persons considered fit, proper and suitably experienced during an emergency.

Under article 35 of the Pharmacy Order 2010, the Registrar may temporarily annotate entries in Part 1 (pharmacists) or Part 2 (pharmacy technicians) of the Register persons or specified groups of persons considered fit, proper and suitably experienced during an emergency.

The purpose of this policy is to identify the persons or specified groups of persons considered fit, proper and suitably experienced to be temporarily registered or annotated during an emergency.

It is important to note that we do not have powers to **require** people who are temporarily registered to return to practise and recognise that people would be doing so on a voluntary basis to help their community, taking account of their own experience and health.

Policy statement

Our approach is based on the need to maximise the number of fit, proper and suitably experienced people while minimising risks to patient safety. We need to act quickly and implement a simple and straightforward plan which minimises delay and is easy to understand.

On declaration of an emergency by the Secretary of State, our priority will be to temporarily register those people who have previously demonstrated the required **knowledge and skills** to practise as a pharmacist or pharmacy technician and who have **recent experience** of pharmacy practice.   Registration will be done in phases which may be combined depending on the scale of the emergency and the pharmacy services required. In terms of recent experience, we will set out in each phase the relevant number of years that a person has been off the register to ensure clarity and will consider whether the number of years may need to be increased in further phases depending on the scale of the emergency and an assessment of patient safety.

On the declaration of an emergency by the Secretary of State, the Registrar may register the following groups for the duration of the emergency:

 Phase 1

Pharmacist registration (Part 1 of the Register)

Former pharmacist registrants who were recently voluntarily removed and whose fitness to practise is not impaired.

Pharmacy technician registration (Part 2 of the Register)

Former pharmacy technician registrants who were recently voluntarily removed and whose fitness to practise is not impaired

Phase 2

Pharmacist registration (Part 1 of the Register)

Former pharmacist registrants who were recently removed for non-renewal of registration and whose fitness to practise is not impaired

Pharmacy technician registration (Part 2 of the Register)

Former pharmacy technician registrants who were recently removed for non-renewal of registration within the last two years and whose fitness to practise is not impaired

Additional phases

In an emergency, we recognise that there may be a demand for additional categories of people to be registered temporarily or to temporarily annotate entries. This may mean including people who have demonstrated many, but not all, of the required knowledge and skills or who have less

recent experience of pharmacy practice. We will maintain close contact with the UK Government and Devolved Administrations to identify whether any further categories of people may need to be registered or annotated.

Standards

All persons entered temporarily on the register will be required to meet the standards for pharmacy professionals. As part of this, they will be required to work within their areas of competence and make clear to their employer if there are specific tasks or practices that they do not feel competent to undertake, perhaps due to developments that have taken place in pharmacy practice since their previous removal from the register.

Application of policy

On declaration of emergency we will enact the policy by publishing the temporary register on our website enabling the individuals themselves and employers to check eligibility. We will produce short guidance for employers to ensure they are aware of their responsibilities for confirming the identity of individuals and to ensure that issues such as indemnity insurance are appropriately addressed. We will use our communication channels to provide information to registrants, patients and the public and others about temporary registration before, during and after an emergency

Measurement and evaluation

After an emergency, we will hold a review on the implementation of this policy and seek feedback from staff, registrants, patients and the public and other stakeholders.

The policy will be evaluated on an annual basis to review if the persons and groups identified are still considered fit, proper and suitably experienced to be temporarily registered or annotated during an emergency.

The policy will be reviewed if there are any amendments or additions to the categories of annotation to Part 1 or Part 2 of the Register.

GPhC
March 2020

Terms of reference of the Audit and Risk and Finance and Planning Committees

Meeting paper for Council on 12 March 2020

Public business

Purpose

This paper proposes minor revisions to the Terms of Reference of the Audit and Risk Committee (ARC) and the Finance and Planning Committee (FPC).

Recommendations

The Council is asked to approve the revised Terms of Reference for the ARC and the FPC.

1. Introduction

1.1   The Terms of Reference of the Council's non-statutory committees (ARC, FPC and the Remuneration Committee) are reviewed in June each year when the committees submit their annual reports to Council.

1.2   The allocation of members to committees for 2020-21 means that there will be six people sitting on both the ARC and the FPC (five Council members and one external member in each case). The current Terms of Reference state that each committee "shall have five members" (including the external) and therefore need to be updated.

2. Additional members for 2020-21

2.1   The current membership numbers for the ARC and FPC mean that not all Council members sit on a committee. In order to facilitate this, it is suggested that the membership of each committee is increased to six.

2.2   The requirements for there to be at least one lay and one registrant member on each committee will remain, as will the provision for ARC to have up to two external members with audit and risk management experience and the provision for FPC to have one external member with investment experience.

2.3   Finally, it will remain the case that the Chair of the Council can be a member of the FPC but cannot be a member of the ARC.

2.4 The proposed update to the ARC Terms of Reference are highlighted in the version attached at **Annex A** and the proposed update to the FPC Terms of Reference are highlighted in the version attached at **Annex B**.

3. Equality and diversity implications

3.1 Increasing the number of members on each committee by one allows each member of Council the opportunity to bring their skills, abilities and experiences to bear in committee as well as at Council meetings and broadens the range of views at committee discussions.

4. Communications

4.1 The Terms of Reference for the Committees are available on the GPhC website.

5. Resource implications

5.1 The proposed change will mean that six people will be entitled to claim expenses for attending committee meetings. This is not a significant addition and there is money available in the relevant budget for this.

6. Risk implications

6.1 Without this change there is a risk that the Council will not be able to make the best use of the skills and experience of all its members. Increasing the number of members on a committee also reduces the risk of the committee not being quorate at any given meeting.

7. Monitoring and review

7.1 The Terms of Reference of all the non-statutory committees are reviewed every year.

8. Recommendations

The Council is asked to approve the revised Terms of Reference for the ARC and the FPC.

