Meeting of the Council
Thursday, 10 December 2015
1 to 16:00
Council Room 1, 25 Canada Square, London E14 5LQ

Agenda

Council Meeting

Public business

1. Attendance and introductory remarks Nigel Clarke

2. Declarations of interest
   Public items
   All

3. Minutes of last meeting
   Public session 12 November 2015
   Nigel Clarke

4. Actions and matters arising
   Nigel Clarke

5. Continuing Fitness to Practise: Update and terms of reference
   Terms of reference for approval
   Osama Ammar

6. Investigating Committee guidance
   For approval
   15.12.C.01
   15.12.C.02
   15.12.C.02a
   Priya Warner

7. Standards of Conduct, Ethics and Performance
   To note
   15.12.C.03
   Priya Warner

8. Any other public business
   Nigel Clarke

Date of next meeting
Thursday, 04 February 2016
Public business

CFtP development – update from research and test phase

Purpose

To:

• provide assurance to Council on the development of the continuing fitness to practise framework at the transition to piloting
• reconfirm the Terms of Reference for the CFtP advisory group, and
• present revised principles for the work to develop the framework

Recommendations

The Council is asked to approve:

• The terms of reference for the CFtP advisory group including revised principles for CFtP (provided as appendix 1)

1. Introduction

1.1 The Council agreed, at its meeting on 11 September 2014, a revised delivery plan for the development of a CFtP framework and the establishment of an advisory group. The first year of work in the three year delivery plan researched and tested the components of the framework, which were previously agreed in November 2013.

1.2 Work has proceeded as planned and there is now an evidence base to inform piloting and more detailed evaluation in 2016/17. This paper provides an opportunity for the Council to seek assurance around the strategic direction of the development programme through consideration of revised principles that guide the work.

1.3 The paper also recommends reconfirming the role of the CFtP advisory group which has been critical in the co-development of the framework.
2. **Activities and the work of the advisory group**

2.1 The work done in the first year of development has comprised learning more about how the components of the framework will operate from a theoretical and practical perspective. As well as engaging in research activities, a test was performed with 241 volunteers from across the roles and settings of pharmacy practice.

2.2 The advisory group, made up of representatives from more than 30 stakeholder organisations, has provided advice to GPhC on draft proposals for research and testing work.

2.3 The table below summarises the activities of the advisory group.

<table>
<thead>
<tr>
<th>Date</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2014</td>
<td>Council agreed revised delivery plan and establishment of the group</td>
</tr>
<tr>
<td>December 2014</td>
<td><strong>Formal meeting in London</strong></td>
</tr>
<tr>
<td></td>
<td>• Confirmation of Terms of Reference</td>
</tr>
<tr>
<td></td>
<td>• Validation of communications and engagement plan and validation of testing plan</td>
</tr>
<tr>
<td>March 2015</td>
<td><strong>Workshop meetings in Scotland and London</strong></td>
</tr>
<tr>
<td></td>
<td>• Validation of testing focus</td>
</tr>
<tr>
<td></td>
<td>• Validation of evaluation outcomes</td>
</tr>
<tr>
<td>May 2015</td>
<td><strong>Workshop meeting in Wales</strong></td>
</tr>
<tr>
<td></td>
<td>• Further validation of evaluation outcomes</td>
</tr>
<tr>
<td></td>
<td>• Validation of the testing forms</td>
</tr>
<tr>
<td></td>
<td>• Validation of the range of roles and settings of pharmacy practice</td>
</tr>
<tr>
<td>September 2015</td>
<td><strong>Workshop meeting in London</strong></td>
</tr>
<tr>
<td></td>
<td>• Advice given on early draft structure of standards of conduct, ethics and performance and their application to CFtP framework</td>
</tr>
<tr>
<td></td>
<td>• Review of early findings from testing to inform further evaluation.</td>
</tr>
<tr>
<td>Throughout the year</td>
<td><strong>Contribution to expert surveys on:</strong></td>
</tr>
<tr>
<td></td>
<td>• Broad principles and purpose of continuing fitness to practise</td>
</tr>
<tr>
<td></td>
<td>• Peer discussion</td>
</tr>
<tr>
<td></td>
<td>• CPD</td>
</tr>
<tr>
<td></td>
<td>• “Other evidence”</td>
</tr>
</tbody>
</table>
3. Summary of outcomes from research and testing

3.1 The findings suggest that the pilot phase should continue to trial a simpler recording method for CPD that directs reflection toward the users of services. This appears to have the dual effect of encouraging reflective behaviours and increasing satisfaction. Improvements for piloting will focus on provision of guidance in the form of examples of good CPD activities and recording.

3.2 The findings suggest there is likely to be broad acceptance across pharmacy of the value of including a peer discussion element, although the practicalities related to locating peers for some roles and settings of practice appear more challenging than others.

3.3 It is also apparent from the review of literature and testing that a formative rather than summative peer discussion leads to high levels of satisfaction and positive outcomes for reflection. However, this must be balanced against the need to ensure the peer relationship is an effective one and robust against collusion (which is at least a perceived risk to the value of peer discussion).

3.4 In the next phase of piloting, based on the evidence collected to date, a range of suggested peer discussion options will be produced to support registrants make appropriate decisions about which peers to select. Further work will also be required to understand how suitable quality assurance of the relationship may be performed by partner organisations rather than directly by GPhC.

3.5 The findings suggest that there is still further work to be done in collaboration with the CFtP advisory group to make the “other evidence” component meaningful for a majority of registrants. Therefore, this part of the framework will be further developed before piloting begins.

3.6 The evidence also suggests our current approach of calling CPD records for all registrants over a five year cycle does not deliver the outcomes intended and that a more proportionate and effective approach should be developed. A sampling approach to CPD ‘Call and Review’ will be trialled calling on a randomly selected cohort of registrants. The random selection will call 2.5% of the register, excluding individuals who have recently been called and therefore have not had time to record new entries. On top of the 2.5% call, we will also call registrants who have required remediation in their last attempt or have recently been restored to the register. We will also evaluate the effectiveness of the sampling approach with the intention that if proved effective we will consult upon adopting the approach permanently in future calls.
4. **Revised principles for CFtP**

4.1 The revised principles for CFtP (presented in appendix 1) merge the previous seven principles into four. The alterations made are:

- emphasising the framework as a driver for positive professional behaviours that provide assurance instead of a single point assessment,
- removing out of date terminology and references
- accounting for opportunity cost in impact assessment
- emphasising the importance of the framework being based on a common standard but flexible across all roles and settings of pharmacy practice.

5. **Communications and engagement**

5.1 A separate communications and engagement plan has been produced and will be shared for comments and improvements with the CFtP advisory group at its meeting in December 2015. The communications and engagement plan will in particular focus on recruiting as representative sample of registrants as possible to participate in piloting. A specific focus of this effort will be targeted toward the roles and settings of practice that have not yet been adequately represented in testing.

5.2 There are also higher profile engagement activities planned for next financial year, including a programme of four events to launch piloting in the three countries.

5.3 The membership of the CFtP advisory group will also be reviewed to ensure it continues to draw upon the appropriate range of organisations in pharmacy to advise GPhC staff and assure the Council.

6. **Equality and diversity implications**

6.1 The next phase of work sees the commencement of full impact assessment and therefore the existing equality and diversity impact analysis will be updated and shared with the CFtP advisory group before activities are undertaken.

7. **Resource implications**

7.1 Resource implications have been factored into a business case and budget for the second phase of the development of the framework as part of organisational planning for 2016-17.
8. **Risk implications**

8.1 Risks related to the programme are recorded in a separate risk register which escalates into the strategy directorate risk register and organisational strategic risk register.

8.2 Emerging risks that have been recorded as a result of the transition into piloting include: an insufficiently representative sample of pilot volunteers across pharmacy practice and professionals, reduced awareness of the development of the framework owed to competing external change programmes (such as the spending review), and failure to differentiate the approach taken by GPhC and other regulators.

9. **Monitoring and review**

9.1 The development work is rigorously monitored using a project management approach. Day-to-day delivery is managed through the strategy directorate, with regular reports going to the Senior Leadership Group and Council.

**Recommendations**

The Council is asked to approve:

- The terms of reference for the CfTP advisory group (including revised principles for CfTP) provided as appendix 1

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*Osama Ammar, Head of Continuing Fitness to Practise*  
*General Pharmaceutical Council*  
*Osama.ammar@pharmacyregulation.org*  
*Tel: 0203 713 7962*  
*25 November 2015*
Appendix 1

Continuing Fitness to Practise Advisory Group

Terms of Reference

Background
1. The Council established a Continuing Fitness to Practise Advisory Group at its meeting on 11 September 2014. These terms of reference set out the role and operation of the Advisory Group.

