

Council meeting

7 March 2019

14:30 to 16:00 **approx.**

Council Room 1, 25 Canada Square, London E14 5LQ

Public business

1. Attendance and introductory remarks	Nigel Clarke
2. Declarations of interest <i>Public items</i>	All
3. Minutes of last meeting <i>Public session on 07 February 2019</i>	Nigel Clarke
4. Actions and matters arising	Nigel Clarke
5. Workshop summary	Nigel Clarke
6. Fees rules 2019 – consultation analysis and responses <i>For approval</i>	19.03.C.01 Duncan Rudkin
7. Draft consultation on guidance for pharmacist prescribers <i>For approval for consultation</i>	19.03.C.02 Mark Voce
8. Any other public business	Nigel Clarke

Confidential business

9. Declarations of interest <i>Confidential items</i>	All
10. Minutes of the last meeting <i>Confidential session on 07 February 2019</i>	Nigel Clarke
11. Confidential actions and matters arising	Nigel Clarke
12. Chairs of non-statutory committees 2019-20 <i>For approval</i>	19.03.C.04 Laura McClintock
13. Any other confidential business	Nigel Clarke

Date of next meeting

Thursday, 11 April 2019

Minutes of the Council meeting held on Thursday 7 February 2019 at
25 Canada Square, London at 13:30

TO BE CONFIRMED 7 March 2019

Minutes of the public session

Present

Nigel Clarke (Chair)
Mary Elford
Digby Emson
Mark Hammond
Mohammed Hussain
Jo Kember

Alan Kershaw
Elizabeth Mailey
Berwyn Owen
David Prince
Samantha Quaye
Jayne Salt

Apologies

Arun Midha

In attendance

Duncan Rudkin (Chief Executive and Registrar)
Carole Auchterlonie (Director of Fitness to Practise)
Claire Bryce-Smith (Director of Insight, Intelligence and Inspection)
Laura McClintock (Chief of Staff)
Francesca Okosi (Director of People)
Mark Voce (Director of Education and Standards)
Osama Ammar (Head of Continuing Fitness to Practise)
Damian Day (Head of Education)
Julian Graville (Head of Inspections)
Rachael Oliver (Head of Communications)
Vanessa Clarke (Finance Manager and Management Accountant)
Janet Collins (Governance Manager)

94. Attendance and introductory remarks

- 94.1 The Chair welcomed all present to the meeting.

95. Declarations of interest

- 95.1 Council agreed that members would make any declarations of interest before each item.

96. Minutes of the last meeting

- 96.1 **The minutes of the public session held on 6 December 2018 were confirmed as a fair and accurate record and signed by the Chair.**

97. Actions and matters arising

- 97.1 Action 61.1 from October 2018 was covered in the performance monitoring report on the agenda for this meeting and further information had been sent to Council separately. Action 72.6 from November was closed for the purposes of the action log – proposals had been presented to the Efficiency and Effectiveness Assurance and Advisory Group (EEAAG) in January 2019 and would be followed up by the group in May.
- 97.2 All other actions were complete.

98. Workshop summary – 6 December 2018

- 98.1 **Council noted the discussions from the December workshop.**

99. Performance monitoring and annual plan progress report

- 99.1 Duncan Rudkin (DR) introduced **19.02.C.01** which reported on operational and financial performance and progress against the annual plan from October to December 2018. There were a small number of factual errors in the data which would be pointed out as the discussion progressed and the data would be re-issued to Council members in a corrected form.

Customer Services

- 99.2 In table 1.2 (Registration totals), the variance in the registrations of pharmacy technicians should have read -82.

- 99.3 Members noted the improvement in the Contact centre data and thanked the team for their work. There was a question as to whether the team had sufficient resources to manage a possible increase in queries related to revalidation. The plan which had been considered by the EEAAG included short, medium and long term aims, quality elements and focussed on the sensible use of resources. EEAAG would monitor the situation.
- 99.4 In relation to table 1.5 (Revalidation for pharmacy professionals) it was noted that a number of voluntary removals from the register was to be expected and contributed to the aim of the register being a list of professionals currently fit to practise. The remediation figures were good and a testament to the preparation work undertaken.
- 99.5 Pharmacy technician applications for registration would go online during 2019-20.

Fitness to Practise

- 99.6 DR introduced Carole Auchterlonie (CA) who had recently taken up post as the Director of Fitness to Practise.
- 99.7 In table 2.1 (Fitness to practise performance standards) on page 31, the Q3 figure for stream 1 cases closed pre-IC should have been 238, not 92.
- 99.8 On-hold cases were being handled more proactively, being reviewed individually to see whether action could be taken without prejudicing any possible criminal proceedings. Those that still needed to be kept on hold would be kept under active review.
- 99.9 Although the number of concerns being received had increased, there was no discernible pattern or increase in particular issues, nor was there a repeating pattern of a winter peak in concerns (which was possible as winter was a busy time in pharmacies). There was currently no evidence of increasing concern about medicines shortages, either in the concerns received or in what inspectors were hearing in pharmacy.
- 99.10 It would be important with the approach to Britain's exit from the European Union to be clear about the regulation of the medicines supply chain and what the Council could and could not do. Discussions about substitution protocols were ongoing and the GPhC was keeping in close touch with the other healthcare regulators to facilitate the provision of co-ordinated and consistent information for patients and healthcare professionals.

Inspection

- 99.11 Members noted that staffing issues were not among the 'top five standards not met' on this occasion. Further information had been provided around standard 4.3 on medicines and medical devices and the reasons for that standard not being met on inspection. The top five issues identified related to:
- monitoring of fridge temperatures;

- adequacy of date checking procedures;
- inadequately labelled medicines;
- controlled drugs not being stored securely; and
- controlled drugs not safeguarded from unauthorised access.

99.12 It was important that this information was fed back to Controlled Drug Accountable Officers (CDAOs). Communications with CDAOs would be reviewed and reported back to Council.

ACTION: JG

99.13 In response to a question about how other, less tangible, standards such as openness and honesty were measured, Claire Bryce-Smith (CBS) noted that this was done by looking at the mechanisms available for staff to speak up about issues, by speaking to staff at all levels and looking at complementary standards such as the setting of targets. For all the standards which would be covered in the published inspection reports, the Knowledge Hub would give examples of good practice from which others could learn.

Human resources

99.14 Members complimented the HR team on the development of the learning plan. In relation to staff turnover it was noted that exit interview data suggested that promotion was the main reason for leaving the organisation. Given that this was mostly among staff at middle management level, there was a limit to what could be done as there were fewer roles for people to move into as they progressed up the organisation. Broader experience through moving into other areas would be explored as an incentive.

Annual plan progress report

99.15 DR noted that the red rating on the development of the approach to FtP was concerning but was explained by the 'main risk' to the work, namely that the people needed to work on the strategy were also engaged in dealing with cases.

99.16 CA noted that there was a balance between keeping case progression moving and needing to engage staff in the strategy. However, there were some things which could be introduced relatively quickly to improve the process.

99.17 In response to a question, CA confirmed that work was taking place on the project looking at the mental health of registrants going through the FtP process and it was on the plan for 2019-20.

99.18 On the publication of inspection reports, Julian Graville (JG) informed Council steps were being taken to ensure consistency of reporting. The framework for reporting had been

updated, inspectors were being paired and more time was being allocated to the quality assurance of reports.

99.19 There were two areas of work rated amber including organisational transformation where there were a number of actions under organisational culture and equality, diversity and inclusion (EDI) which had not been progressed. Francesca Okosi (FO) assured members that the culture work would be completed on time and that they would see progress on the EDI work in the Council workshop in March. Members expressed support for the proposed BAME and Women's networks.