Janet Collins, Governance Manager
General Pharmaceutical Council

28 February 2020

Terms of reference of the Finance and Planning Committee

Effective from April 2020

1. Role and purpose

1.1 The Council has established the Finance and Planning Committee to provide the Council with assurance on the continuing efficiency and effectiveness of the organisation, and to support the Council by overseeing and monitoring the implementation of the GPhC's investment strategy and policy.

1.2 The Committee is a non-executive committee and has no executive powers except as set out in these Terms of Reference.

1.3 The Council is ultimately responsible for determining and reviewing the overall investment policy, objectives, risk appetite and target returns. However, the investment portfolio represents an important asset for the GPhC and the Committee fulfils an important role in the long-term stewardship of those assets. Administration of the GPhC's financial and other resources is delegated to the Chief Executive & Registrar.

1.4 Under the Council's Scheme of Delegation, the Committee has delegated authority to:

- Oversee the organisation's business and financial planning, to ensure that it aligns with the overall strategy set by the Council.

- Review the organisation's ongoing work to improve the efficiency and effectiveness of the GPhC, including any metrics, evaluation and benchmarking.

- Oversee and monitor the investment strategy and policy, including the GPhC's ethical policy, to ensure it remains appropriate, and to recommend any changes to Council.

- Make recommendations to Council regarding the appointment or termination of investment managers, where appropriate.

- Monitor and evaluate the performance cost and cost-effectiveness of services provided by investment managers appointed by the Council.

- Oversee the GPhC's internal business improvement investment activities, including reviewing the organisation's business and financial planning, and work to improve its efficiency and effectiveness.

- Ensure that all policies and work within the Committee's remit take account of and promote the GPhC's culture and values, and commitment to equality, diversity and inclusion.

- Report annually to the Council on the activities of the Finance and Planning Committee.

1.5   The Committee may request the attendance of any employee or member, as set out in section 5 of these Terms of Reference, and may incur expenditure for the purpose of obtaining advice, where required.

2.   Duties and activities

2.1   The group's primary activities in relation to investment are set out in more detail at **Annex A**.

3.   Accountability and reporting

3.1   The Committee is accountable to the Council. The minutes of each Committee meeting shall be circulated to Council in confidential business. The Committee shall report to the Council annually on its work.

4.   Membership

4.1   The Committee shall have no more than six members, but may operate with fewer while a vacancy exists, provided the quorum is maintained. Committee members may include the Chair of Council, Council members, and include at least one lay member and one registrant member. The group may also include one external member with appropriate skills and investment experience.

4.2   The Council will appoint one of the Council members serving on the group as Chair, based on relevant background and skills. In the absence of the Chair, the Committee shall elect another of its members to chair the meeting.

4.3   The Committee, including its Chair, is appointed through arrangements agreed by the Council. This will be carried out in line with the Appointment of members of the non-statutory committees (Audit & Risk, Remuneration Committees and the Finance and Planning Committee policy (reference 0021).

5.   Quorum

5.1   The Committee will be quorate with two members of Council.

6.   Attendance

6.1   Only members shall be entitled to attend Committee meetings. The Chief Executive & Registrar, and the Associate Director of Finance and Procurement will attend the meetings along with other key members of staff, as necessary.

6.2   Other Council members may attend meetings at the invitation of, or with the agreement of, the Chair of the Committee.

6.3   The Committee may request any employee or member to attend a meeting to assist with its discussions on any particular matter or to provide any information it may reasonably require in order to fulfil its remit. All employees and members are directed to co-operate with any reasonable request made by the Committee.

6.4   The Committee may ask any or all non-members to withdraw for all or part of a meeting if it so decides. In such an instance, the Chair shall ensure that a proper record is made of the meeting.

6.5   Investment managers who are appointed to manage investment funds on behalf of the GPhC will be expected to attend Committee meetings, as required.

7.   Secretariat

7.1   The Chief Executive & Registrar shall ensure that appropriate secretariat support is provided to the Chair and to the Committee.

8.   Frequency of meetings

8.1   The Committee shall meet not less than four times a year. Additional meetings may be scheduled if necessary.

9.   Dealing with concerns

9.1   Processes have been agreed by Council for raising concerns (Raising concerns policy ref: 0022)

9.2   Within these processes, the Chair of the Committee is identified as a point of contact for individuals who still have concerns having followed the policy or where they feel matter is so serious that is cannot be discussed by senior management.

9.3   Further information on how matters are handled is detailed within the Raising Concerns policy. The Chair of the Committee will receive appropriate training in this area.

Key investment activities

In relation to the GPhC's investment portfolio, the Committee is responsible for:

a. Ensuring the management of assets is consistent with the investment strategy and policy set by Council.

b. Monitoring the investment strategy and policy, including the ethical policy, to ensure it remains appropriate, and to recommend changes to Council where necessary. This includes scrutinising the implementation of any changes approved by the Council.

c. Agreeing the terms of appointment of the investment managers. This includes the level of portfolio management discretion and fee scales.

d. Setting and reviewing with the investment managers appropriate investment mandates, ensuring consistency with the investment strategy and policy. This includes setting performance benchmarks for investment managers and monitoring performance over relevant time periods.

e. Monitoring the organisation's response to legislative, financial and economic changes affecting, or potentially affecting, investment policy. The Committee may engage external professional advisers to undertake a periodic review of the investment arrangements, as required.

f. Reviewing the investment policy so that it remains consistent with, and supportive to, Council's overall business plan, budget and reserves policy. This includes periodically reviewing the fees paid and appraising value for money.

g. Reviewing the Investment Risk Register, taking into account the Council's agreed risk appetite.

h. Reporting annually to the Council on investment performance.

Policy author:	Duncan Rudkin
Job title:	Chief Executive & Registrar
Policy reference:	GPhC0035
Effective from:	[select effective date]
Review date:	31 March 2021

Agreed by:	Council on 11 April 2019
Reviewed:	Council – 12 March 2020

Deputising arrangements for Chair of Council

Meeting paper for Council on 12 March 2020

Public

Purpose

To note the deputising arrangements for the Chair of Council

Recommendations

The Council is asked to note the arrangements for the deputy Chair, should the Chair be unavailable.