Role
2. The group will, using the principles for continuing fitness to practise (see annex one) as a guide, provide advice to the executive and assurance to Council on the development programme for the draft continuing fitness to practise framework, including:

   a. The proposed methodologies of comprising the framework (CPD, peer review and performance indicators).
   b. The suitability of the range and scope of testing and piloting of the elements of the framework.
   c. The suitability of evaluation criteria and methodology for the tests, pilots and draft framework.
   d. The impact assessment methodology and criteria (including cost, and equality and diversity).
   e. The communications and engagement strategy to ensure that our policy and operational development take into account the views of patients and users of pharmacy services, as well as registrants and all forms of pharmacy professional, employer and commissioner.

Composition
3. The Advisory Group Chair is appointed by the Chair of Council.
4. The Advisory Group will include two Council members (one registrant, and one lay) appointed by the Chair of Council.
5. The remaining members of the Advisory Group will be drawn from external stakeholders to the GPhC. Nominations for members will be sought from stakeholder organisations.
6. The group will be divided into attending and corresponding members. Attending members will be invited to formal meetings and all other forms of engagement. Corresponding members will receive papers for formal meetings and be invited to all other forms of engagement.
7. As much as possible, the membership of the attending members group will be small to facilitate effective decision-making. The corresponding group membership will not be capped so the maximum number of stakeholder organisations can be involved.

8. A broad representation of stakeholders will be invited into the membership to include the following groups:
   - Pharmacists
   - Pharmacy technicians
   - Employers across a range of contexts of pharmacy practice
   - Patients and the public
   - Training providers (post-registration)
   - Commissioners / funding bodies
   - Unions
   - Students and trainees
   - Training providers (pre-registration)

9. The group may also wish to invite other parties to attend meetings or engagement activities, such as other regulators (both professional and systems), or subject matter specialists.

**Frequency and format of meetings**

10. One formal meeting will be held each year and account for one working days including travel.

11. A total of four further working days will be used to engage the group in advising on specific aspects of the development programme. Methods of engagement will include: workshops, online engagement, email and telephone.

12. All meetings and engagement with the group will account for no more than a total of six working days for each member of the group.

13. Minutes will be kept of formal meetings and notes from other engagement activities. Comments from members will not be attributable to individuals.

14. Business of the meetings will be treated as public and records may be subject to Freedom of Information Requests.

**Duration and review of role**

15. The group will operate for the life of the development programme. The Council will review the group’s role and the requirement for future meetings in December of each year.

16. The Chair of Council will review the Council members on the group at a regular interval to ensure that membership remains current (Council members’ terms may expire during the course of the advisory group) and that fresh perspectives and contributions are made to the group. The proposed interval is two years.
Expenses

17. Reasonable expenses for attendance at meetings will be paid in line with the GPhC expenses policy.
18. Accommodation bookings should be made through GPhC staff when required to ensure the best available price is achieved.
Annex one

Principles for continuing fitness to practise

1. The primary role of continuing fitness to practise is to reaffirm registrants continue to meet the core standards of conduct, ethics and performance.

The framework will seek to have a positive impact on the behaviours and development of professionals and will not pursue a fixed point assessment. Assurance will be based on affirming the core standards for safe and effective pharmacy practice on a continuous basis by driving behaviours toward engagement with professional responsibilities for maintaining and developing professional knowledge and skills through reflection and collaboration.

2. The framework will need to take account of the full range of roles and settings of pharmacy practice and as a result be based upon a common standard and flexible process and evidence requirements.

Additional assurance must be received from external sources and be related to a registrant’s current context of practice. This will mean the evidence requirements and processes to record and review this evidence must be flexible to the diversity of roles and settings of pharmacy practice. However, the core standard will be common across all pharmacy professions.

3. The framework will complement and where possible incorporate existing mechanisms provided by organisations within pharmacy that support continuing fitness to practise assurance.

We will develop the framework in association with partner organisations and pharmacy bodies working to support the highest professional standards. Some of these organisations already provide continuing fitness to practice related activities that complement the framework’s ambitions and we will seek to align with suitable existing services.

4. Any framework would need to be appropriately tested, piloted and evaluated using robust evaluation criteria including impact assessment of intended and unintended consequences.

It will be important that any proposed framework is properly costed taking into account costs to GPhC and the pharmacy sector, including opportunity costs. Testing, piloting and evaluation should be based on robust evaluation criteria which make reference the generic principles agreed by the Department of Health non-medical revalidation working group, November 2008, but also take into account the developing evidence base around already implemented continuing fitness to practise models. Impact assessment must also take into account the full sector of pharmacy and characteristics of the individuals making up the pharmacy professional registers.
Public business

Reviewing our Investigating Committee Guidance

Purpose
To update the Council on the investigating committee guidance consultation and agree both the revised guidance and implementation date.

Recommendations
The Council is asked to:

i. note the consultation report (see Appendix 1)

ii. agree the Good decision-making: Investigating committee meetings and outcomes guidance (see Appendix 2)

iii. agree the guidance will come in to effect on 13 January 2016

iv. agree to delegate authority to the Chief Executive and Registrar to make any future factual and legal amendments to the document.

2. Introduction

2.1 The Investigating Committee (IC) was established under the Pharmacy Order 2010 to consider allegations that a registrant’s fitness to practise is impaired and decide whether the allegation ought to be considered by a Fitness to Practise (FtP) committee. IC committees are independently appointed and make decisions independently of the GPhC. Its decisions are made in private.

2.2 The IC currently uses a range of guidance documents to assist it in considering how to most appropriately dispose of a case. The current guidance it uses is set out below.

- Investigating Committee Referral Criteria
- Guidance on Making Decisions on Warnings
- Procedural Guidance to the Investigating Committee on Warnings
- Guidance on Issuing Undertakings (including undertakings bank)
2.3 As a result of the coming into force of the *Amendment of Miscellaneous Provisions Rules* responsibility for agreeing the content of the Investigating Committee’s *Referral Criteria* reverted to the GPhC Council. The rules came into effect on 5th February and the Council, at its February 2013 meeting, agreed to transitional arrangements in advance of any consultation.

2.4 Given the important role of the IC; requiring it to consider all cases referred to it and decide whether the allegation should be considered by the FtP committee - the IC guidance is an important resource for decision-makers, registrants and the public.

2.5 Our aim throughout the review has been to provide a more useful resource for all those involved in investigating committee meetings, and to produce guidance to assist in proportionate, consistent and transparent decision making by the IC.

3. **The Consultation**

3.1 The consultation on the draft IC guidance ran from 2 July 2015 to 11 September 2015 during which we received 24 responses.

3.2 We used this consultation to seek views on the entire guidance, and its structure, tone and content. The aim of the consultation was to ensure that the revised guidance improves consistency, leads to greater transparency and improves the quality of committee decisions.

3.3 The consultation report can be found in Appendix 1. The report summarises what we heard through the consultation, it identifies the key themes and sets out our proposed response to these.

4. **Revised IC guidance**

4.1 Through the consultation, the GPhC received a number of helpful comments and suggestions to improve the quality of the guidance. Alongside drafting suggestions, a number of key themes emerged. The table below sets out the key themes and references the consultation report which explains the feedback we received and the action we have taken.
5. **Equality and diversity implications**

5.1 We have undertaken an equality impact assessment. This included assessing the implications of the guidance, through an established internal protocol, against a series of characteristics (race, disability, sex age etc.) to ascertain if there is any impact on groups or individuals.

5.2 This process did not identify any implications that would discriminate or unintentionally disadvantage any individuals or groups. We believe that the guidance will promote consistent decision making and clearly sets out our commitment to equality throughout the fitness to practise process.

5.3 The introduction of this guidance enhances transparency at the IC and strengthens our approach to ensuring consistent and fair decision making. The implementation of the guidance should therefore have positive implications for all groups involved or interested in an IC meeting, including registrants and those that have raised a concern, as it ensures everyone is treated fairly and equally and subject to the same process.

6. **Communications**

6.1 The guidance will be published on our website, and sent to stakeholders and committee associates. We will also undertake some training with associates to ensure they are aware of the new guidance and the implications it has for decision making at committee meetings.

6.2 Whilst the guidance will not come into effect until 13 January, we will communicate the guidance as soon as possible, to provide an opportunity for stakeholders, staff and associates to read and familiarise themselves with the guidance.
7. **Resource implications**

7.1 The resource requirements are primarily focussed around training of staff and committee associates. However these resources are accounted for in the current budget.

8. **Risk implications**

8.1 There are no immediate anticipated risks. All risks in relation to ensuring consistent and proportionate decision making are mitigated through training with all IC members and legal advisers prior to implementation and auditing committee decisions post implementation.