99.20 **Council noted the performance management report and annual plan progress report for October to December 2018 and the management accounts for December 2018.**

100. Engagement and communications report

100.1 Rachael Oliver (RO) introduced **19.02.C.02**, which provided a quarterly update on communications and engagement with stakeholders. The report also highlighted upcoming events and activities.

100.2 In response to a question about engagement with the public on the publication of inspection reports, RO noted that there had been discussions with the Patients Association and Healthwatch, that signs would be placed in pharmacies and that a guide would be produced to help patients understand the reports. A further update would be provided nearer the point of publication.

ACTION: RO

100.3 Members welcomed the introduction of ReciteMe, a cloud-based web accessibility feature which allowed visitors to the GPhC website to customise it for their use, including text-to-speech functionality, a translation tool and dyslexia software. ReciteMe would be in place in March 2019.

100.4 In relation to members attending events, RO agreed that future lists of event opportunities would include the time of the event to help members plan. The Chair encouraged all members who were able to attend events to do so.

100.5 Laura McClintock (LM) gave an update on the GPhC's work following the report of the Gosport Independent Panel. The joint work with the Royal Pharmaceutical Society and the Association of Pharmacy Technicians UK was complete and would be launched the following week, having first been sent to members.

100.6 The Chair thanked LM and the team for the work on Gosport, which provided proactive support to pharmacy professionals.

100.7 **Council noted the Engagement and communications report.**

101. Annual plan 2019-20

- 101.1 CB-S presented **19.02.C.03(i)** setting out the Annual plan for 2019-20, which would be year three of the current strategic plan and a transition year to the ten-year vision. The quarterly progress report templates were provided in advance to provide timelines for the various pieces of work.
- 101.2 Members liked the broad shape and approach of the plan. They wanted to see the data behind the descriptors and firmer success measures including numbers, some of which would come through the balanced scorecard which was being developed.
- 101.3 It was noted that the standards for the initial education and training of pharmacists were shown as being implemented in the quarter after they were agreed. However, there would be a long lead time for the schools to put the standards in place and the plan needed to reflect this.
- 101.4 In response to a point about the contrast between the vision described in the introduction and the more process-related way that the success measures were set out, CB-S clarified that the success measures related to the annual plan, rather than the ten-year vision.
- 101.5 Members noted that the development of an EDI strategy had appeared in the plans for several years and asked when one might be developed. DR reassured members that progress had been made which was not reflected in the wording in the plan. The Chair noted that Council wished to see progress in this area as a matter of priority.
- 101.6 Members agreed that the language used in several places needed to be reviewed. Further work would be done on how implementation would be reported, including via the balanced scorecard, and Council would see the progress at its workshop in March.
- 101.7 **Council approved the annual plan for 2019-20.**

ACTION: CB-S

102. Budget 2019-20

- 102.1 DR presented **19.02.C.03(ii)** which set out the proposed budget for 2019-20. Although an assumption on fee levels had been made for the purpose of preparing the budget, this was not pre-judging the decision on fees and members were reminded that the proposed budget was subject to possible change in the light of that decision.
- 102.2 The proposed budget met a number of challenges presented by Council in relation to the cost base, the move away from deficit budgeting within a limited timeframe and the provision of more information about the size of the registered pharmacy sector and therefore volume projections. While the proposed cost reduction was substantial, it was not a large percentage of expenditure and should not cause operational difficulties.

102.3 Council welcomed the work done to develop the model and provide greater understanding on projections.

102.4 **Council approved the budget for 2019-20.**

103. Revalidation for pharmacy professionals - update

103.1 Osama Ammar presented **19.02.C.04** which provided Council with an update on the progress of the implementation of revalidation for pharmacy professionals, nearly one year after it was introduced.

103.2 Of the 42 162 registrants in the cohort expected to renew their registration and revalidate by 31 October 2018, there had been 1430 voluntary removals from the register. 1600 registrants had been issued with notices of intent to remove them from the register but only 145 (0.3% of the cohort) were removed from the register for non-compliance at the end of the process.

103.3 The challenge in the first year had been getting some registrants to engage with the GPhC. The challenges for the coming year would be around reflection and peer review.

103.4 The process gave the GPhC more certainty about what registrants were doing to keep up to date and develop their practice and could also be said to improve the currency of the register. It was too early to draw out themes or consider the impact on patients but evaluation activities were being planned and would begin in 2020-21 after the scheme had been running for two years.

103.5 **Council noted the information provided as an update on the implementation of revalidation for pharmacy professionals.**

Evelyn McPhail left the meeting

104. International registrants

104.1 Mark Voce (MV) presented **19.02.C.05** which set out action taken in response to a request received from the Professional Standards Authority (PSA) in December 2018. The request arose from the discovery that an individual had been admitted to the General Medical Council's register in 1995 on the basis of forged documentation. The PSA had asked the other healthcare regulators whether the issue might be relevant to them and whether they intended to take any action. In particular, the PSA was interested to know whether historic processes might have been vulnerable to fraud.

104.2 The paper set out the current and historic registration processes for international registrants, including previous reciprocal arrangements, and concluded that all

processes were robust and provided the necessary assurance. The information had been provided to the PSA.

104.3 **Council noted the paper.**

105. Deputising arrangements for the Chair of Council 2019-20

105.1 Item **19.02.C.06** set out the deputising arrangements for the Chair for 2019-2020. In the event that a deputy was needed between 1 April and 30 September 2019, Mark Hammond would fill the role and between 1 October 2019 and 31 March 2020 it would be Jayne Salt.

105.2 **Council agreed the deputising arrangements for the Chair for 2019-20.**

106. Unconfirmed minutes of the Audit and Risk Committee

106.1 Digby Emson presented **19.02.C.07**, the unconfirmed minutes of the Audit and Risk Committee meeting held on 23 January 2019. There was a correction to the paper – Francesca Okosi had sent apologies for the meeting.

106.2 **Council noted the minutes of the Audit and Risk Committee**

107. Any other business

107.1 The Chair gave members an update on the appointment process for new Council members who would be joining from 1 April 2019.

107.2 There being no further public business, the meeting closed at 15:40.

Date of the next meeting:

Thursday 7 March 2019

Council actions log

Meeting date	Ref.	Action	Owner	Due	Status	Comments/update
7 February 2019	99.12	Information on how we obtain information/intelligence from Controlled Drug Accountable Officers and how we share information with them	CB-S/JG	Apr 19	Open	
7 February 2019	100.2	Further update on engagement with the public on the publication of inspection reports to be provided before publication begins	MV/RO	May 19	Open	
7 February 2019	101.6	Progress on reporting of annual plan implementation to be provided at March workshop	CB-S	Mar 19	Closed	Covered in the March workshop

Meeting paper

Council on Thursday, 07 March 2019

Public business

Council Workshop Summary

Purpose

To provide an outline note of the discussions at the Council workshop on 7 February 2019.

Recommendations

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

1. Introduction

- 1.1. The Council holds a workshop session alongside its regular Council meetings each month (there are no meetings in January and August). The workshops give Council members the opportunity to:
 - interact with and gain insights from staff responsible for delivering regulatory functions and projects;
 - receive information on projects during the development stages;
 - provide guidance on the direction of travel for work streams via feedback from group work or plenary discussion; and
 - receive training and other updates.
- 1.2. Following each workshop there is a summary of the discussions that took place, presented at the subsequent meeting. This makes the development process of our work streams more visible to the GPhC's stakeholders. Some confidential items may not be reported on in full.
- 1.3. In the workshop sessions the Council does not make decisions. The sessions are informal discussions to aid the development of the Council's views.