1.   Introduction

1.1   In February 2010 the Council agreed to establish a rota of Council members to deputise for the Chair if required. It was agreed that a rota of volunteers, chosen at random, was more appropriate than a formal election process, given that the need for a deputy would arise only if the Chair was absent or unable to perform his or her duties. This system would also avoid the impression that there was a 'Deputy Chair' with a different role and status from other Council members.

1.2   It was also agreed that a rotation every six months, agreed in advance, would allow arrangements to be made quickly should the Chair be unexpectedly absent.

2.   Deputising rota for 2020-21

2.1   The current rota expires at the end of March 2020. The new rota to cover the next twelve months is as follows (the rota for the last five years is included for reference):

New rota:

Name	Deputising start date	Deputising end date
Elizabeth Mailey	01 April 2020	30 September 2020
Aamer Safdar	01 October 2020	31 March 2021

Current and previous rotas:

Name	Deputising start date	Deputising end date
Jayne Salt	01 October 2019	31 March 2020
Mark Hammond	01 April 2019	30 September 2019
Samantha Quaye	01 October 2018	31 March 2019
Joanne Kember	01 April 2018	30 Sep 2018
Mohammed Hussain	01 October 2017	31 March 2018
Arun Midha	01 April 2017	30 September 2017
Mary Elford	01 October 2016	31 March 2017
David Prince	01 April 2016	30 September 2016
Evleyn McPhail	01 October 2015	31 March 2016
Digby Emson	01 April 2015	30 September 2015

3. Equality and diversity implications

3.1 There are no specific equality and diversity implications.

4. Communications

4.1 Council members and staff need a clear understanding of the arrangements for deputising for the Chair, if required. These will be communicated to staff via the intranet.

5. Resource implications

5.1. These arrangements are to provide cover for single events over short periods of time and as such have no specific resource implications. Should the position of Chair become vacant for a longer period of time, other arrangements would need to be put in place.

6. Risk implications

6.1 If the Council does not have a process in place for identifying a deputy in advance should the need arise, it runs the risk of having no leadership for a period of time should the Chair be absent without warning or the position of Chair become temporarily vacant for any reason. These arrangements mitigate that risk.

7. Monitoring and review

7.1 The rota is considered annually.

8.   Recommendations

The Council is asked to note the arrangements for the deputy Chair, should the Chair be unavailable.

Janet Collins, Governance Manager
General Pharmaceutical Council

10 February 2020

Procedure for dealing with complaints against statutory committee members

Meeting paper for Council on 12 March 2020

Public

Purpose

To seek the Council's approval on the revised Complaints Policy for statutory committee members and following consideration of recommendations made by Council on 12 February 2020.

Recommendations

The Council is asked to approve the following policy:

  i.   Procedure for dealing with complaints against statutory committee members (SCMs).

1.   Introduction

1.1   The GPhC (Statutory Committees and their Advisers) Rules 2010 (the Rules) require that the Council determine the procedure for the suspension or removal of a member of the Statutory Committee and the removal of a person from the reserve list.

1.2   A complaint was made against two SCMs in 2018. This complaint was dealt with under the existing procedure for the suspension and removal of SCMs. Feedback from the members concerned was that the existing procedure was not proportionate in that it did not include an informal mechanism for dealing with complaints, focusing solely on the possibility of suspension and removal.

1.3   Subsequently the Assurance and Appointments Committee has developed a complaints procedure that incorporates an informal approach to dealing with less serious complaints as well as a procedure for suspending and removing SCMs as required by the Rules.

1.4   On the advice of the GPhC's Governance Team, this procedure has been fully consulted on with all SCMs. It has subsequently been further reviewed by the GPHC's Governance Team and has been agreed by the Assurance and Appointments Committee.

1.5   Once the Council have approved the procedure it will be circulated to all SCMs (full and reserve) as required by the Rules.

2. Key Considerations

2.1 The Council is asked to approve the procedure for dealing with complaints against statutory committee members.

2.2 Council considered the policy on 12 February 2020, and made the following recommendations:

1. At paragraph 5.9 of the policy, the AAC should set out the dismissal of a complaint as an outcome;

2. there should be consideration of an appeals process;

3. there should be consideration of a joint policy with Council Members.

2.3 The General Pharmaceutical Council (Statutory Committees and their Advisers Rules (Order for Council 2010) does not envisage an appeal process and therefore our legal interpretation is that there is no power to have such a process. The policy has however been amended to make it clear a complainant and/or member/reservist can question the process followed by the AAC but not the decision reached by the AAC.

The Rules at paragraph 14 provide for a specific process for suspension and removal of Statutory Committee Members and persons on the reserve list. It is therefore necessary to have a separate policy for statutory committee members from Council Members in accordance with this legislation.

3. Equality and diversity implications

3.1 Equality and diversity implications have been considered in the updating of individual policies and the changes recommended in this paper do not raise any specific equality or diversity issues.

3.2 This policy sets out the expectations of SCMs and the role of the Assurance and Appointments Committee and its Chair when dealing with complaints against SCMs in alignment with the Rules.

4. Communications

4.1 Subject to approval by the Council, we will publish the updated policy on our intranet and raise awareness through a variety of mechanisms including the SCM Newsletter – received by all members. Policies affecting non-staff will also be shared through the relevant channels.

5. Resource implications

5.1 There are no specific resource considerations associated with the policy and procedure review. Subject to approval by the Council, we will publish the updated policies on our intranet and raise awareness through a variety of mechanisms including the Capsule - our all staff e-newsletter.

6. Risk implications

6.1 It is essential that our policies and procedures are fit for purpose and reflect the Rules, current legislation or other good practice guidance. It is also important that policies are

clear, published in an accessible format, and circulated appropriately, so that Associate and Partners understand their responsibilities and what they can expect from the organisation.