9. **Monitoring and review**

9.1 The performance of committees is regularly reviewed and the consistency of Committee decisions will be monitored to ensure the document is used appropriately by all involved in committee meetings, remains fit for purpose and is accessible to a wide range of stakeholders.

9.2 The guidance will be reviewed regularly on a cycle of five years. However, given its importance and the range of areas it covers it will be reviewed if there is a significant change to regulatory practice, approach or to the legislation.

**Recommendations**

The Council is asked to:

- note the consultation report (see Appendix 1)
- agree the *Good decision-making: Investigating committee meetings and outcomes guidance* (see Appendix 2)
- agree the guidance will come in to effect on 13 January 2016
- agree to delegate authority to the Chief Executive and Registrar to make any future factual and legal amendments to the document.

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*Priya Warner, Head of Standards and Fitness to Practise policy*
*General Pharmaceutical Council*
*Priya.warner@pharmacyregulation.org*
*Tel 020 3713 7958*

*Jerome Mallon, FtP policy manager*
*General Pharmaceutical Council*
*Jerome.mallon@pharmacyregulation.org*
*Tel 020 3713 7982*

19 November 2015
Appendix 1

Consultation report

Investigating Committee Guidance

Contents
Section 1: About the consultation
Section 2: Who we heard from
Section 3: What we heard
Section 4: Next Steps

Appendix A: List of respondents and those we engaged with
Section 1: About the consultation

- The General Pharmaceutical Council (GPhC) consulted on draft guidance for use by those involved or interested in an investigating committee (IC) meeting. The IC was set up under the Pharmacy Order 2010. It makes decisions independently of the GPhC. It must decide whether allegations should be considered by a Fitness to Practise Committee (FtPC) or whether an alternative outcome is more appropriate. This consultation formed part of our review of our statutory committee guidance.

- When pharmacists or pharmacy technicians fall short of the expected standards, their fitness to practise may be called into question. This can lead to a referral to the GPhC, an investigation, a potential referral to an IC and ultimately a hearing before an independent FtP committee.

- We published a consultation on 2nd July; this ran for ten weeks until 11th September. The consultation sought views on the draft guidance, including structure and tone, and we included questions on some of the specific areas we wanted feedback on.

- The aim of the consultation was to ensure interested parties had an opportunity to influence and shape the content of the new guidance. The guidance will help to ensure consistent, fair and proportionate decision-making across all committees. It will also ensure that the issues considered by an IC when deciding on an outcome are consistent with other FtP guidance.

- This report sets out how we engaged and who responded during the consultation period. It brings together what we heard and what actions we propose to take to address those issues in the final guidance document.
Section 2: Who we heard from

Overall, we received 24 responses to the consultation.

To supplement what we heard through the survey we also engaged directly with IC members and patient and public groups. We held three face to face meetings with committee members. We also engaged with two community based groups to ensure a broad range of views were received. We met with the North Wales Community Health Council and a local Age Concern group. A list of those who responded and who we engaged with is included in the appendix.

<table>
<thead>
<tr>
<th>Total number of respondents:</th>
<th>24</th>
</tr>
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</table>

This information summarises feedback received for questions 1 – 4.

<table>
<thead>
<tr>
<th>Individual respondents</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Pharmacy professionals</td>
<td>4</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Of whom:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists</td>
<td>2</td>
</tr>
<tr>
<td>Pharmacy technicians</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Committee members (including legal advisers)</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members of the public</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
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</table>

<table>
<thead>
<tr>
<th>Countries of individual respondents</th>
<th></th>
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<tbody>
<tr>
<td>England</td>
<td>23</td>
</tr>
<tr>
<td>Scotland</td>
<td>1</td>
</tr>
<tr>
<td>Wales</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>-</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Organisations responding</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total respondents</td>
<td>12</td>
</tr>
</tbody>
</table>

Some respondents did not fully complete the information below.
Section 3: What we heard

This section summarises what we heard. It includes quantitative detail from those that responded to survey questions. It also incorporates qualitative detail from survey responses, individual responses and views received during engagement activity.

Q1a Do you think the structure and tone of the document is clear and accessible?

16 respondents answered this question.

<table>
<thead>
<tr>
<th></th>
<th>Very clear and accessible</th>
<th>Clear and accessible</th>
<th>Neutral</th>
<th>Unclear and inaccessible</th>
<th>Very unclear and very inaccessible</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response</td>
<td>4</td>
<td>10</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>16</td>
</tr>
</tbody>
</table>

We did not seek any comments in response to this question.

Q1b If you think it is unclear or very unclear, please let us know the areas that can be improved.

9 respondents provided further detail on how it could be improved.

Summary of comments

The majority of respondents found the guidance document both clear and accessible. The two part approach included in the document was favoured by a range of respondents including registrants, legal firms and committee members. Some welcomed the consistency of approach with the guidance for fitness to practise committees.

A couple of respondents thought the guidance was too simplistic for committees but equally too technical for members of the public and lacked sufficient detail relevant to them.

Other respondents provided detailed comments on specific areas including:

- the consistent use of terms and language throughout
- the use of hyperlinks and references and
- some sections, for example applications for rescission, were not in plain English.
Our response

We are proposing some amendments to the structure of the document to reflect these comments. These amendments better reflect the sequencing of outcomes and actions an IC can take and removes duplication. However, we will retain a two part approach similar to what we adopted for the guidance used by the fitness to practise committee.

We have reviewed the draft guidance to ensure there is consistency of language and have removed instances of duplication throughout. We have listened to the feedback in relation to applications for rescission and this section has been reviewed for clarity and accuracy.

To ensure the guidance is accessible to all stakeholders the guidance will be subject to a plain English review.

Q2a Do you think Part a: The investigating committee clearly sets out what the IC can do?

16 respondents answered this question.

<table>
<thead>
<tr>
<th></th>
<th>Very clear</th>
<th>Clear</th>
<th>Neutral</th>
<th>Unclear</th>
<th>Very unclear</th>
<th>Total</th>
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</thead>
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<tr>
<td>Response</td>
<td>5</td>
<td>8</td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>16</td>
</tr>
</tbody>
</table>

We did not seek any comments in response to this question.

Q2b Do you think Part a: The investigating committee clearly sets out the roles of those involved in an IC meeting?

16 respondents answered this question.

<table>
<thead>
<tr>
<th></th>
<th>Very clear</th>
<th>Clear</th>
<th>Neutral</th>
<th>Unclear</th>
<th>Very unclear</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response</td>
<td>5</td>
<td>8</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>16</td>
</tr>
</tbody>
</table>

We did not seek any comments in response to this question.

Q2c Do you think Part a: The investigating committee clearly sets out the process it follows to reach a decision?

16 respondents answered this question.
We did not seek any comments in response to this question.

### Q2d Do you have any views on how this section could be improved?

13 respondents answered this question.

#### Summary of comments

We are encouraged by the positive feedback from a range of stakeholders on this part of the document. The majority of respondents believed the process set out in the draft guidance was either very clear or clear.

Some respondents asked for:
- further detail on the accountability of IC decisions
- clarity on certain actions an IC can take
- detail on the roles of those that attend an IC meeting, and the inclusion of the specialist adviser.

We received feedback in relation to the real prospect test, both in presentation in the guidance and application when a committee reaches a decision on referral to an FtPC. There were detailed comments on the section on ‘rescission’ which requested further clarity on the process.

A number of respondents and committee members thought that a flowchart or process diagram would be of significant benefit in understanding who decides what, and when.

#### Our response

We have listened to feedback and have made some significant drafting changes to Part A. We have:
- included further detail on the accountability of decisions and the fact that these may be subject to judicial review
- clarified points around resolving conflicts of evidence to make clear the IC’s role
- included additional detail on the roles of the medical adviser, and lay and registrant members of committees.

The section on rescission has been amended to fully reflect the legislation and the real prospect test has been set out in its two parts for the purposes of clarity and to aid committee decision making. Feedback on the real prospect test was also received in response to question 3b and those issues are addressed below.
We agree that visual illustration of the process and key decision points would be useful for the purposes of understanding the path a complaint takes. However, we believe this would be best presented as a representation of the entire fitness to practise process end-to-end and not within a single guidance document. Therefore, we will explore how to explain the decision-making process and, in addition, explore the most appropriate way to make it accessible.

**Q3a Do you think Part b: Guidance on outcome gives clear guidance to help you understand the outcomes available?**

16 respondents answered this question.

<table>
<thead>
<tr>
<th></th>
<th>Very clear</th>
<th>Clear</th>
<th>Neutral</th>
<th>Unclear</th>
<th>Very unclear</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Response</td>
<td>5</td>
<td>9</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>16</td>
</tr>
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</table>

We did not seek any comments in response to this question.

**Q3b Do you think Part b: Guidance on outcome gives clear guidance to help committees decide which outcome would be appropriate in a given case?**

17 respondents answered this question.