2. Summary of the December workshop

Professional Standards Authority (PSA): The new Standards of Good Regulation

- 2.1 Alan Clamp (Chief Executive Officer) and Mark Stobbs (Director of Scrutiny and Quality) at the Professional Standards Authority presented a session on the new Standards of Good Regulation.
- 2.2 The Standards of Good Regulation were used by the PSA to report on the performance of the regulators that they oversaw. The current Standards had been in place since 2010 and, in June 2017, the PSA started a two-stage consultation process, to ensure that the standards remain fit for purpose

and appropriate given the changes in regulatory practice. The PSA welcomed the fact that the GPhC had asked their Council members to be directly involved in the consultation by meeting with the PSA.

- 2.3 The PSA Board approved the final iteration of the new Standards in November 2018, and they would be used to assess the performance of regulators from the performance review round beginning in 2020.
- 2.4 Council members noted that the Standards were broadly unchanged and continued to cover the core activities of the regulators: standard-setting, education, registration and fitness to practise. Some Standards in these areas had been rationalised, to remove duplication. Additionally, the PSA had introduced five new Standards relating to all aspects of how the regulator delivered its regulatory functions, including how regulators shared learning across the organisation, and how they understood the diversity of their registrant population and its service users and ensured that its processes did not impose inappropriate barriers or otherwise disadvantage people with protected characteristics. The new Standards would be supported by an updated evidence framework, on which the PSA was currently engaging with the regulators.
- 2.5 Prior to implementation in 2020, the regulators were also being asked to take part in piloting the new Standards between April to September 2019. The pilots would run concurrently with the live performance review round for 2018/19.
- 2.6 Finally, there was some broad discussion and questions from the Council about the extent to which the PSA had a role in sharing good practice and driving improvement, and how this might be done through the performance review. The PSA discussed their thinking about how more might be done in this area through the review process, as well as wider plans for the development of a new strategic plan which responded to key issues within professional regulation more widely.

Exploring charitable status

- 2.7 The second session was an exploration of the principles and ethical considerations of the GPhC applying for charitable status led by Duncan Rudkin (DR). The legal and financial implications were being explored in parallel.
- 2.8 Members had a number of questions, including whether the aims of the GPhC could be described as charitable and the fact that once an organisation became a charity it could not revert back to non-charitable status.
- 2.9 Council directed that the issue should be kept under review.

Investment

- 2.10 The third session was also led by DR and focussed on the principles of ethical investment. Members were asked for their views on an initial draft as a basis for an ethical investment policy and discussed how such a policy should relate to:
 - the Council's statutory objectives;

- its independence and objectivity in delivering its regulatory functions; and
- wider environmental, social and governance issues.

2.11 This was an opportunity for members to feed in to the development of a draft investment policy. Following a table-based discussion, members were asked to note down their views on the early draft and also to set-down any red lines i.e. areas in which they strongly believed the Council should not invest funds. The views were collected and would inform the further development of the draft policy.

Protocol for dealing with patient safety issues

2.12 Mark Voce (MV) presented a session on the protocol for dealing with patient safety issues which had been developed following the earlier discussion with Council in respect of sodium valproate and Avastin. Council had emphasised the importance of having clear criteria for deciding when to act, given the potential volume of medicines alerts.

2.13 The proposed approach was a four-step model, namely:

1. Anticipate
2. Assess (against criteria)
3. Act (if criteria met)
4. Review.

2.14 Council welcomed the model and the suggested criteria to be used in stage 2

Recommendations

3.1 Council is asked to note the discussions from the workshop

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General Pharmaceutical Council

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Meeting paper

Council on Thursday, 07 February 2019

Public

2019 fees rules and consultation analysis

Purpose

To provide the Council with a final draft of the 2019 fees rules and an analysis of the fees rules consultation held from November 2018 to January 2019.

Recommendations

The Council is asked to:

- Note the analysis of the fees rules consultation (appendix one)
- Approve the changes to fees summarised at section five
- Make *The General Pharmaceutical Council (Registration and Renewal Fees) (Amendment) Rules 2019* (appendix two) and agree that the GPhC's corporate seal be affixed to these rules

1. Introduction

- 1.1. The Council approved draft fees rules for consultation in October 2018. The consultation closed on 24 January 2019. We received 5,409 completed responses from a range of individuals and organisations. The analysis of responses is attached at appendix one. This paper highlights how the analysis has been taken into account in amending the proposed fees rules and commitments for further work.
- 1.2. The rules which the Council is now asked to make (appendix 2) would come into force on 1 July 2019. It is necessary to consult on and make the fees rules well in advance as our governing legislation requires us to send out renewal notices at least three months before registration is due to expire.

2. Background

- 2.1. In setting fees, the Council must ensure that the GPhC has sufficient funds to protect the public through effective regulation.

2.2. In making decisions on the fees, the Council may wish to consider:

- the cost projections for the budget for 2019/20; agreed by Council in February 2019
- the resources required to enable us to deliver the last year of the three year rolling strategy (2017-20), which is a transitional year toward the new strategic plan
- the principle that we wish to ensure a fair and proportionate allocation of fees to registrant groups, taking into account the burden of costs of regulation
- our ongoing desire to avoid significant fluctuations in fee levels in future years to any single, or all, registrant groups
- our commitment to continue to improve our efficiency and effectiveness across all areas of the GPhC.

3. Summary of consultation analysis

3.1. The consultation analysis report (appendix one) provides a full break down of qualitative and quantitative responses.

3.2. In summary:

- 70% of respondents disagreed with increasing the pharmacist entry and renewal fee by £7 from £250 to £257
- 66% of respondents disagreed with increasing the pharmacy technician entry and renewal fee by £3 from £118 to £121
- 51% of respondents disagreed with increasing the registered pharmacy entry and renewal fee by £21 from £241 to £262
- 41% of respondents disagreed that our proposals were in line with our fees policy.

3.3. Respondents expressing agreement with our proposals agreed with the rationale presented in the consultation document and often reported it back in the responses. Additionally, they indicated that they felt the increase was inevitable and reasonable, with some suggesting they thought it might be higher. Some who agreed, did so on the understanding that fees would remain fixed for a period of time.

3.4. Respondents expressing disagreement did so based on many reasons that can be summarised as:

- There were statements that the prevailing financial conditions on pharmacy professionals and pharmacies make any increase in fees a challenge to absorb and will have a negative impact on individuals, pharmacies and in some cases services and patient safety. It was further stated by some respondents that the GPhC is insulated from the same financial challenges facing the sector.
- There were also expectations for the GPhC to play a role representing the professions' or sector's interests in matters such as managing workforce numbers and negotiating staff salaries and contractor remuneration. These expectations often lead to an assessment that entry and renewal fees are not good value for money.
- There were expectations for the GPhC to demonstrate further efficiency and effective improvements before fee increases are proposed. Examples provided included considering savings related to accommodation, staff and Committee and Council remuneration, and fitness to practise litigation.
- There were requests for fee arrangements to be more sensitive to income for individuals and pharmacies. There were calls for more flexible fee options that could account for differences in income.

For individuals this might be linked to protected characteristics in some instances, with examples including discounts or pro-rata payments for people on parental leave or people with disabilities. Some called for discounts for part-time workers who may be more likely have protected characteristics or simply earning less through working fewer hours. There were also suggestions that fees should be proportional to regulatory activity, such as additional or increased fees for people in fitness to practise processes.