7. Monitoring and review

7.1 Each policy has a review date at which point the effectiveness of the policy is reviewed as well as currency with relevant guidance and best practice. Policies are reviewed earlier if there are changes in legislation or other processes, which need to be reflected.

8. Recommendations

The Council is asked to approve:

The procedure for dealing with complaints against statutory committee members (SCMs).

Melissa Nurse-Barrow, Associates and Partners Manager
Melissa.Nurse-Barrow@pharmacyregulation.org

General Pharmaceutical Council

04 March 2020

Procedure for dealing with complaints against statutory committee members

GPhC09AAC Version 2.0

This policy sets out the procedure for dealing with complaints about statutory committee members.

Policy details

Policy reference	GPhC09AAC
Version	2.0
Policy author	Clare-Mitchell, Interim Associates and Partners Manager
Approved for issue by	Council, 2020
Effective from	19 March 2020
Next review	19 March 2022

Version control tracker

Version	Approved date	Description of change	Amendments by
1.0	May 2019	New policy	Assurance and Appointments Committee
1.1	December 2019	Revised wording	Laura McClintock
1.2	January 2019	Templated	Melissa Nurse-Barrow
2.0	March 2020	Post Council Recommendations and amendments	Melissa Nurse-Barrow and Paul Cummins

i.   Introduction

1.1   The Council established the Appointments Committee pursuant to its powers in article 4(7) of the Pharmacy Order 2010 for the purpose of exercising the functions conferred on it by the GPhC (Statutory Committees and their Advisers) Rules 2010 and other functions delegated to it by the Council.

1.2   These functions include overseeing the training, development, performance review and appraisal of members, and where appropriate the suspension of members and removal of members or reservists, including chairs and deputy chairs, of the statutory committees.

1.3   The Appointments Committee's working title is the Assurance and Appointments Committee (AAC) and it is referred to as the AAC throughout the remainder of this procedure.

ii.   Purpose

1.2   This document sets out the procedure for dealing with complaints about statutory committee members. Wherever possible the preferred route will be informal resolution and with a focus on reaching a mutually acceptable outcome. However, there will be circumstances in which this is not possible and this document includes the process that will be followed for formal resolution, including the procedure for the suspension and/or removal of a member of a statutory committee, and the removal of a person from the reserve list, on the grounds set out in the GPhC (Statutory Committees and their Advisers) Rules 2010 ("the Rules").

i.   Handling of complaints

3.1   This procedure should be used when a complaint or concern is raised about a statutory committee member (including reserve members), where it is alleged or appears that the conduct of the member or reservist has fallen below the standards expected in the GPhC's Values, Conduct and Behaviour for GPhC Council Members, Associates and Partners. This procedure refers to "complaints" but may apply equally in circumstances where a concern about conduct has come to the GPhC's or the AAC's attention without a complaint being made.

3.2   Complaints about statutory committee members or reservists should be submitted to the Associates and Partners Manager for the attention of the Chair of the AAC. Communications will be channelled through the Associates and Partners team in the first instance.

3.3   The complaint will be acknowledged within three working days of receipt by the GPhC or the AAC Chair. The acknowledgment will advise the complainant of the procedure for handling complaints and seek to obtain their consent to share the complaint with the member or reservist concerned.

3.4   The member or reservist concerned will be informed of the complaint within seven working days of receipt. The member or reservist will be advised of the procedure for handling complaints and that they may wish to seek support from a source external to the GPhC (subject to point 5.8 below). Information provided to the member or reservist about the complaint may be redacted, e.g. if it includes personal information about another individual. The member or reservist will have seven working days to respond.

3.5   The AAC Chair may then request further information from the complainant and/or the member/reservist before making a decision on the most appropriate course of action.

3.6   The following options are open to the AAC Chair following review of the complaint:

*   Dismissal of the complaint (this may include on the basis that the complaint or concern raised is about a minor issue or if the Chair has sound reason to believe the complaint is of a vexatious nature).

*   Resolution by informal means (which should be the preferred route wherever possible) under Stage 1 of this procedure.

*   Where the complaint is so serious that the AAC Chair judges that resolution by informal means is not appropriate the procedure for formal resolution as set out in Stage 2 below will be used.

    The complainant and the member/reservist will be informed of the decision and the next steps.

ii.   Procedure for informal resolution of complaints (Stage 1)

4.1   The Chair of the AAC will seek to resolve the complaint amicably through contact with the interested parties, taking into account any information they may wish to supply. Where appropriate, a meeting will take place between the Chair of AAC, the complainant and the member/reservist concerned. A note taker may be present. This meeting is separate to any formal investigatory meeting that may subsequently be required under paragraph 5.8 of Stage 2 of the procedure.

The outcome of the informal resolution may be:

*   An invitation to the member/reservist to make an apology;

*   A requirement that the member/reservist should undertake additional training;

*   Advice in writing to the member/reservist.

    This is not an exhaustive list and the method of resolution and the outcome is at the discretion   of the AAC Chair.

4.2   The complainant and member/reservist will be informed of the outcome of Stage 1 of the process normally within 20 working days once the outcome of the informal resolution process has been decided.

4.3   If it has not been possible to resolve the complaint informally, or the AAC Chair is of the view that the complaint is so serious that informal resolution is not appropriate, then the matter will be taken forward under Stage 2 of this procedure, set out below.

iii. Procedure for formal resolution including potential suspension or removal (Stage 2i)

<u>Investigation</u>

5.1   If it is not possible/appropriate to resolve the complaint through informal resolution, the AAC Chair may appoint an independent person unconnected with the complaint to carry out the investigation. In the first instance the Chair may seek advice from the GPhC's Governance team.