<table>
<thead>
<tr>
<th></th>
<th>Very clear</th>
<th>Clear</th>
<th>Neutral</th>
<th>Unclear</th>
<th>Very unclear</th>
<th>Total</th>
</tr>
</thead>
<tbody>
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<td>Response</td>
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<td>8</td>
<td>3</td>
<td>2</td>
<td>-</td>
<td>17</td>
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</tbody>
</table>

We did not seek any comments in response to this question.

**Q3c Do you have any views on how this section could be improved?**

11 respondents answered this question.

**Summary of comments**

The majority of feedback on this section was positive. However, some respondents believed further information about warnings and undertakings was required to ensure a better understanding of the implications of each outcome has on registrants.

Several respondents believed that further clarification on the application of the civil standard of proof was required. There were a series of comments on different aspects of mitigation and aggravation including clarification on how an IC can
consider insight and testimonials. One believed that we could go further with mitigation and aggravation without being prescriptive.

The majority of comments were made on the real prospect test and its application in an IC meeting. Comments were made on both the clarity of existing drafting but also whether the test, as set out, was correct. Respondents wanted to see the test set out in two stages and clarity on what each part of the test means.

There were minor drafting issues raised to further clarify points including consistent use of terms and sequencing of outcomes.

**Our response**

We have made some significant amendments to reflect the issues raised by respondents. This includes setting out the real prospect test in more detail, addressing both parts of the test in turn. It also includes further detail on the principles the IC should consider when assessing if allegations, once it has considered the real prospect test, ought to be considered by an FtPC. This important ‘ought to’ consideration is now more explicit in this part and throughout the guidance.

We have not included further detail on the civil standard of proof as this is not something the IC has to consider. It has to be mindful of, but not employ it, in the course of its decision making. We have amended aspects of mitigating and aggravating factors to ensure it is tailored and specific to the needs of the IC. This should avoid any confusion of its role, particularly in comparison to the role of the FtPC.

We have made some further minor drafting amendments to the document and included further detail in the table to ensure clarity of the impact of each outcome.

### Q4 Do you have any other comments on the draft guidance?

11 respondents answered this question.

**Summary of comments**

The majority of comments in this section were positive. Some respondents welcomed the box setting out impairment and thought that the document was accessible to a range of stakeholders. Some comments were similar to those made in other sections, for example the inclusion of a flowchart would be beneficial. Other comments from respondents included:

- a request for further detail on interim orders
- an explanation of case management directions
- the Undertakings Bank to be cross referenced and ideally included as an appendix
- it is not clear whether the IC will be aware of the identity of registrants whose cases they are considering.
**Our response**

The bulk of these comments have been addressed throughout the guidance. The Undertakings Bank is being reviewed separately and will be made available to committees, and published, once completed. We have included additional information on interim orders and case management directions to assist understanding the actions an IC can take.

**Section 4: Next Steps**

We are encouraged about the support and positive responses our draft guidance has received, especially as it is a significant move away from the current guidance. The legislation that sets out the IC’s role and function says that it does not consider cases in public, so we hope this guidance goes some way towards making the decision-making process – and the considerations of the committee – as transparent as possible. We will publish this guidance once it has been agreed by council and will undertake training with IC members to ensure they are fully aware of the implications this guidance has on their role.

This training will take place in December 2015 and the guidance will be implemented in January 2016.
Appendix A: List of respondents and those we engaged with

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<th>Stakeholder Group</th>
<th>Breakdown of respondents</th>
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<tr>
<td>Pharmacy professionals</td>
<td>Two pharmacists, two pharmacy technicians</td>
</tr>
<tr>
<td>Council and Committee members</td>
<td>Responses from a council member, fitness to practise panel member, investigating committee members (including a legal adviser). Three stakeholder events with committee members (including legal advisers).</td>
</tr>
</tbody>
</table>
| Healthcare                      | • PDA  
• APTUK  
• Pharmacy Voice  
• PSA  
• Guild of Healthcare Pharmacists  
• NHS Ayrshire and Arran Area Pharmaceutical Professional Committee  
• NHS Employers                                                                                                                                                  |
| Patient and public              | • North Wales Community Health Council  
• Age Concern (local group)  
• Healthwatch Bromley & Lewisham  
• Healthwatch City of London                                                                                                                                       |
| Law firms                       | • BLM  
• Charles Russell  
• Blake Morgan                                                                                                                                                    |
Good decision-making: Investigating committee meetings and outcomes guidance

January 2016
About us

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales. It is our job to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy.

Our principal functions include:

- approving qualifications for pharmacists and pharmacy technicians and accrediting education and training providers
- maintaining a register of pharmacists, pharmacy technicians and pharmacy premises
- setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD)
- establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies
- establishing fitness to practise requirements, monitoring pharmacy professionals’ fitness to practise and dealing fairly and proportionately with complaints and concerns

We are committed to protecting, promoting and improving the health and safety of people who use pharmacy services in England, Scotland and Wales. An important part of that role is dealing with the small number of pharmacists and pharmacy technicians who fall short of the standards that the public can reasonably expect from healthcare professionals.
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<td>Administrative procedures</td>
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1 Introduction

What this guidance is about

1.1 This guidance tells you about the investigating committee (IC) and its meetings. It sets out how decisions are made and the outcomes or actions an IC can decide on. It also gives guidance for an IC to use when deciding what outcome is appropriate in any given case and, in particular, how to decide which cases to refer to a fitness to practise committee (FtPC).

1.2 This guidance is in two parts:
   Part a: The investigating committee
   Part b: Guidance on outcome

1.3 This guidance will come into effect on 13 January 2016 and will replace the guidance the IC currently uses. It will apply to any new cases considered by the IC after this date.

Who this guidance is for

1.4 This guidance is aimed at anyone who is involved in an IC meeting, has raised a concern about a registrant, or has had a concern about them referred to an IC meeting.

1.5 This includes GPhC staff, IC members, and registrants and their representatives. It will also be useful to anyone who is interested in the fitness to practise process\(^1\), including:
   - people thinking about raising a concern with the GPhC about a registrant
   - patients and their representatives
   - defence organisations
   - other regulatory bodies, including the Professional Standards Authority (PSA), and
   - the courts

1.6 We will regularly review this guidance to:
   - take account of changes to legislation and case law
   - make sure it is consistent with other associated guidance documents
   - make sure it stays ‘fit for purpose’ and accessible to all stakeholders

Equality and diversity

1.7 The GPhC is committed to promoting equality, diversity and inclusion when it does its work. We value diversity and individuality in our staff, our associates\(^2\), the

\(^1\) https://www.pharmacyregulation.org/raising-concerns
\(^2\) All members of statutory committees
profession and our council. Our aim is to make sure that our processes are fair, objective, transparent and free from discrimination, and that all stakeholders receive a high level of service. We keep to the principles set out in the Equality Act 2010 and have developed an equality, diversity and inclusion scheme.

1.8 All GPhC staff are expected to demonstrate our values at all times during the fitness to practise process. The GPhC will act in accordance with the rights set out in the European Convention on Human Rights (ECHR) as incorporated into domestic law by the Human Rights Act 1998.
2 Investigating committee meetings

2.1 An IC meeting is just one part of a process that starts when a concern has been received and investigated by the GPhC\(^3\). This process can end at different stages:
- after the investigation
- at an IC meeting
- at a fitness to practise committee hearing\(^4\)

The guidance used at each stage of the fitness to practise process

- **Threshold criteria**\(^5\) are used at the investigation stage to decide whether to refer a case to the IC.
- **This guidance** covers IC meetings, the decision-making process and the outcomes of IC meetings.
- **Good decision-making: Fitness to practise hearings and sanctions guidance** covers fitness to practise hearings and the decisions made by an FtPC during a hearing.

2.2 Decision-making guidance is used at each stage to decide what action to take. The guidance is based on the law and established procedures. It also includes specific guidance for decision-making, including criteria and thresholds:
- **Threshold criteria**\(^5\) are used at the investigation stage to decide whether to refer a case to the IC.
- **This guidance** covers IC meetings, the decision-making process and the outcomes of IC meetings.
- **Good decision-making: Fitness to practise hearings and sanctions guidance** covers fitness to practise hearings and the decisions made by an FtPC during a hearing.

2.3 The IC should be aware of all the guidance listed above.

2.4 It must take into account this guidance when making a decision on outcome\(^6\). This guidance is not intended to interfere with the committee’s decision-making discretion but should help an IC to decide on whatever outcome it considers is

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\(^3\) Those allegations that are within the GPhC’s jurisdiction

\(^4\) Some cases are referred directly by the registrar – Article 52(2)(b) and Article 54 (1)(a) of the Pharmacy Order 2010

\(^5\) http://www.pharmacyregulation.org/sites/default/files/The%20threshold%20criteria%20po.pdf

\(^6\) Rule 9(3)(a)(ii) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010
appropriate in individual cases. If the IC departs from this guidance it should make this clear in its reasons.