For pharmacies there were also suggestions that fees should be more proportional to regulatory activity. This was often supported by statements that having the same fee for all types of registered pharmacy may not be fair for the different models of pharmacy (eg independent, small multiple, large multiple, online).

4. Summary of responses to consultation

- 4.1. Respondents mostly disagreed with our proposed increases to entry and renewal fees for pharmacists, pharmacy technicians, and registered pharmacies. However, our income and fees must ensure that we can continue to work effectively as regulator in the long term. Effective regulation benefits not only patients and the public, but also registrants. Being a registered professional, or providing services from a registered pharmacy, means that patients can have confidence in the safety and effectiveness of pharmacy services.

- 4.2. We recognise the financial climate and uncertainty in which our registrants are working, whether that be in community pharmacy, primary care, hospitals or other settings. Our decisions in previous years to freeze fees and also to avoid significant increases in this year took into account the financial challenges of individuals on our register and the sector at large. The GPhC faces similar financial challenges and in order to continue effectively in our role in protecting the public we need to take necessary steps to increase our fees.
- 4.3. We need to do more to address some of the misunderstandings amongst some of our registrants about the role that we perform on behalf of members of the public through regulation of pharmacy. And we need to make clear that this role sets us apart from the pharmacy sector. This means that the options to challenge our costs are not the same as pharmacy organisations and we are not able to represent the views of the professions and sector on matters that are for professional and trade associations.
- 4.4. We will continue to challenge our costs and improve efficiency and effectiveness. Our annual plan for 2019-20 makes clear some of the measures that we intend to consider to achieve this goal. Now included within our work for next year is the initiation of a review of our current accommodation and future options. We are also intending to continue to make improvements to our systems to improve service experience and improve efficiency and effectiveness. And we will continue to challenge our costs more generally and our 2019-20 budget includes a further £720,000 efficiency saving.
- 4.5. Alongside our work to drive efficiency and effectiveness improvements will be the development of our medium to long term financial strategy. This work, which has already started, will include the comprehensive review of our costs and fees. Through this work, we will explore how we might be able to develop a more flexible set of fee arrangements and better allocate the cost of regulations to our registrants. As always, it is difficult to commit to particular options for discounts or pro-rata payments until the review is complete because we must be mindful that the cost of administration of a more complex fee structure may be prohibitive or lead to additional cost for some registrant groups above others and raise questions of fairness.

5. Summary of changes to fees rules

- 5.1. Having considered the consultation responses, we would propose the following fee structure, to come into force on 1 July 2019:
 - increasing the pharmacist entry and renewal fee by £7 from £250 to £257
 - increasing the pharmacy technician entry and renewal fee by £3 from £118 to £121
 - increasing the registered pharmacy entry and renewal fee by £21 from £241 to £262

6. Equality and diversity implications

- 6.1. An equality impact analysis has been published alongside this paper. This highlighted the potential impacts of increases to fees on individuals or groups with protected characteristics.
- 6.2. The analysis also considered the respondent profile to the consultation on draft 2019 fees rules.
- 6.3. The outcomes of the analysis will be carried forward into the comprehensive review of costs and fees with a commitment to explore fee options to help mitigate against disproportionate impacts for individuals or groups with protected characteristics.

7. Communications

- 7.1. The consultation analysis and the final version of the 2015 fees rules will be published on the GPhC's website and highlighted to the pharmacy media. The fees will be set out clearly in relevant communications with registrants, prospective registrants and pharmacy owners, including on application and renewal forms.

8. Resource implications

- 8.1. As an independent regulator, the GPhC must set fees to cover the costs of its activities. It should also be able to cover the fluctuations in expenditure, and maintain a reasonable level of reserves.
- 8.2. The setting of fees is integral to the management of GPhC's resources.
- 8.3. The resource implications for 2019/20 were fully laid out in the budget paper that Council considered in February.

9. Risk implications

- 9.1. The most significant risk for patients and the public is if the GPhC does not have sufficient resources to carry out its regulatory functions appropriately.
- 9.2. As described within the fees consultation and earlier in this paper, there are additional risks if we are unable to achieve our strategic aims successfully.
- 9.3. We recognise the responsibility that the GPhC has to maintain the confidence of all our stakeholders, including registrants.
- 9.4. Failure to set fees in an appropriate way, or failure to communicate any recommended changes in an open and transparent manner, could create reputational risks for the organisation.
- 9.5. Failure to consult adequately on the fees rules would mean that the GPhC would not be complying with its statutory duties.

10. Monitoring and review

- 10.1. The fees rules will come into force on 1 July 2019. The income generated as a result of the new rules will be reported in the Council performance monitoring report.
- 10.2. We will continue to review our approach to costs and fees through our comprehensive review, which will be used to consider any future fee levels.
- 10.3. We will continue to monitor and improve our efficiency and effectiveness through the Efficiency and Effectiveness Assurance Group, which reports into Council.

Recommendations

The Council is asked to:

- Note the analysis of the fees rules consultation (appendix one)
- Approve the changes to fees summarised at section five
- Make *The General Pharmaceutical Council (Registration and Renewal Fees) (Amendment) Rules 2019* (appendix two) and agree that the GPhC's corporate seal be affixed to these rules

Duncan Rudkin, Chief Executive and Registrar

General Pharmaceutical Council

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28 February 2019

Appendix one – Consultation on the draft 2019 fees rules: analysis report

Appendix two - The General Pharmaceutical Council (Registration and Renewal Fees) (Amendment) Rules 2019

Consultation on the draft 2019 fees rules: analysis report

The consultation: what we did

1. Policy background

- 1.1. Between November 2018 and January 2019 we consulted on proposals to make changes to our fees for entry to and renewal of registration as a pharmacist, pharmacy technician and registered pharmacy.
- 1.2. Our role is to protect the public and give them assurance that they will receive safe and effective care when using pharmacy services. We have an important responsibility to make sure we have the necessary financial resources to fulfil this role and our statutory duties.
- 1.3. Our income comes from the fees that we charge to pharmacists, pharmacy technicians and registered pharmacies. Every year we have to review our fees to consider whether we need to change them in order to have sufficient income for the year ahead.
- 1.4. We know that our fees have an impact on the finances of pharmacy professionals and registered pharmacies. And we recognise that pharmacy professionals and pharmacies are facing increases in their workloads, growing costs and funding challenges.
- 1.5. We therefore only propose fee increases when necessary, taking account of our ongoing work to challenge and contain our costs and to make appropriate efficient use of the financial reserves we hold.

2. Summary of our proposals

- 2.1. We proposed to increase the entry and yearly renewal fees for:
 - pharmacists by £7 from £250 to £257.
 - pharmacy technicians by £3 from £118 to £121.
 - pharmacy premises by £21 from £241 to £262.
- 2.2. We also highlighted our ongoing work to develop a longer-term financial strategy through a comprehensive review of our costs and fees.

3. About the consultation

3.1. Overview

The consultation was open for 12 weeks, beginning on 1 November 2018 and ending on 24 January 2019. To make sure we heard from as many individuals and organisations as possible:

- an online survey was available for individuals and organisations to complete during the consultation period. We also accepted postal and email responses
- we promoted the consultation through a press release to the pharmacy trade media, via our social media and through our e-bulletin Regulate

3.2. Survey

- We received a total of **5,409** written responses to our consultation; **5332** of these respondents identified themselves as individuals and **77** responded on behalf of an organisation.
- Of these responses, **5,407** had responded to the consultation survey. The vast majority of these respondents completed the online version of the survey, with the remaining respondents submitting their response by email, using the structure of the consultation questionnaire.
- Alongside these, we received **two** responses from organisations writing more generally about their views. This means quantitative totals for responses from organisations will be out of **75**. Qualitative analysis was conducted against all **77** responses provided on behalf of organisations.