5.2   The AAC Chair may, at their discretion, refer the complaint to the relevant regulator (e.g. the SRA for legally qualified statutory committee chairs) for consideration under its fitness to practise procedures. The complaint may also be referred to other relevant agencies. Wherever possible the investigation under this procedure will continue to progress. However, each situation will need to be reviewed on a case by case basis, and there may well be situations where the GPhC's investigation needs to be put on hold pending the outcome of a parallel investigation,

5.3   Once the investigation is complete, details of the evidence obtained from the investigation will be shared with the member/reservist and the AAC Chair, who will then convene an investigatory meeting if required. The member/reservist will be offered the opportunity to make written or oral representations on the complaint(s) before the AAC. Oral representations would be made at the investigatory meeting of the AAC as per the arrangements detailed in section 5.8 below.

<u>Suspension during investigation</u>

5.4   Rule 14(3)[4] states that the AAC may suspend a member of a statutory committee while investigations are being undertaken into that member's suitability to remain as a member of that statutory committee.

5.5   In considering whether to exercise the power to suspend the member while investigations are ongoing the AAC Chair shall consider the nature and gravity of the complaint(s) received and whether the failure of the AAC to suspend the member has the propensity to bring the Council into disrepute. If the AAC Chair is of the view that the member should be suspended then they will make a recommendation to the Committee.

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[4] There is no express power within the Rules to allow the suspension of reserve statutory committee members pending an investigation

5.6   If the AAC determines that suspension pending investigation is necessary and appropriate then the member should be promptly notified of the decision to take such action and of the fact that the investigation is ongoing and they will be notified in due course of the outcome of such investigation.

5.7   If the AAC decides to suspend a member whilst investigations are ongoing there is no route of appeal.

The investigatory meeting

5.8   Rule 14(4) states that the AAC must afford any member of a statutory committee, or any person on the reserve list, who is under investigation the opportunity to make written and oral representations before reaching a decision on whether to remove that member from the statutory committee or that person from the reserve list. The member or reservist will be offered the opportunity to meet with the AAC as set out below. The member or reservist may choose to be accompanied at this meeting but it would not be appropriate for a member to be accompanied by a trade union representative or for them to have legal representation as members are not employees of the GPhC and these are not FtP proceedings.

        5.8.1 The AAC will be required to meet to consider the evidence from the investigation and the member or reservist and reach a decision. A note taker must be present.

        5.8.2 The AAC must have a minimum of three members and voting should be done by simple majority. If a member of the AAC abstains from a vote at a meeting then the member's abstention must be treated as a vote against the motion that has been put to the vote.

        5.8.3 The conduct of the meeting (and the procedures to be adopted) is to be determined by the AAC on a case-by-case basis, subject to nature and complexity of the complaint(s), any representations received from the member or reservist, the requirements of fairness and the rules of natural justice.

5.9   Following its consideration of all of the evidence in the case and any representations received from the member/reservist the AAC may:

- Dismiss the complaint;
- Invite the member/reservist to make an apology;
- Require that the member/reservist should undertake additional training;
- Provide advice in writing to the member/reservist
- Formally give a warning to the member or reservist about their future conduct (this warning is separate to a warning under the GPhC's fitness to practise arrangements and does not require declaration by registrant committee members to the GPhC unless otherwise directed by the AAC Chair). The warning will set out that if similar behaviour is repeated, or other causes for concern arise that result in a further warning, then the

cumulative effect of these matters will be the termination of the associateship (in line with Terms of Associateship and Partnership para 18a). Warnings are issued in writing and will be held on file for 12 months after which time they will cease to have effect;

Direct that the member or reservist should be removed from the statutory committee or from the reserve list.

5.10 The AAC will consider whether it is appropriate, necessary or justifiable to share the outcome of the investigation with any other body on which the member or reservist might sit or serve. In each case, the AAC will consider whether it is in the public interest to do so. This includes consideration of the relevant law, our main objectives, and the interests of the individual concerned. In doing so, the AAC may seek advice from the GPhC governance and legal team before proceeding.

5.11 The AAC **must** remove from a statutory committee any member **who in the opinion** of the AAC:

- has ceased to be an appropriate person to be a member of a statutory committee (for example, by reason of misconduct or a criminal conviction);
- has seriously or persistently failed to meet the standards of performance, conduct, attendance or participation in training required of a member of a committee in the ordinary course of a member's duties;
- is unable to perform the duties of a member because of ill health;
- has improperly disclosed confidential information obtained by the member in the course of membership of a statutory committee;
- has brought the Council into disrepute;
- has failed to comply with the code of conduct for statutory committee members; or
  should no longer continue to be a member of a statutory committee in the public interest.

5.12 The AAC **must** also remove from a statutory committee any member who resigns from membership of the statutory committee in question and any member whose term of office for the statutory committee has expired.

5.13 Furthermore, the AAC **must** also remove from the reserve list any person **who in the opinion** of the AAC:

- has ceased to be an appropriate person to be a member of a statutory committee (for example, by reason of misconduct or a criminal conviction);
- is unable to perform the duties of a member because of ill health;
- has brought the Council into disrepute;
  should no longer remain on the reserve list in the public interest.

5.14   The AAC **must** also remove from the reserve list any person who requests removal from the reserve list.

5.15   The member or the reservist should be notified of the AAC's decision and reasons within 14 days. No appeal lies from the decision of the AAC which shall be final.

5.16   Complaints and Feedback Management Policy

There is no right of appeal of the decision of the AAC.   If the Member/Reservist feels that the correct procedure has not been followed, they may raise a complaint via the GPhC's organisational complaints process. They also have the option of seeking independent legal advice.

iv.   Procedure for immediate suspension and removal (Stage 2ii)

6.1   The AAC **must** immediately remove a registrant statutory committee member, full or reserve, who has ceased to be entered in the register. In this circumstance the AAC has no discretion and no investigation is required other than confirmation that the registrant member is no longer entered in the register and the reason for this. The AAC will be presented with this information and asked to formally remove the member. Removal will be confirmed to the member in writing. In these circumstances Stage 2i of this procedure does not apply.