**About the investigating committee**

2.5 Once an investigation has taken place, and if an allegation meets the threshold criteria, it is usually referred to an IC meeting. The IC operates, and makes decisions, independently of the GPhC. It is accountable\(^7\) for the decisions it makes and must give reasons for its decisions. The registrar receives, investigates and refers the case to the IC. The registrar is the most senior employee of the GPhC and has responsibility on behalf of the GPhC for the investigation of cases.

2.6 The IC meets to consider allegations that are referred to it. It meets in private\(^8\) and all papers and discussions remain confidential. This means that the person raising the concern, the registrant and GPhC investigations staff do not attend the meetings.

2.7 The IC does not hear oral evidence\(^9\) from registrants or witnesses. However, the registrant concerned will be invited to provide ‘written representations’ on the allegation, and on any recommendations the registrar makes for dealing with the case\(^10\).

2.8 An IC meeting usually includes four people (a chair or deputy chair, two registrant members and a lay member). There must be at least three\(^11\) members of the committee at an IC meeting before it can reach a decision, including at least one professional and one lay person.

2.9 The chair, registrant and lay members of the IC should work within the framework set out in this guidance. They are expected to behave in a fair and balanced way when reaching a decision. They are all equally responsible for the decision-making process and for the content of the IC’s determination (its formal, written decision).

2.10 Other people may also be at the meeting, including the IC secretary, a legal adviser and a clinical adviser. In some cases the committee may ask for advice from a specialist adviser\(^12\). All IC attendees must respect the confidential and sensitive nature of the information received. You can see the present members of the committee [here](#).

---

\(^7\) Investigating committee decisions may be challenged through a judicial review – for example, if the IC has failed to apply the appropriate test to its decision-making or has provided inadequate reasons to explain its decision. Decisions are scrutinised from time to time by the Professional Standards Authority (PSA).

\(^8\) Rule 9(1) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010

\(^9\) Rule 9(2) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010

\(^10\) Rule 7(2)(f) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010

\(^11\) Rule 18 – The General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010

\(^12\) Rule 23 – The General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010
The role of the IC secretary

2.11 The IC secretary\textsuperscript{13} is responsible for the administrative arrangements of the committee.\textsuperscript{14} The secretary plays an important role in the work of the IC and helps make sure this guidance is followed. The secretary attends all IC meetings. They do not take part in decision-making, or discussion, and are not entitled to vote.\textsuperscript{15} The secretary must keep a record, or make sure a record is kept, of all decisions made by the IC and the reasons for them.\textsuperscript{16}

2.12 The IC secretary must, in consultation with the IC chair, identify any legal, clinical and specialist advisers who will attend a particular IC meeting.\textsuperscript{17}

The role of the clinical adviser

2.13 The role of the clinical adviser\textsuperscript{18} is to advise the IC on any issues within their area of medical expertise, and to intervene if there is a possibility of a mistake being made. The clinical adviser should answer questions the IC may have about medical conditions or health-related matters that apply to the case.

2.14 The clinical adviser should not make a diagnosis, dispute the diagnosis of a medical practitioner who has examined the registrant, nor give an opinion about the registrant’s fitness to practise.\textsuperscript{19} The clinical adviser should explain only the medical evidence available – answering specific medical questions and giving advice about the nature, consequences and natural progress of the medical condition disclosed by the expert reports or medical records. They must not take part in the decision-making of the IC.

2.15 A clinical adviser must be present at any meeting of the IC if it is to consider the health of the registrant who is the subject of the case. The adviser may also be present at any other IC meeting if health-related issues are to be considered.

2.16 If an IC does not accept advice given by the clinical adviser, the IC chair must give reasons for this and these must be recorded formally.\textsuperscript{20}

\textsuperscript{13} The IC secretary is an employee of the GPhC
\textsuperscript{14} Rule 17 (4) – The General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010
\textsuperscript{15} Rule 17 (7) – The General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010
\textsuperscript{16} Rule 17 (6) – The General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010
\textsuperscript{17} Rule 17 (5) – The General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010
\textsuperscript{18} Rule 22 – The General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010
\textsuperscript{19} Sandra Watson v General Medical Council [2005]EWHC 1896 (Admin)
\textsuperscript{20} Rule 26 – The General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010
The role of the legal adviser

2.17 The role of the legal adviser\textsuperscript{21} is to advise the IC on questions of law, and to intervene if there is a possibility of an error of law being made. They must also make sure that IC meetings – and the proceedings which are followed by the IC – are fair, proper and in line with the legal framework. The legal adviser must tell the committee when this may not be the case.

2.18 A legal adviser may be present at any meeting if the IC secretary asks for this, after consulting the chair. However, because of the importance of the role, we believe that a legal adviser should be present at all IC meetings as this will support good decision-making.

2.19 The legal adviser must not take part in the decision-making of the IC. If the chair asks, they can advise the IC on the structure and format of the reasons for a decision by that IC.

2.20 If an IC does not accept advice given by the legal adviser, the IC chair must give reasons for this and these must be recorded formally\textsuperscript{22}.

What an investigating committee can do

2.21 The IC must make decisions about allegations that are referred to it, and must decide whether they ought to be considered by an FtPC\textsuperscript{23}. The IC has a range of outcomes it can decide on, depending upon its assessment of the evidence. Unless the registrant has asked for the case to be referred to an FtPC\textsuperscript{24}, the available outcomes include:

- take no action
- give advice to the registrant (or to another person or body involved in the allegations)
- issue a warning
- agree undertakings with the registrant, if the registrant admits their fitness to practise is impaired
- refer to an FtPC

2.22 If the IC decides to refer an allegation to an FtPC, and considers that case management directions\textsuperscript{25} should be issued or that an interim order\textsuperscript{26} should be made, it must tell the FtPC. An interim order can only be imposed if it is necessary to

\textsuperscript{21} Rule 21 – The General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010
\textsuperscript{22} Rule 26 – The General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010
\textsuperscript{23} Article 53 – The Pharmacy Order 2010
\textsuperscript{24} Article 53(3) – The Pharmacy Order 2010
\textsuperscript{25} Case management directions put obligations on the parties involved concerning the disclosure of information and evidence
\textsuperscript{26} Rule 9(3)(b)(i) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010 imposes restrictions on registration while allegations about their conduct are resolved
protect the public or is otherwise in the public interest, or in the interests of the registrant.

2.23 The IC can also:
- adjourn its meeting until it has more information
- ask for further investigation
- require a registrant to have a medical examination
- get advice from a legal, clinical or other specialist adviser
- consider rescission (cancelling a referral to an FtPC)
- tell the registrar that the GPhC should consider bringing criminal proceedings against a registrant

**Adjourning the meeting and asking for further investigation**

2.24 An IC may adjourn a meeting in particular circumstances. It may adjourn a meeting until the registrant has had a medical examination and a report on this has been prepared. It may also, if it needs more information, adjourn until it receives the information it has asked for, or until it receives any comments it has asked for from the person that raised the concern.

2.25 It may also ask for further investigations to take place. If further investigations\(^{27}\) are needed, the IC should adjourn the case to allow these to be carried out. It should make clear its reasons for asking for further investigation, and the specific issues about which further investigation is needed.

2.26 If the registrar decides that the further investigation requested is not necessary, or should not be undertaken, the allegations will be returned to the IC. This will include a clear explanation of the registrar’s decision.

**Requiring a medical examination**

2.27 When dealing with a health allegation, the IC may\(^{28}\):
- require the registrant to agree to be medically examined by a registered medical practitioner chosen by the council, and
- if it receives information that the registrant has refused to cooperate fully with a medical examination, refer that refusal to the FtPC as a separate allegation of misconduct

**Considering rescission**

2.28 When an allegation has been referred to the FtPC, but a hearing has not yet taken place, the council’s representative in the proceedings may consider that the hearing should not be held. If so, they must give the IC their opinion and the reasons for it\(^{29}\).

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\(^{27}\) Rule 9(3)(b)(i) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010

\(^{28}\) Rule 9(5) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010
2.29 The council’s representative must consider that the hearing should no longer be held and that the allegations should be reconsidered by the IC. This may be based on, for example:

- the evidence available
- other information the council has, or
- new information about the case that has come to light after the case has been referred to an FtPC

2.30 Rescission means that the referral of the case to an FtPC is cancelled (‘rescinded’). It is rare, and the council’s representative will only give the IC their opinion that the hearing should not be held after carefully considering the evidence.