3.3. Social media

- We monitored social media activity during the consultation period and collated the feedback for inclusion in our consultation analysis.

4. Our approach to analysis and reporting

4.1. Overview

- Every response received during the consultation period including social media activity has been considered in the development of our analysis. Our thematic approach allows us to represent fairly the wide range of views put forward, whether they have been presented by individuals or organisations.
- The key element of this consultation was a self-selection survey, which was hosted on the Smart Survey online platform. As with any consultation, we expect that individuals and groups who view themselves as being particularly affected by the proposals, or who have strong views on the subject matter, are more likely to have responded.
- The purpose of the analysis was to identify common themes amongst those involved in the consultation activities rather than to analyse the differences between specific groups or sub-groups of respondents.
- The term ‘respondents’ used throughout the analysis refers to those who completed the consultation survey. It includes both individuals and organisations.
- For transparency, Appendix 1 provides a list of the organisations that have engaged in the consultation through the online survey and email responses.
- The consultation questions are provided in Appendix 2.

4.2. Quantitative analysis

- The survey contained a number of quantitative questions such as yes/no questions. All responses have been collated and analysed including those submitted by email or post using the consultation document. Those responding by post or email more generally about their views are captured under the qualitative analysis only.
- Responses have been stratified by type of respondent, so as not to give equal weight to individual respondents and organisational ones (potentially representing hundreds of individuals). These have,

however, been presented alongside each other in the tables throughout this report, in order to help identify whether there were any substantial differences between these categories of respondents.

- 160 individuals submitted more than one response. These were identified by matching an email address and name. In these cases, the individual respondent's most recent response was included in the quantitative analysis and all qualitative responses were analysed.
- The tables contained within this analysis report present the number of respondents selecting different answers in response to questions in the survey. The ordering of relevant questions in the survey has been followed in the analysis.
- Percentages are shown without decimal places and have been rounded to the nearest whole number. As a result, some totals do not add up to 100 per cent. Figures of less than 0.5 per cent are represented as <1 per cent, instead of 0 per cent.
- Skipped answers have not been included. Cells with no data are marked with a dash.

4.3. Qualitative analysis

- This analysis report includes a qualitative analysis of all responses to the consultation, including online survey responses from individuals and organisations, email responses and social media activity.
- A coding framework was developed to identify different issues and topics in responses, to identify patterns as well as the prevalence of ideas, and to help structure our analysis. The framework was built bottom up through an iterative process of identifying what emerged from the data, rather than projecting a framework set prior to the analysis on the data.

Analysis of consultation responses: what we heard

5. Changes to pharmacist, pharmacy technician and pharmacy entry and renewal fees

Table 1. Changes to pharmacist entry and renewal fees

Do you agree or disagree with our proposal to increase the entry and renewal fee for pharmacists by £7, from £250 to £257?	N and % individuals	N and % organisations	Total N and %
Agree	1,264 (24%)	16 (21%)	1,280 (24%)
Disagree	3,725 (70%)	58 (77%)	3,783 (70%)
Don't know	343 (6%)	1 (1%)	344 (6%)
Total N of responses	5,332 (100%)	75 (100%)	5,407 (100%)

Table 2. Changes to pharmacy technician entry and renewal fees

Do you agree or disagree with our proposal to increase the entry and renewal fee for pharmacy technicians by £3, from £118 to £121?	N and % individuals	N and % organisations	Total N and %
Agree	1,397 (26%)	19 (25%)	1,416 (26%)
Disagree	3,502 (66%)	52 (69%)	3,554 (66%)
Don't know	433 (8%)	4 (5%)	437 (8%)
Total N of responses	5,332 (100%)	75 (100%)	5,407 (100%)

Table 3. Changes to registered pharmacy entry and renewal fees

Do you agree or disagree with our proposal to increase the entry and renewal fee for pharmacy premises by £21, from £241 to £262?	N and % individuals	N and % organisations	Total N and %
Agree	1,740 (33%)	12 (16%)	1,752 (32%)
Disagree	2,681 (50%)	63 (84%)	2,744 (51%)
Don't know	911 (17%)	0 (<1%)	911 (17%)
Total N of responses	5,332 (100%)	75 (100%)	5,407 (100%)

Table 4. Views on our fees policy and the proposed changes to entry and renewal fees

Do you agree or disagree that our proposals are in line with our fees policy?	N and % individuals	N and % organisations	Total N and %
Yes	1,460 (27%)	22 (29%)	1,482 (27%)
Disagree	2,176 (41%)	34 (45%)	2,210 (41%)
Don't know	1,696 (32%)	19 (25%)	1,715 (32%)
Total N of responses	5,332 (100%)	75 (100%)	5,407 (100%)

- 5.1. We proposed to increase the entry and renewal fees for pharmacists by £7 from £250 to £257. The largest proportion of respondents disagreed with our proposal (70%). 24% of respondents agreed with the proposal. 6% of respondents did not know if they agreed or disagreed. Levels of agreement were broadly similar between the individuals and organisations although a slightly higher proportion of organisations disagreed with the proposals (77% of organisations compared with 70% of individuals).
- 5.2. We proposed to increase the entry and renewal fees for pharmacy technicians by £3 from £118 to £121. The largest proportion of respondents disagreed with our proposal (66%). 26% of respondents agreed with the proposal. 8% of respondents did not know if they agreed or disagreed. Levels of agreement were similar between individuals and organisations.
- 5.3. We proposed to increase the entry and renewal fees for registered pharmacies by £21 from £241 to £262. The largest proportion of respondents disagreed with our proposal (51%). Disagreement with the proposed increase was higher amongst organisations as compared to individuals (84% of organisations and 50% of individuals). 32% of respondents agreed with the proposal. 17% of respondents did not know if they agree or disagreed with the proposals.

- 5.4. We asked whether our proposals were in line with our fees policy, which informs our decisions to make changes to our fees. The largest proportion of respondents disagreed that our proposals were in line with our fees policy (41%). 32% of respondents did not know if they agreed or disagreed whether the proposals were in line with our fees policy. 27% of respondents agreed that our proposals were in line with our fees policy. Levels of agreement were similar between individuals and organisations.
- 5.5. Over 2,400 comments were provided to explain responses to survey questions on fees for pharmacists, pharmacy technicians, registered pharmacies and our fees policy.
- 5.6. Respondents who expressed **agreement with the proposals** to increase entry and renewal fees gave the following explanations:
- that they accepted the proposed increase on the condition that fees will be fixed for a period of time
 - the increases are “small”, “reasonable”, “fair”, “in line with inflation” or “affordable”
 - the GPhC has an increased workload and therefore requires additional income
 - that costs are generally increasing so it is justifiable that the fee increases
- 5.7. A smaller number of respondents who agreed with the proposals said:
- the GPhC requires more funding to become more efficient and effective
 - the consultation provided transparency and a rationale for the increase
 - the GPhC requires more funding to carry out its essential functions which are beneficial to patients and the professions
 - the introduction of revalidation justifies the increase and was a demonstration of improvements we had made to our services
 - that fees have not been increased since 2015 and therefore an increase now is expected and in some instances lower than they anticipated
 - that regular incremental increases are preferable to infrequent more substantial increases
 - the proposed fee is lower than when the GPhC was formed
- 5.8. Some respondents expressed disagreement with pharmacist fees increasing, but agreed with increases for pharmacy technicians. In some instances, the reason for this was given as the developing role of pharmacy technicians and increases in pharmacy technician salaries. Some respondents said that in their view the fees for pharmacists and pharmacy technicians should be the same because they are both regulated professions and should require equal resources to regulate