6.2   If restored to the register at a subsequent date, the member may request reappointment by the AAC. This would not be automatic and the AAC would need to consider the circumstances which resulted in the registrant's removal from the register

Update on the 'Report of the Independent Inquiry into the issues raised by Paterson'

Meeting paper for Council on 12 March 2020

Public

Purpose

To update the Council on the 'Report of the Independent Inquiry into the issues raised by Paterson', published February 2020.

Recommendations

The Council is asked to note the update.

1.   Introduction

1.1   As an organisation, we regularly monitor, consider and respond to external inquiries and reports in the health and social care context, even if these do not raise specific issues or make recommendations about the GPhC or the wider pharmacy sector. We do this because we want to apply any relevant lessons to our own work, in order to prioritise and improve patient safety.

1.2   In 2018/19, we had a specific focus on the Report of the Gosport Independent Panel; the PSA Lessons Learned Review into Furness General Hospital; and, the Professor Sir Norman Williams Review of Gross Negligence Manslaughter in Healthcare. We provided the Council with regular progress updates about our work in these areas, through formal papers as well as updates at Council workshops and meetings.

1.3   As part of this work, we have also been monitoring the progress of the independent Inquiry, set up following the conviction of surgeon Ian Paterson. In April 2017, Paterson was convicted of 17 counts of wounding with intent and three counts of unlawful wounding relating to nine women and one man, whom he had treated as private patients between 1997 and 2011. Paterson was sent to prison for 15 years. Later that year, the sentence was increased by the Court of Appeal to 20 years.

1.4   In December 2017, the Government commissioned the independent Inquiry, chaired by Bishop Graham James, to investigate the malpractice and make recommendations to

improve patient safety. Members of the Inquiry team had experience of working on other independent inquiries, including the Hillsborough Independent Panel, the investigation into Jimmy Savile at Leeds Teaching Hospitals, The Independent Inquiry into Child Sexual Abuse and the Gosport Independent Panel.

1.5   The Inquiry's report was subsequently published on 4 February 2020 and presented to Parliament by the Parliamentary Under Secretary of State for Mental Health, Suicide Prevention and Patient Safety, Nadine Dorries.

2.   Key considerations

2.1   We initially updated the Council on the report and key themes during the workshop session on 13 February 2020. This included a commitment to report more formally to the Council at its next meeting on 12 March 2020.

2.2   Overall, the Inquiry made a number of formal recommendations for the Government, employers and for a number of other healthcare regulators. Although the report did not highlight any specific pharmacy, or pharmacy regulation issues, or make recommendations for the General Pharmaceutical Council, we have chosen to reflect on this and to identify any wider learnings with relevance to our own work.

2.3   Below is a short overview of the main findings and recommendations:

- **Information to patients** – patients reported that much of the information they received was unreliable, and the result of hearsay and an inflated local reputation. **The Inquiry recommended** that it should be standard practice that consultants in both the NHS and the independent sector should write to patients, outlining their condition and treatment, in simple language, and copy this letter to the patient's GP, rather than writing to the GP and sending a copy to the patient.

- **Consent** –patients often felt under pressure to decide to go ahead with surgery and options for treatment, including the risks associated with procedures, were not explained clearly before they gave consent for surgery. **The Inquiry recommended** that there should be a short period introduced into the process of patients giving consent for surgical procedures, to allow them time to reflect on their diagnosis and treatment options, and that the GMC monitors this as part of 'Good Medical Practice'.

- **Multidisciplinary teams** - decisions about patients' treatment were either not discussed at properly constituted MDT meetings or when they were discussed, the quality of those discussions varied. **The Inquiry recommended** that CQC, as a matter of urgency, should assure itself that all hospital providers are complying effectively with up-to-date national guidance on MDT meetings and that patients are not at risk of harm due to non-compliance in this area.

- **Clinical indemnity** - medical defence organisations cover the costs of claims and damages awarded to patients. However, they are not subject to financial conduct regulation, and the indemnity cover they provide is discretionary. The Medical Defence Union used its discretion to withdraw cover since Paterson's activity was criminal. This left patients without cover. **The Inquiry recommended** that Government should reform

the current regulation of indemnity products for healthcare professionals and introduce a nationwide safety net to ensure patients are not disadvantaged.

- **Investigating practice and behaviour** - senior managers and healthcare professionals in both the NHS and the independent sector said that Paterson could and should have been suspended by the Trust earlier than he was. HR processes were used to investigate, even though the concerns from 2003 related to clinical practice. **The Inquiry recommended** that if, when a hospital investigates a healthcare professional's behaviour, including the use of an HR process, any perceived risk to patient safety should result in the suspension of that healthcare professional.

- **Complaints** – patients who were treated in the NHS were not satisfied with the response to their complaints and did not appear to know about the role of the Parliamentary and Health Service Ombudsman (PHSO). Private patients had limited options and, in some cases, no options for independent investigation or adjudication of their complaint. **The Inquiry recommended** that information about how to escalate a complaint to an independent body is communicated more effectively in both the NHS and independent sector and all private patients should have the right to mandatory independent resolution of their complaint.

- **Corporate accountability -** patients felt that they did not receive any meaningful apology from the hospitals. Apologising was conflated with admitting legal liability. The Inquiry received no evidence to show how boards accept and implement accountability for apologising. **The Inquiry recommended** that when things go wrong, boards should apologise at the earliest stage of investigation and not hold back from doing so for fear of the consequences in relation to their liability.

- **Regulatory system** – the Inquiry found that despite the scale of the regulatory system, it does not come together effectively to keep patients safe. They also heard that it is not accessible or understood by patients. **The Inquiry recommended** that the Government should ensure that the current system of regulation and the collaboration of the regulators serves patient safety as the top priority. However, the creation of additional regulatory bodies is not the answer to this.

2.4 Looking across these themes and applying them in the context of pharmacy and pharmacy regulation, there many different mechanisms already in place, to help prioritise patient safety and mitigate the risk of similar issues arising. For example:

- All pharmacy professionals, regardless of sector or setting, must meet our Standards for Pharmacy Professionals. These include clear requirements relating to person-centred care, raising concerns and speaking up when things go wrong, and working in partnership with others including multidisciplinary teams.