2.31 The IC must consider whether the referral to the FtPC is to be rescinded. To do so it must consider the ‘real prospect’ test when reaching a decision (please see part b for more on what we mean by impairment and the real prospect test). The IC must not rescind a referral without first giving the person raising the concern a reasonable opportunity to comment on the proposed rescission.

2.32 The IC may decide whether to rescind all of, or part of, the case against the registrant. Or the IC may decide that the hearing should not go ahead and that advice, a warning, undertakings or no further action is a more appropriate outcome. It must give reasons for its decision.

Bringing a prosecution

2.33 If the IC believes that the GPhC should consider using its powers to bring criminal proceedings it must tell the registrar and give reasons for its decision.

Reaching a decision

2.34 Making sure that an IC decides on the appropriate outcome is important for public confidence both in relation to the pharmacy professions generally but also in relation to individual pharmacy professionals. The IC may consider allegations that relate to a registrant’s personal or professional life – as concerns about either can damage the trust and confidence in pharmacy or present a risk to patients. The IC is not restricted to considering just the draft allegations recommended by the registrar and must consider the entire case.

2.35 Before reaching a decision on the appropriate outcome the IC must consider the evidence, the “real prospect” test and whether the allegation “ought to” be considered by an FtPC. The IC will:

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29 Rule 38 of the General Pharmaceutical Council’s (Fitness to Practise and Disqualification etc Rules) Order of Council 2010
30 Article 53(4) – The Pharmacy Order 2010
31 Article 53(1) – The Pharmacy Order 2010
• consider the evidence and decide if there is enough information on which to reach a decision
• decide whether there is a real prospect of the facts of an allegation being proven
• decide whether the facts, if proven, would mean that there is a real prospect that the FtPC will make a finding that the registrant’s fitness to practise is impaired
• decide on whether the matter ought to be considered by an FtPC or whether another outcome is more appropriate

2.36 In reaching its decision the IC should recognise that it is conducting a limited, paper-based exercise on the information before it, and should not make findings of fact. The IC must decide whether any allegations – and if so, which allegations – should be considered by an FtPC.

2.37 The IC must clearly identify which allegations, if any, are supported by evidence and which, if any, are not. It should clearly say what conclusions it has reached, why it has reached them and how it has reached them.

2.38 It can also decide that an allegation should not be referred to an FtPC. If an allegation is not referred, the IC can decide on a number of outcomes (please see part b for details of the available outcomes).

Recording the decision

2.39 The IC must give a formal statement setting out its decision and its reasons for that decision. The formal statement should be clear and allow anyone to easily understand the decision. The reasons must leave the reader with a clear understanding of:
• the factors considered
• the decision made
• why the decision was made
• how the decision was reached (including the “real prospect” test and whether it “ought to” be considered)
• why any advice or material was rejected, if this happened
• why the IC chose not to follow the registrar’s recommendation, if this happened, and
• why it chose not to follow this guidance, if this happened
2.40 Reasons do not need to be elaborate or lengthy, but they should tell everyone involved in broad terms why the IC reached its decision\(^32\). Repeating the real prospect test or stating the conclusion does not amount to giving reasons. When giving advice, the IC should clearly say what that advice is. Decisions are shared with the person raising the concern, the registrant and, in some cases, the registrant’s employer.

2.41 If the IC is recommending that further allegations should be considered by the council, then the IC should make clear what these allegations are and the reasons for considering them.

\(^32\) Lutton v GDC [2011]CSOH 96
Part b: Guidance on outcome

This part gives guidance on the approach that the IC should take when deciding whether to refer a matter to the FtPC. In particular, it provides guidance on the application of the real prospect test and whether it ought to refer an allegation to an FtPC. It also includes guidance on the possible outcomes that the IC can decide on, what they mean and what an IC should consider before deciding on a particular outcome. IC members must use their own judgement when considering the information available and deciding on the appropriate and proportionate outcome. By ‘proportionate’ we mean that an outcome should be no more serious than it needs to be to achieve its aims33.

3 The real prospect test

3.1 When deciding on the outcome the IC should first decide whether it considers that there is a real prospect of an allegation being proven before an FtPC. This is the ‘real prospect’ test.

3.2 The real prospect test is in two parts, and applies to:
   a the factual allegations themselves, and
   b the question of whether the facts, if proven, would demonstrate that the registrant’s fitness to practise is impaired

3.3 A “real prospect” means that something must be a genuine possibility, not one that is merely remote or fanciful34. The IC should consider all the information before it. It is entitled to assess the relevance and weight of the evidence, but should not try to resolve significant conflicts of – or disputes about – evidence. That is a matter for an FtPC.

3.4 The IC should not try to consider what the FtPC will, or might, decide. The IC should only decide whether or not there is a real prospect of a matter being established before an FtPC. It should consider whether there is a real prospect that the FtPC will make a finding that the registrant’s fitness to practise is currently impaired.

3.5 It is the responsibility of an FtPC to decide whether any facts are proved, and, if so, whether the registrant is currently impaired.

Considering the factual allegations (part a. of the test)

3.6 The IC must first assess the evidence before it and decide whether there is a real prospect of the alleged facts being established. Only then can it consider the second part of the test. When considering the real prospect test, the IC should bear in mind that it is for the council to prove, on the balance of probabilities, the truth of the alleged facts at an FtPC hearing.

33 Chaudhury v General Medical Council [2002] UKPC 41
34 Swain v Hillman (2001) 1 All ER 91
3.7 A case may consist of more than one allegation. If so, the IC should consider the first part of the real prospect test for each allegation separately.

3.8 If there is no real prospect of the alleged facts being proven, then no further action should be taken by the IC. The case should be closed without giving advice or a warning. If the IC decides that there is a real prospect of proving the alleged facts, it should then go on to consider whether there is a real prospect that the FtPC could make a finding of current impairment (part b of the test).

Impairment (part b. of the test)

3.9 The second part of the test is that the IC should ask itself whether there is a real prospect that the FtPC will make a finding that the registrant’s fitness to practise is impaired. This does not mean the IC must decide whether the registrant’s fitness to practise is currently impaired, as this is a decision for an FtPC.

3.10 When considering impairment the FtPC looks at current impairment, not whether the registrant was impaired at the time the incident occurred. However, to decide on a registrant’s fitness to practise, the FtPC will have to take account of the way the person concerned has acted or failed to act in the past.

3.11 If the IC concludes that there is no real prospect of the FtPC deciding that the registrant’s fitness to practise is currently impaired, but decided that there is a real prospect of the alleged facts being proven, then it should consider whether advice or warning is appropriate in the circumstances of the case.
What we mean by ‘impairment’

A pharmacy professional is ‘fit to practise’ when they have the skills, knowledge, character, behaviour and health needed to do their job safely and effectively. In practical terms, this means maintaining appropriate standards of competence, demonstrating good character, and also adhering to the principles of good practice set out in our various standards, guidance and advice.

Fitness to practise can be impaired for a number of reasons including misconduct, lack of competence, ill-health or a conviction for a criminal offence* (this is not a full list).

The fitness to practise committee may consider allegations that occur in either personal or professional life. They must decide whether the registrant’s fitness to practise is currently impaired, not whether it was at the time the incident occurred. The committee must take into account relevant factors, which include whether or not the conduct or behaviour^:
- presents an actual or potential risk to patients or to the public
- has brought, or might bring, the profession of pharmacy into disrepute
- has breached one of the fundamental principles of the profession of pharmacy
- shows that the integrity of the registrant can no longer be relied upon

The committee should also consider whether:
- the conduct which led to the complaint is able to be addressed
- the conduct which led to the complaint has been addressed
- the conduct which led to the complaint is likely to be repeated
- a finding of impairment is needed to declare and uphold proper standards of behaviour and/or maintain public confidence in the profession

The decision on impairment is a matter for the judgement of the committee. The committee has to make its own decision about impairment even when it is admitted by the registrant. It should make clear what factors it has taken into account when deciding on impairment.

* Article 51 - Pharmacy Order 2010
^ Rule 5 - The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010

Key factors to consider

3.12 In deciding whether the real prospect test is met, the IC should consider:
- all documents placed before it by the registrar\(^{35}\)
- The circumstances of the allegation
- the registrant’s behaviour, attitude and actions
- the regulatory standards

\(^{35}\) Rule 9(3) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010
• the registrar’s recommendation\(^{36}\) (the IC is not bound by this)
• any written representations received from the registrant concerned
• any representations offered by a relevant patient or the person raising the concern
• any relevant fitness to practise history
• any guidance issued by the GPhC to the statutory committees, including this guidance
• any other guidance issued by the GPhC

3.13 Aggravating and mitigating factors may also be relevant to the decision on part b of the real prospect test. However, generally such aggravating and mitigating factors are of more relevance to considering whether the IC “ought to” refer the matter to the FtPC or decide on some other outcome.