- 5.9. Conversely, some respondents expressed disagreement with pharmacy technician fees increasing, but agreed with increases for pharmacists. In some instances, the reason for this was given as the relatively lower salaries of pharmacy technicians compared to pharmacists. Some respondents said that pharmacy technicians should pay a lower fee or no fee at all
- 5.10. The most frequent reasons given by respondents who expressed **disagreement with proposals to increase entry and renewal fees for pharmacists and / or pharmacy technicians** were as follows:
- the fees are already too high, especially when taken alongside other fees for professional body membership, indemnity cover and learning and development organisations
 - that pharmacy professional salaries have been declining or remained static
 - that there is currently financial pressure and uncertainty affecting pharmacy as a whole and any increase, no matter how small, will have a negative impact both on finance and morale. It was argued in a small minority of responses that the financial pressure and stress may have a consequential impact on pharmacy practice and patient safety
 - that only fees for registered pharmacies should be increased and fees for pharmacy professionals should not be increased.
 - the GPhC should do more to challenge costs, including reducing costs from information requests by publishing more information, moving from its current accommodation, challenging costs related to fitness to practise litigation, and reducing staff, Council and committee member costs
 - the GPhC does not provide additional value for the increase in fees
 - the GPhC does not do enough to support or represent the interests of pharmacy professionals
 - that part-time workers, women on maternity leave, people on extended sick leave and newly qualified pharmacy professionals will find it harder to manage the increase in fees because their income is lower
 - that respondents wanted to see the GPhC play a role in negotiating salaries for the profession or managing the number of people in the pharmacy workforce
- 5.11. The following explanations were given by a smaller number of respondents but still represented common themes in responses:
- that costs have been increasing generally and the additional burden on pharmacy professionals and their household income is too great
 - that some employers do not reimburse registrants for their registration fees. Some respondents also felt that, if the fees increased, some employers may decide to stop reimbursing fees

- the GPhC should provide a hardcopy magazine or offer learning and development programmes in exchange for fees
- that increased fees may act as a disincentive to entering or remaining in the professions and lead to shortages in the workforce, in the context of existing difficulty in recruiting and retaining staff. This point was made particularly for pharmacy technicians who can work in similar un-registered roles
- that pharmacy professionals should not have to pay any fees to be able to work. Some said that the cost of regulation should be borne by others and not the professions

5.12. A small minority of respondents who disagreed with the proposals gave the following reasons:

- the fees are high when compared to some professional regulators
- the GPhC does not regulate registered pharmacies effectively and instead disproportionately focuses its attention on pharmacy professionals
- that a simpler and / or more detailed breakdown of our expenditure is required to justify the proposed increase
- that they had negative customer service experiences when dealing with the GPhC and felt this needed to be improved to justify a fee increase

5.13. Respondents who expressed **disagreement with our proposals to increase fees for registered pharmacies** expressed similar views as above but gave the following additional explanations:

- Many respondents stated the financial pressures on registered pharmacies made the increase difficult to absorb and it may have an impact on staff wages and numbers, learning and development offerings for staff, and services and costs for patients. Some said that the proposed increase in fees may lead to pharmacy closures. This issue was more prevalent in organisational responses than in individual responses and together with the point below seems to account for the larger difference between individual and organisational degrees of disagreement with the proposal to increase fees for registered pharmacies (84% of organisations and 50% of individuals)
- Some respondents said the fees for registered pharmacies were too low and so were expressing disagreement because they felt the increase should be higher. Some respondents stated that the fees for registered pharmacies should be increased further to account for the cost of regulation of pharmacies and so that the fees for pharmacy professionals could remain static or decrease. This view was more prevalent in individual responses than in organisational responses
- Some respondents said that the percentage increase for registered pharmacy fees was too great an increase, above inflation and was comparatively much higher than the increase for pharmacy professional fees

- A few respondents said that the way we calculated fees should change to recognise the differences between types of pharmacy (independent, multiple, online)
- A respondent drew comparison to the fee for pharmacy registration in Northern Ireland and asked for an explanation of the difference in fee amounts

5.14. There were a smaller number of comments in relation to answers to the question we asked about our fees policy. These comments were:

- The proposals are in line with the fees policy
- An opportunity was not provided to comment on the fees policy in the consultation
- The fees are not sensitive enough to the differences between people on our register. It was argued that the fees we charge do not account for pay differences within and across the two professions or potential risk factors from some types of practice such as prescribing or the effort of regulating registered pharmacies
- Efficiency savings have not been well enough demonstrated to justify an increase in fees
- Further clarification was requested on the reasons for the increase in fitness to practise concerns being raised with us
- We have not sufficiently demonstrated that we have reviewed the fees policy
- We have not adequately considered the external financial environment and its impact on pharmacy and pharmacy professionals. It was further argued that in making changes to our approach to regulating registered pharmacies we are also increasing regulatory burden and cost. It was also argued that the fact that the increases are in some cases higher than inflationary indicators for a single year suggests that we have not taken into consideration the wider financial environment. Finally, some respondents suggested that the pharmacy sector has challenged itself to do more with less and that the GPhC has not done the same
- A respondent wanted the GPhC to conduct a post-implementation review to demonstrate financial sustainability and further efficiencies as well as provide a time-scale for the publication of our longer term financial strategy

6. Understanding the impact of our proposals

- 6.1. We asked two questions to further develop our understanding of the impact our proposals. The first question was targeted at understanding the impact on people or groups with protected characteristics and is reported on further in a separate equality impact analysis, published alongside this consultation analysis. The second question was a broader one to understand impact on any other individuals or groups not linked to protected characteristics.
- 6.2. Over 800 comments were provided to explain responses to both questions on impact. Comments are summarised below and related to each question.

Table 5. Impact on individuals or groups with protected characteristics

Do you think any of the changes will have an impact – positive or negative – on certain individuals or groups who share any of the protected characteristics listed above?	N and % individuals	N and % organisations	Total N and %
Yes	1,673 (31%)	19 (25%)	1,692 (31%)
No	2,530 (47%)	37 (49%)	2,567 (47%)
Don't know	1,129 (21%)	19 (25%)	1,148 (21%)
Total N of responses	5,332 (100%)	75 (100%)	5,407 (100%)

- 6.3. The largest proportion of respondents did not think our proposals would have positive or negative impacts on individuals or groups with protected characteristics (47%). 31% thought there will be positive or negative impacts. 21% thought they did not know if there would be positive or negative impacts. Levels of agreement were broadly similar between individuals and organisations with a slightly higher proportion of individuals identifying an impact than of organisation (31% and 25% respectively).
- 6.4. Some respondents who said there would be **no impact or did not know if there would be an impact on individuals or groups with protected characteristics** gave the following explanations:
- that the increases were very small and would not have an impact at all
 - the changes would affect everyone equally, either positively or negatively, whether they had protected characteristics or not. This issue was more prevalent in organisational responses than in individual responses
 - that they did not have enough information to make a judgement or that it is not possible to estimate the impact until after the proposals have been implemented