- We publish guidance to support pharmacists and pharmacy technicians to meet the standards. This includes detailed guidance on consent and the associated responsibilities.

- We regularly collaborate with others in the wider health and social care system to keep patients safe, including through information-sharing and joint working initiatives.

- We are developing our new Fitness to Practise Strategy, which includes looking at how we can work more closely with employers so that, where possible, concerns can be resolved quickly and effectively at a local level. We have also applied the learnings and themes from a range of other independent reports, including the Paterson Report, to influence the development of our new strategy more widely.

2.5   We will also monitor any future responses from the Government or others to the formal recommendations identified through the report and assess their impact / relevance to our own work, as well as any future action we may need to take as a result.

3.   Equality and diversity implications

3.1   The Inquiry's report did not make any specific recommendations relating to equality and diversity. However, as highlighted in the themes above, the report identified some broader concerns relating to equity and fairness for patients, and the recommendations set out how these should be addressed going forward.

4.   Communications

4.1   As highlighted above, we will monitor any future responses from the Government or others to the formal recommendations identified through the report and assess their impact / relevance to our own work, as well as any future action we may need to take as a result. We will also continue to monitor the media and parliaments/assemblies, including parliamentary questions, debates and relevant committees across the three countries that we regulate.

5.   Resource implications

5.1   There are no additional resource implications associated with this work as it currently stands. This will of course be monitored in line with any future regulatory action we may need to take in response to the reports and recommendations, or the work of others.

6.   Risk implications

6.1   It is essential that we consider the wider lessons learned, to ensure that we are regulating in a way that continues to be fit for purpose and prioritises patient safety.

7.   Monitoring and review

7.1   We will continue to provide the Council with updates on external, independent reports and inquiries as and when relevant.

Recommendations

The Council is asked to note the update.

Laura McClintock, Chief of Staff
General Pharmaceutical Council

02 March 2020

General Pharmaceutical Council

Minutes of the **Audit and Risk Committee** meeting held on **Wednesday 05 February 2020** at 25 Canada Square, London at 10:00

TO BE CONFIRMED 12 May 2020

Minutes of the public session

Present

Digby Emson (Chair)
Rima Makarem
Aamer Safdar
Jayne Salt

Apologies

Helen Dearden

In attendance

Duncan Rudkin (Chief Executive and Registrar)

Carole Auchterlonie (Director of Fitness to Practise): Items 17 and 18

Jonathan Bennetts (Director of Finance)

Mark Voce (Director of Education and Standards): Items 1-9

Rob Jones (Risk and Audit Manager)

Janet Collins (Governance Manager)

Carole Gorman (Information Governance Manager): Item 7

Thanzil Khan (TIAA)

Ashley Norman (TIAA)

Tim Redwood (Crowe Clark Whitehill)

1. **Attendance and introductory remarks**

1.1   The Chair welcomed those present to the meeting. Jayne Salt noted that this was the Chair's last meeting and thanked him, on behalf of the committee, for all his work.

1.2   The Chair welcomed Rob Jones, Risk and Audit Manager at the GPhC, to his first meeting.

2. **Declarations of interest**

2.1   Members were asked to declare any interests at the start of each item.

3.   Minutes of the last meeting

 3.1   The minutes of the public session of the meeting held on 24 October 2019 were agreed as a true and accurate record.

4.   Actions and matters arising

4.1   There were no outstanding actions or matters arising. One action was not yet due and the other three were dealt with on the agenda for this meeting.

4.2   In relation to the report on email tampering (ref. 11.1 on the action log for the meeting on 24 October), the GPhC response was included in the papers for the meeting and it was noted that it was very positive

5.   Chief Executive's update

5.1   This item was to give the committee some context around the items on the agenda. The issues mentioned at the previous meeting as taking considerable time, effort and leadership focus (namely responding to issues around the online supply of medicines and the rapidly changing nature of pharmacy practice) were still continuing.

5.2   There had been two significant changes since the last meeting – one external and one internal. Externally, the election of a new government with a majority had increased the prospect of legislation which would affect the work of the GPhC. The Queen's Speech had included a Medicines and Medical Devices Bill, the impetus for which was Brexit-related but the scope of which went wider than Brexit and included, for example, the legal framework around the supply of medicines. There was also an increased prospect of regulatory reform, with legislation being drafted to produce a consistent primary legislative framework across all the healthcare regulators which was likely to lead to the introduction of smaller, unitary Boards.

5.3   Internally, the need to challenge costs and efficiency continued. A consultation was taking place with staff on a small number of redundancies. The numbers were small but the impact on the staff was not under-estimated.

6.   Update on Council recruitment

6.1   Laura McClintock (LM) introduced **20.02.ARC.01**, updating the committee on the Council recruitment process for the new members who would take up office in April 2020. The process had been successful and had attracted the broadest range of candidates to date. The PSA had confirmed that it had confidence in the process undertaken and the Privy Council had subsequently made the offers, all of which had been accepted. The

PSA had also said that the robustness of the process had been demonstrated to an extent which meant that future processes could be reported more selectively.

6.2   One new member needed to agree stand-down arrangements from their current position and the new members would be announced once that was finalised.

7.   Information security – deep dive

7.1   Carole Gorman (CG) joined the committee to present **20.02.ARC.02** which was a 'deep dive' into the GPhC's work on information security .

7.2   The aim of the work was to ensure that the GPhC complied with relevant legislation, had appropriate levels of information security, to maintain the confidence of those who shared their information with the organisation, to provide reliable evidence of activities and decisions.

7.3   The security policies were designed to prevent data compromise and loss, ensure that data was shared lawfully and securely and that employees had good awareness and training.

7.4   CG explained the frameworks of both the ICO data protection checklist and the ISO standard 27001 for information security management systems and also set out the current areas of focus for the GPhC, including areas of risk and relevant controls.