4 Deciding on the outcome

4.1 If the IC decides that the real prospect test has not been met then it must not refer the allegation to an FtPC\(^{37}\). If it decides that there is a real prospect of the alleged facts being proven, but there is no real prospect of a finding of current impairment, then it should go on to consider whether advice or a warning is appropriate in the circumstances of the case.

4.2 However, if the IC decides that there is a real prospect of the alleged facts being proven and a real prospect that such facts, if proven, will lead the FtPC to reach a decision that the registrant’s fitness to practise is currently impaired it should consider whether it ought to refer the allegation to the FtPC or whether some other outcome is appropriate\(^{38}\). Usually the IC will refer such an allegation.

4.3 In deciding whether to refer to an FtPC, the IC must consider whether referral is in the public interest and whether such a referral is a proportionate outcome. It should consider relevant mitigating and aggravating factors. It should also bear in mind those particular types of allegation for which further guidance has been provided to the FtPC in the GPhC Hearings and sanctions guidance.

4.4 If the specific circumstances of a case mean the IC concludes that it ought not to be considered by the FtPC, then the IC should consider alternative outcomes. It should explain the reasoning behind its decision and why an alternative outcome is more appropriate.

4.5 If the IC is unsure about whether the real prospect test is met, or whether it ought to refer, it should favour referring the allegation(s) to the FtPC.

\(^{36}\) Rule 9(3)(a)(i) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules)
Order of Council 2010
\(^{37}\) Rule 9(7)(a) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010
\(^{38}\) Article 53(1) Pharmacy Order 2010
Key factors to consider

4.6 In deciding whether the allegation ought to be referred to the FtPC or whether some other outcome is more appropriate, the IC should consider:

- the public interest
- any aggravating or mitigating factors
- The circumstances of the allegation and whether there is an ongoing risk to members of the public
- The registrant’s behaviour, attitude and actions
- all evidence placed before it by the registrar
- the regulatory standards
- the registrar’s recommendation
- any written representations received from the registrant concerned
- any representations offered by a relevant patient or the person raising the concern
- any relevant fitness to practise history
- whether a lesser outcome would be appropriate
- section on More guidance on particular areas in Good decision-making: Fitness to practise hearings and sanctions guidance
- any other guidance issued by the GPhC

The public interest

4.7 In reaching a decision on outcome, the IC should give appropriate weight to the wider public interest. Public interest considerations include:

- protecting the public
- maintaining public confidence in the profession
- maintaining proper standards of behaviour

Aggravating and mitigating factors

4.8 Aggravating factors are the circumstances of a case that can make what happened more serious. Aggravating factors could, for example, include the level of harm caused or an apparent lack of insight shown by the registrant. Mitigating factors are the opposite. They are factors that make what happened less serious. Relevant aggravating and mitigating factors can be considered by an IC when assessing the real prospect test or when deciding on an outcome (which includes whether the allegation ought to be referred to an FtPC).

4.9 Although both mitigating and aggravating factors are important elements to consider, there are limits to how much the IC can consider them. This is because,

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39 Rule 9(3) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010
40 Rule 9(3)(a)(i) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010
unlike the FtPC, the IC cannot test any evidence before it. Therefore the IC should not usually consider any purely personal mitigation – for example, character references or professional testimonials. This is evidence that the FtPC will usually only consider once it has concluded that a registrant’s fitness to practise is impaired.

4.10 However, as part of their decision-making, the IC can take account of any features of the case that would be considered by an FtPC as either aggravating or mitigating ones. These may include expressions of regret or apology, or evidence of remediation undertaken by the registrant.

The circumstances

4.11 The circumstances in which the alleged incident occurred may be relevant to the decision on outcome. The IC should consider the implications or risks to patient safety as a result of the incident. It may also want to consider, for example:
- whether the incident was a ‘one-off’ one or repeated
- the setting in which the incident took place
- if there is a relevant history of fitness to practise concerns

4.12 The IC should consider if the incident involved:
- an abuse or breach of trust
- an abuse by the registrant of their professional position
- any financial gain on the part of the registrant

4.13 They should also consider any previous fitness to practise findings involving the registrant that are relevant to the case. Other factors might include if the registrant was under the influence of alcohol or drugs, or if there was harm or a risk of harm to a patient or another person present.

Behaviour and attitude

4.14 Evidence of the registrant’s behaviour and attitude before, during and after the incident in question and before and during proceedings, is also important – for example, co-operation with the investigation. The IC may want to consider whether the registrant has:
- shown any remorse or set out to put things right – including by offering an apology
- demonstrated insight into the concerns in question and actions taken to avoid repetition of them
- undertaken further training

The Registrant’s actions

4.15 The registrant’s actions are important elements for the committee to consider when deciding on an outcome. Factors the committee may want to consider include whether the:
- conduct was pre-meditated or not
- registrant attempted to cover up wrongdoing
- conduct was sustained or repeated over a period of time
- registrant took advantage of a vulnerable person
## 5 Available outcomes

5.1 The IC has the power to decide on a range of outcomes for any given case. The table below shows the outcomes that are available, and the circumstances the IC should consider when deciding on the most appropriate and proportionate outcome.

5.2 An IC may decide on any of the outcomes below after it has considered the real prospect test. The table includes details of what outcomes can be displayed on the online register. Our publication and disclosure policy\(^ {42} \) shows how long they are displayed on the register for.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Impact on registration</th>
<th>Circumstances to consider when deciding on this outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take no action</td>
<td>No action will be taken, the case will be closed and no details will be recorded on the register.</td>
<td>The IC is satisfied there is no real prospect of proving the factual allegations or no real prospect of the registrant’s fitness to practise being found to be impaired, and no other outcome is needed. There is no advice that should be offered to the registrant.</td>
</tr>
<tr>
<td>Advice</td>
<td>The IC gives advice to the registrant about any issue it considers necessary, to make sure they address any specific areas so that they meet the relevant professional standards. It will not be recorded on the register. There are no restrictions on registration.</td>
<td>The IC is satisfied there is a real prospect of proving the factual allegations but the allegations do not need to be considered by an FtPC. Although there is no impairment of fitness to practise, a letter of advice about a registrant’s future conduct or performance may be appropriate. The IC should consider whether specific advice can deal with the issue. Advice may be appropriate if there are no aggravating factors, or if the registrant has demonstrated insight and taken action to remedy the wrongdoing themselves. Advice can be offered to a registrant about their future conduct. An advice letter can be sent to the registrant or any other person involved in the investigation – for example, a superintendent pharmacist.</td>
</tr>
</tbody>
</table>

\(^ {42} \) Sanctions are placed on the register for a period given in our publication and disclosure policy

If the IC decides advice is appropriate it should clearly set out what that advice should be. It should form part of its reasons for the decision, and be included in the letter to the registrant. Any advice should also be relevant to the allegations that are being considered by the IC.

When considering whether to issue a letter of advice to any other person involved in the investigation, the IC should carefully consider the recipient and the potential benefits of the advice, and make sure it is tailored to the circumstances of the case it is considering.

When deciding on whether a warning or advice is appropriate the IC must have regard to the over-arching objective of the Council.$^{43}$

<table>
<thead>
<tr>
<th>Warning</th>
<th>The IC gives a warning to the registrant. There are no restrictions on the registrant’s ability to practise. The fact of this warning will be recorded on the register. A registrant has the right to ask to be referred to an FtPC instead of having a warning imposed by the IC. If a request for referral is made, the IC must refer.$^{44}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undertakings$^{45}$</td>
<td>Undertakings may include restrictions</td>
</tr>
</tbody>
</table>

The IC is satisfied there is a real prospect of proving the factual allegations, but the allegations do not need to be considered by an FtPC.

The IC is satisfied that the behaviour cannot be addressed solely by advice, but that more serious action is needed. There is a need to demonstrate to a registrant, and more widely to the profession and the public, that the conduct or behaviour fell below acceptable standards.

A warning will not be appropriate if there is a risk to the public or patients which means that the registrant’s registration must be restricted. Generally, warnings will not be appropriate if the allegation relates solely or mainly to the registrant’s mental or physical health.

$^{43}$ Health and Social Care (Safety and Quality) Act 2015
$^{44}$ Article 53(3) – The Pharmacy Order 2010
$^{45}$ Undertakings are taken from a published undertakings ‘bank’.
on practice or behaviour or a commitment to undergo supervision or retraining.

Undertakings allow a registrant to continue to practise, while putting right any shortcomings in their practice and dealing with any health issues.

Undertakings can be set for up to two years. The fact the undertaking was issued will be recorded on the register.

impairment is admitted or could be found at an FtPC, but the allegations do not need to be considered by an FtPC.