- 6.5. A few respondents disagreed with the question, suggesting that seeking views on the subject of protected characteristics was pointless or bureaucratic
- 6.6. The most frequent reasons given by respondents who said there would be an **impact for individuals and groups with protected characteristics** were as follows:
- that younger pharmacy professionals would be disproportionately affected because of their lower incomes upon entering the professions. There were recommendations that there should be discounts for this group
 - that pregnant women and women on maternity leave are negatively impacted. This issue was more prevalent in individual responses than in organisational responses. The explanation for this was that women had to pay for a full year of registration when they were not working for the entire period. There were recommendations that there should be a discount or pro-rata calculation for this group. Some respondents echoed this view for other forms of parental leave
 - that women make up a majority of the pharmacy workforce and therefore would be impacted more than men. Additionally, it was stated that the gender pay gap in pharmacy shows that women may be disproportionately affected. It was also remarked upon that women were more likely to work part-time to balance caring responsibilities and may also therefore be disproportionately affected. It was recommended that there should be discounts for people working part-time
 - that people with disabilities, who may carry additional costs related to their disability or work part-time, may be disproportionately impacted by the increase in fees
- 6.7. A consistent reason presented by a smaller number of respondents was that people from black and minority ethnic communities, who are likely to also experience a pay gap, may be disproportionately impacted.
- 6.8. A small minority of respondents provided the following explanations:
- that older pharmacy professionals would be reducing their hours of work as they approached retirement and therefore would be disproportionately affected compared to someone working full-time
 - that the proposals would disproportionately impact upon all individuals or groups with any protected characteristics because of the prevailing forms of discrimination they face generally
 - that married people, people in civil partnerships and people transitioning gender would be impacted but provided no explanation

Table 6. Impact on any other individuals or groups

Do you think our proposals would impact – positively or negatively – on any other individuals or groups?	N and % individuals	N and % organisations	Total N and %
Yes	2,268 (43%)	41 (55%)	2,309 (43%)
No	1,692 (32%)	18 (24%)	1,710 (32%)
Don't know	1,372 (26%)	16 (21%)	1,388 (26%)
Total N of responses	5,332 (100%)	75 (100%)	5,407 (100%)

- 6.9. The largest proportion of respondents said that our proposals would impact either positively or negatively on other individuals or groups (43%). 32% of respondents said that they would not have an impact. 26% of people said that they did not know if the proposals would have a positive or negative impact. Impact of the proposals on other individuals and groups was identified by a higher proportion of organisations as compared to individuals (55% of organisations and 43% of individuals).
- 6.10. Respondents who said there would be **no impact or that they did not know if there would be an impact on any other individuals or groups** gave similar explanations for their answers as the previous question: that the increase was small and therefore had no impact, that the impact was equitably positive or negative across all registrants, that it was not possible to determine until the proposals were implemented or that there was insufficient information provided in the consultation document.
- 6.11. The most frequent reasons given by respondents who said that there will be an **impact on individuals or groups on our register** were as follows:
- that NHS employees, who are less likely to have their fees reimbursed by the employer would be disproportionately impacted compared to other pharmacy professionals working in other sectors
 - that people already experiencing financial hardship for a variety of reasons would also be more negatively impacted
 - unlinked to people or groups with protected characteristics, that people working part-time who inherently therefore have lower pay are disproportionately impacted by our fees. This issue was more prevalent in Individual responses than in organisational responses. It was recommended that we offer discounts for this group
 - that people with families or caring commitments would find it harder to absorb the increase in fees. In particular, single parents were provided as an example of a group who might be more negatively impacted by our proposals. Conversely, a few respondents stated the impact may be greater on single people without dependents when compared to people in relationships or with families

6.12. The following explanations were given by a smaller number of respondents but still represented common themes in responses:

- that because locum rates of pay have been decreasing that this group would be more negatively impacted compared to other groups of people on our register
- that pharmacy owners, who often are pharmacists, would be disproportionately affected because they would need cover the cost of registration of their pharmacy, themselves and in some cases their employees

6.13. A small minority of respondents gave the following reasons:

- that the impact of increasing fees may not solely be financial but may negatively affect morale of people working in pharmacy
- that particular situations of not currently being employed, taking extended sick leave or carer's leave, working primarily overseas, taking career breaks, or being dual registrants means that they are disproportionately impacted by our fees compared with other registrants. It was recommended that we offer discounts or pro-rata registration fees for these groups. This issue was more prevalent in organisational responses than in individual responses
- that smaller organisations would be disproportionately affected by the increase in registration fees for registered pharmacies. Conversely, a few respondents also stated that larger pharmacy organisations with multiple pharmacies would be disproportionately impacted

7. Other comments and suggestions

7.1. Respondents made comments and suggestions on how we may reform our approach to fees. These comments included:

- Many respondents expressed a view that fees should be proportionate to the income of individuals or size of pharmacy. Some examples provided by respondents where they felt our current approach to fees could be improved were:
 - a higher earning pharmacy technician will pay a lower fee than a lower earning pharmacist
 - a small independent pharmacy will pay the same fee as a large multiple pharmacy chain. Respondents gave opposing views on this matter, with some saying independent pharmacies should pay a lower fee than a multiple pharmacy because they are smaller entities to regulate, while others said multiple pharmacies should pay a lower fee because of quality mechanisms across the whole organisation which reduce the effort to regulate each individual pharmacy
- Many respondents suggested that we offer discounts or pro-rata payment arrangements. Suggestions for groups for whom these arrangements could apply included: newly qualified registrants, part-time workers, registrants on parental leave, dual registrants, registrants primarily practising overseas,

registrants on extended sick leave or on career breaks. This issue was more prevalent in organisational responses than in individual responses

- Some said we should increase fees or charge additional fees for areas of pharmacy practice that may carry more risk or generate more work for us. Examples provided to us by respondents include: charging more for prescribing annotations, online pharmacy regulation, or individuals undergoing fitness to practise processes
- Some respondents suggested that monthly direct debit payments would make the cost of registration easier to manage. We currently offer direct debit payments on an annual and quarterly basis
- Some respondents made specific mention of not being able to claim tax relief on their fee payments, which suggests that some registrants remain unaware that this is a possibility to help manage the costs of registration
- A few respondents had negative comments about the consultation exercise. These respondents indicated that they felt their responses would not be listened to and that the GPhC had already made its decision
- A few respondents requested more clarity on how we reach our fee proposals through calculations based on allocation of expenditure across pharmacy professionals and registered pharmacies
- A respondent requested information on the source of payment of registration fees, for example whether they were paid by individuals or their employers
- A respondent requested more detail and transparency on anticipated expenditure linked to particular projects
- A respondent stated that projections for increases in registrant numbers should mitigate against fee increases

8. Respondent profile: who we heard from

A series of introductory questions sought information on individuals' general location, and in what capacity they were responding to the survey. For pharmacy professionals, further questions were asked to identify whether they were pharmacists, pharmacy technicians or pharmacy owners, and in what setting they usually worked. For organisational respondents, there was a question about the type of organisation that they worked for. The tables below present the breakdown of their responses.