7.5   In terms of incidents, the GPhC had recorded 27 in Q1-3 of 2019/20, including six incidents of data being emailed to an incorrect recipient and six of inaccurate data. Recorded incidents included near-misses. Three incidents had been reported to the ICO (for context, the ICO received 8870 incident reports over the same period). These were the possible credit card fraud already reported to the ARC, one case where a doctor's surgery sent medical records to the GPhC which were never received and one where hearing bundles were inadvertently switched during production. None of the incidents reported to the ICO had resulted in a sanction.

7.6   It was estimated that approximately two thirds of the GPhC incidents related to confidentiality of information and were the result of human error. These had been dealt with through training, which would a continuous process. Incidents were shared with the relevant teams to allow learning when human error was identified, the circumstances around it were explored. It was known that training had helped to avert attempts at phishing by allowing staff to recognise them and take appropriate action.

7.6   The presentation also covered future developments. The key messages for the committee were that:

- the audit into GDPR compliance had provided reasonable assurance;
- work was being carried out to address the actions identified by the audit;
- that work was being prioritised according to risk; and

- that the organisation was aware of the need to keep improving practice in this area in order to keep pace.

7.7 This item had followed a deep dive into cyber security as a way of providing Council with assurance. A way of keeping Council updated in both areas would be developed.

7.8 **The committee noted the contents of the deep dive.**

Carole Gorman left the meeting

8. Freedom to speak up

8.1 LM updated the committee on the work which had been done to consider whether the GPhC should have a Freedom to Speak Up Guardian, following a request by the committee when the Raising Concerns policy had been updated.

8.2 A workshop had been held on 21 October with a number of staff in related areas. The workshop had included a presentation from the GMC's Freedom to Speak Up Guardian, Lindsey Mallors who had given the GMC's perspective on how the role was working. The staff present at the workshop had felt that there were other ways in which the organisation could encourage speaking up and the Senior Leadership Group had agreed with this when it had discussed the outputs from the workshop. The SLG had also agreed that staff would raise the topic in various stakeholder meetings to find out what other organisations were doing.

8.3 The confidence of staff in speaking up would be explored in the staff survey which was due in the next month and the SLG would consider next steps based on the learning from the survey.

8.4 The committee discussed whether staff might be confused as the appropriate ways to raise different issues and it was agreed that clearer communications for staff would help. A member of the committee had experience of acting as a Freedom to Speak Up advocate, which included signposting people with concerns to the correct route for raising them and it was agreed that this would be helpful.

9. Internal audit progress report and Q3 audits

9.1 Ashley Norman (AN) presented **20.02.ARC.03**, the progress report and the two internal audit reports which covered Key Financial Controls and the Integrity of the Register.

Internal audit progress report

9.2 Of the seven recommendations made by the previous auditors and still to be actioned, five were not yet due and two were overdue. Revised implementation dates had been agreed for both.

9.3 Of the 22 actions identified by TIAA to date, nine had been implemented, ten were not yet due and three were overdue (two on GDPR compliance and one on procurement). Revised implementation dates had been agreed for all three. While reasons for certain

actions being overdue were included in the report, it was agreed that it would be helpful to include the reasons in the summary in future.

Key financial controls

9.4 The Key financial controls audit had been carried out to assess the arrangements in place to ensure that key financial controls were robust and fit for purpose. It focussed specifically on payment systems, sales invoicing and credit control, journals, payroll control and control account reconciliations. The audit had provided a substantial level of assurance (the highest assurance level in the audit scheme) and was rated green. There were four recommendations, all of which were rated as routine.

Integrity of the Register

9.5 The Integrity of the Register audit had been carried out to review the quality of the data held on the register and how the quality assurance process was undertaken. The audit had provided a substantial level of assurance and was rated green. There were two routine recommendations, one of which had already been actioned, and two operational suggestions to improve good practice.

9.6 The committee noted the improvement since the previous audit and asked that its thanks be passed on to the teams concerned for the work they had undertaken to achieve it.

9.7 In relation to action 6.3 from the October meeting, Mark Voce (MV) updated the committee on the secure destruction and archiving of data. Progress continued to be made in moving the higher-volume registrant activities online, meaning that registrants could log into a secure portal to make payments and there would be no manual handling of payment details. The online process had now been implemented for pharmacy technicians (in addition to pharmacists and pre-registration trainees). Payments for the registration assessment would go online in May and for independent prescriber annotations in Q3 of 2020-21, subject to sign-off of the budget by Council. This would lead to a reduction of approximately 5,000 manual payments per year.

9.8 For the processes not yet online, the message had been reinforced with the applications team that all payment data must be destroyed after use and any pending payments kept securely in locked cupboards. Where payment details had previously been provided by email, the relevant mailboxes had been archived in what was now a continuous process. Access to the archive folders was user-controlled and could only be granted by a manager.

9.9 **The Committee noted the audit reports on key financial controls and the integrity of the register**.

Mark Voce left the meeting

10. Internal audit plan 2020-21

10.1 The Committee considered **20.02.ARC.04** which set out the internal audit plan for the following twelve months. The scope of the audits on fitness to practise process changes

and accreditation methodology needed some revisions which would be agreed outside the meeting.

10.2 **The Committee approved the internal audit plan for 2020-21, subject to the revisions to scope of the audits on fitness to practise process changes and accreditation methodology.**

11. Internal audit recommendation tracker

11.1 **The Committee noted the updates provided in the recommendation tracker**

12. External audit plan for year ending 31 March 2021

12.1 Tim Redwood of Crowe Clark Whitehill (CCW) presented **20.02.ARC.06** – the external audit plan for 2020-21. Under the new International Standards on Auditing, the audit report would include specific references to going concern. It was agreed that CCW would provide a short summary to be considered alongside the accounts explaining why the GPhC could be considered a going concern.

12.2 **The Committee approved the External audit plan for the year ending 31 March 2020**

13. Any other public business

13.1 There being no further public business to discuss, the meeting closed at 12.15.

Date of the next meeting:

Thursday 14 May 2020