The IC has the power, if the registrant admits that their fitness to practise is impaired, to agree undertakings

The IC is satisfied that the registrant will comply with the undertakings – for example, because they have genuine insight into their behaviour and the potential for remediation. Undertakings may be appropriate if there are identifiable areas of the registrant’s practice which are in need of review, assessment or retraining. They may also be appropriate if there is evidence that the registrant has sufficient insight into any health problems and is prepared to agree to keep to undertakings relating to medical supervision and treatment.

They will not be appropriate if patients will be put at risk, either directly or indirectly, as a result of continued registration with undertakings.

Undertakings, and the reasons for them, should be made clear so that when there is a review the IC (and the GPhC) is able to evaluate whether the aims have been achieved. If they need to be in place for longer than two years, to ensure public protection, the IC should consider referring the case to an FtPC.

<table>
<thead>
<tr>
<th>Referral to FtPC</th>
<th>There is no immediate restriction on a registrant’s registration and the case will be considered by an FtPC which has a range of outcomes at its disposal.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The IC is satisfied that both parts of the real prospect test are met and the allegation(s) ought to be considered by an FtPC.</td>
</tr>
<tr>
<td></td>
<td>When deciding on referral, the IC should be aware of the guidance provided to the FtPC. The IC should consider whether an interim order is appropriate in the circumstances of the case.</td>
</tr>
</tbody>
</table>

46 Rule 10(1) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010

47 Please see Good decision-making: Fitness to practise hearings and sanctions guidance
Administrative procedures

5.3 If the registrar makes a recommendation, in all cases the registrant will be invited to make a written representation about this to the IC within 21 days, and before the IC holds its meeting. If the IC has decided on an outcome that includes an undertaking or warnings, there are some important procedures to follow to ensure a decision made by the IC is formal and recorded. These are given below.

Issuing a warning

5.4 If the IC decides that a warning is the appropriate outcome, and it has been recommended by the registrar, there is no need to adjourn the meeting to invite representations from the registrant about the warning.

5.5 If no recommendation has been made by the registrar – or if the IC disagrees with the recommendation made, but decides a warning is the appropriate outcome – the IC must adjourn the meeting to allow the registrant to make written representations specifically on that warning.48

5.6 When the case comes back to the IC it must take into account any written representations made – and this guidance – when deciding whether or not to issue the warning. The IC can decide that a warning can be imposed without the consent of the registrant.

Agreeing undertakings

5.7 Once the IC reaches a decision to offer undertakings, the IC secretary will write to the registrant within 10 days. They will send them a copy of the undertakings and the reasons for offering them. If the registrant agrees to accept the undertakings, they must sign the undertakings form and send it back to the IC secretary within 14 days. If they do not accept or comply with the undertakings then the case may be referred to a fitness to practise committee.

5.8 It should be made clear that the registrant must meet the cost of complying with their undertakings.

5.9 Undertakings may be reviewed by an IC before the end of the period they were originally set for. The information provided by the GPhC may show that:
• the registrant has complied with the undertakings and their health and performance has improved
• they are in breach of their undertakings, or
• the GPhC has concerns about the registrant’s fitness to practise

48 No later than 21 days after the date of the issue of the letter inviting submissions
5.10 If the IC receives information that undertakings have not been complied with, it may:\(^{49}\):

- refer the original allegation to the FtPC, and treat the failure to comply with the undertakings as a separate allegation of misconduct and refer that allegation to the FtPC, or
- decide not to refer the original allegation to the FtPC, but treat the failure to comply with the undertakings as a separate allegation of misconduct and refer that allegation to the FtPC

5.11 If the IC receives information that undertakings may no longer be appropriate, it may\(^{50}\):

- with the agreement of the registrant, vary those undertakings, or
- decide that those undertakings no longer apply

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\(^{49}\) Rule 10(2) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010

\(^{50}\) Rule 10(3) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010
Public business

Reviewing our standards of conduct, ethics and performance

Purpose
To update the Council on the review of the standards of conduct, ethics and performance.

Recommendations
The Council is asked to note this paper.

1. Introduction
1.1 The GPhC announced the review of its standards of conduct, ethics and performance at the end of 2014. They are the core professional standards that pharmacists and pharmacy technicians must apply and meet whatever their scope of practice.

1.2 The standards set out the behaviours, attitudes, qualities and attributes that are expected of pharmacy professionals by patients, the public, the regulator, and by pharmacy professionals themselves.

2. Revised professional regulatory standards of conduct, ethics and performance
2.1 Work to revise the standards of conduct, ethics and performance have been developed and informed by:
   i. the GPhC strategic plan and the Council’s clear commitment to promoting a culture of patient-centred professionalism and putting people and patients at the heart of what we do;
   ii. the feedback we have received through the discussion paper ‘Patient-centred professionalism in pharmacy’;
   iii. the GPhC regulatory standards policy;
iv. the Governments’ visions and strategies for the delivery of healthcare services and in particular the increasing role that pharmacy will play in the future;

v. the IPSOS MORI research about public perceptions of pharmacies and

vi. the changing models of service delivery.

2.2 We expect that the proposed professional regulatory standards will be based on a smaller number of core standards and will be supported by guidance proposed in a wide range of areas.

3. Patient-centred professionalism in pharmacy

3.1 Underpinning the work to develop new professional regulatory standards has been our initiative to engage on patient-centred professionalism.

3.2 On 24 April 2015, the GPhC published a discussion paper, *Patient-centred professionalism in pharmacy*, to begin a national conversation about what it means to be a pharmacy professional in the 21st century and what patients and the public expect from pharmacy professionals today.

3.3 The discussion paper sought views on the characteristics that someone who is patient-centred and professional demonstrates. We also asked about the barriers and enablers to demonstrating professionalism, and finally asked for examples to support this.

3.4 The GPhC used a wide variety of methods to engage with patients and the public, pharmacy professionals and organisations across England, Scotland and Wales. The discussion paper was published on our website alongside an online survey, and it was shared with key stakeholders. The GPhC also used social media to raise awareness of the discussion paper and as a means of hearing from people; this included a Twitter chat supported by #WePharmacists.

3.5 We engaged with pharmacy professionals at a number of events including the Clinical Pharmacy Congress, the Association of Pharmacy Technicians UK Conference and several Local Pharmacy Committee meetings across England. We engaged with patients and the public at meetings with organisations including the Greater London Forum for Older People and through focus groups that we held with members of the public in England, Scotland and Wales.

3.6 We heard from 502 individuals, including 35 organisations across England, Scotland and Wales over the course of nine weeks. Of these, 112 identified themselves as patients and members of the public, and 249 identified themselves as pharmacy professionals. Individuals and organisations shared their views and in some cases submitted existing research.
3.7 There was a lot of consistency in what we heard from the feedback, in particular a consistent view that being patient-centred and being professional are one and the same thing. We grouped what we heard into key themes, which included: behaviours, communication, leadership, team work, judgement and patient-centeredness.

3.8 The GPhC launched an animation and short report to summarise what we heard in September 2015.

4. Testing and consultation

4.1 Prior to a full, formal consultation the GPhC is testing the draft standards with a range of stakeholder organisations which represent patients and pharmacy professionals, as well as with members of the public through focus groups in England, Scotland and Wales.

4.2 The feedback we have received to date has been broadly positive, and we will continue to reflect on what we hear to inform the draft standards.

4.3 The Council will be asked to agree a consultation, including draft standards and guidance in early 2016.

5. Equality and diversity implications

5.1 We will engage and consult with a wide range of audiences including hard to reach groups.

5.2 The GPhC will develop an equality impact assessment consistent with our responsibilities as set out in the Equalities Act 2010.

6. Communications

6.1 The GPhC is committed to engaging and consulting on the professional standards on a wide scale.

6.2 Building on the success of the initial discussion paper about patient centred professionalism in pharmacy, the GPhC will use a variety of communication tools, both traditional and innovative to enable all individuals and organisations to contribute to this work.

6.3 Working with and alongside other organisations to extend our reach to pharmacy professionals and patients will ensure that we engage widely on this work.

6.4 We are also beginning work to reflect on the way in which we will communicate the implementation of the standards, towards the end of 2016, to pharmacy professionals, patients and people who use pharmacy services and others.
7. **Resource implications**

7.1 The resource requirements for this piece of work have been budgeted.

8. **Risk implications**

8.1 Failure to develop standards that enable and empower registrants to deliver patient-centred care will impact on patient safety and the ability for pharmacy professionals to play the role that ministers across Great Britain have set out to unlock the full potential of pharmacy as a whole, and the capacity of pharmacy professionals.

**Recommendations**

The Council is asked to note this paper.

_Priya Warner, Head of Standards and Fitness to Practise policy_
_General Pharmaceutical Council_
_Priya.warner@pharmacyregulation.org_
_Tel 020 3713 7958_

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