8.1. Category of respondents

Table 7. Responding as an individual or on behalf of an organisation

Are you responding:	N	% of total
As an individual?	5,332	99%
On behalf of an organisation?	75	1%
Total N of responses	5,407	100%

8.2. Profile of individual respondents

Table 8. Individual respondents - countries

Where do you live?	N	% of total
England	4,435	83%
Scotland	549	10%
Wales	264	5%
Northern Ireland	6	<1%
Other	78	1%
Total N of responses	5332	100%

Table 9. Type of individual respondent

Are you responding as:	N	% of total
A pharmacist?	3,868	73%
A pharmacy technician?	1,368	26%
Other?	66	1%
A pharmacy owner or employer who is not registered as a pharmacist or pharmacy technician?	23	<1%
A member of the public?	7	<1%
Total N of responses	5,332	100%

Table 10. Pharmacy owner: yes/no

Are you a pharmacy owner or employer?	N	% of total
Yes	436	8%
No	4,800	92%
Total N of responses	5,236	100%

Table 11. Main area of work

Please choose the option below which best describes the area you mainly work in: ¹	N	% of total
Community pharmacy	2,398	45%
Hospital pharmacy	1,827	34%
Primary care organisation	297	6%
GP practice	297	6%
Other	182	3%
Pharmaceutical industry	135	3%
Research, education or training	130	2%
Prison pharmacy	44	1%
Care home	15	<1%
Total N of responses	5,325	100%

Table 12. Type of community pharmacy

Which of the following best describes the community pharmacy you work in or own? ²	N	% of total
Independent pharmacy (1 pharmacy)	382	16%
Independent pharmacy chain (2-5 pharmacies)	332	14%
Small multiple pharmacy chain (6-25 pharmacies)	237	10%
Medium multiple pharmacy chain (26-100 pharmacies)	195	8%
Large multiple pharmacy chain (Over 100 pharmacies)	1,252	52%
Total N of responses	2,398	100%

¹ This question was answered by individuals working in pharmacy

² This question was answered by individuals working in community pharmacy

8.3. Profile of organisational respondents

Table 13. Responding on behalf of a registered pharmacy

Are you responding on behalf of a registered pharmacy?	N	% of total
Yes	65	87%
No	10	13%
Total N of responses	5332	100%

Table 14. Type of registered pharmacy

Which of the following best describes the registered pharmacy you represent? ³	N	% of total
Community pharmacy	63	97%
Hospital pharmacy	1	2%
Other registered pharmacy	1	2%
Prison pharmacy	0	<1%
Total N of responses	65	100%

Table 15. Type of community pharmacy

Which of the following best describes the community pharmacy you represent? ⁴	N	% of total
Independent pharmacy (1 pharmacy)	39	62%
Independent pharmacy chain (2-5 pharmacies)	11	17%
Small multiple pharmacy chain (6-25 pharmacies)	9	14%
Medium multiple pharmacy chain (26-100 pharmacies)	2	3%
Large multiple pharmacy chain (Over 100 pharmacies)	2	3%
Total N of responses	63	100%

³ This question was answered by everyone representing a registered pharmacy

⁴ This question was answered by everyone representing a community pharmacy

Table 16. Organisational respondents: type of organisation

Please choose the option below which best describes your organisation:	N	% of total
NHS organisation or group	1	10%
Organisation representing pharmacy professionals or the pharmacy sector	8	80%
Other	1	10%
Organisation representing patients and the public	0	0%
Research, education or training organisation	0	0%
Government department or organisation	0	0%
Regulatory body	0	0%
Total N of responses	10	100%

9. Monitoring questions

Data was collected on respondents' protected characteristics, as defined within the Equality Act 2010. The GPhC's equalities monitoring form was used to collect this information, using categories that are aligned with the census, or other good practice (for example on the monitoring of sexual orientation). The monitoring questions were not linked to the consultation questions and were asked to help understand the profile of respondents to the consultation, to provide assurance that a broad cross section of the population had been included in the consultation exercise. A separate equality impact assessment has been carried out and will be published alongside this analysis report.

Appendix 1: Organisations

The following organisations engaged in the consultation through the online survey, and email responses and did not request that their response be kept confidential. 29 respondents requested that their response be kept confidential.

Accrington Pharmacy

Al Ghani Ltd

Anfield Pharmacy

Association of Pharmacy Technicians UK (APTUK)

Avenue Pharmacy Sunderland Ltd

Baycona Ltd

Boots UK

Borth Pharmacy

C & S Pharmacy Ltd

Carrick Knowe Pharmacy Ltd

Central Pharmacy (Liverpool) Ltd

Community Pharmacy Lancashire

Community Pharmacy Scotland

Community Pharmacy Wales

Company Chemists' Association / Association of Independent Multiple Pharmacies (joint response)

County Pharmacy Ltd

EJ'S Pharmaceuticals Ltd

Fearns Pharmacy Ltd

G Payne Chemists Ltd

Gateacre Chemists Ltd

Greatvale Ltd

Guild of Healthcare Pharmacists

Haxby Group Pharmacy Ltd

Healthcare-2-U Ltd

Hindu Council UK

Housley Pharmacy

K's Chemist Ltd
McKesson UK
NHS Scotland
Norvik Pharmacies Ltd
National Pharmacy Association (NPA)
Numark Ltd
Pearn's Pharmacies Ltd
Pharmacists' Defence Association
Pharmacy Bond
Pitman Pharmacy
Popsons Pharmacy
Pro-Health Pharmacy Ltd T/A Newington Pharmacy
RPMG Pharmacy
S B Carr Ltd
Saffron Apothecaries Ltd
Stepping Hill Healthcare Enterprises Ltd
Sterling Pharmacy Ltd
Sydney Blum & Co. Ltd T/A Parry Jones Pharmacy
Sykes Chemists Ltd
Taw Hill Pharmacy
Weldricks Pharmacy
Whitecroft (UK) Ltd

Appendix 2: Consultation questions

1. Do you agree or disagree with our proposal to increase the entry and renewal fee for pharmacists by £7, from £250 to £257?
2. Do you agree or disagree with our proposal to increase the entry and renewal fee for pharmacy technicians by £3, from £118 to £121?
3. Do you agree or disagree with our proposal to increase the entry and renewal fee for pharmacy premises by £21, from £241 to £262?
4. Do you agree or disagree that our proposals are in line with our fees policy?
5. Do you have any comments explaining your answers to the questions above?
6. We want to understand whether our proposals may discriminate against or unintentionally disadvantage any individuals or groups sharing any of the protected characteristics in the Equality Act 2010. We are also interested to find out whether the proposals will benefit any of these individuals or groups. The protected characteristics are:
 - Age
 - Disability
 - Gender reassignment
 - Marriage and civil partnership
 - Pregnancy and maternity
 - Race
 - Religion or belief
 - Sex
 - Sexual orientation
 - None of the above
7. Do you think any of the changes will have an impact – positive or negative – on certain individuals or groups who share any of the protected characteristics listed above? If yes, please give comments explaining your answer. Please describe the nature of the impact and the individuals or groups concerned.
8. We also want to know if there will be any other impact of our proposals on any other individuals or groups (not related to the protected characteristics). For example, patients, pharmacy owners or pharmacy staff. Do you think our proposals would impact – positively or negatively – on any other individuals or groups?

If yes, please give comments explaining your answer. Please describe the nature of the impact and the individuals or groups concerned.

The General Pharmaceutical Council (Registration and Renewal Fees) (Amendment) Rules 2019

The General Pharmaceutical Council has made these Rules in exercise of the powers conferred by articles 36(1) and 66(1) of the Pharmacy Order 2010^(a).

In accordance with those provisions, the General Pharmaceutical Council has consulted such persons and organisations as it considered appropriate, including the persons and organisations listed in article 36(6)(a) to (d) of that Order and, in relation to rules made under Part 4 of that Order, the persons and organisations listed in article 66(3)(a) to (h) of that Order^(b).

Citation and commencement

1.—(1) These Rules may be cited as the General Pharmaceutical Council (Registration and Renewal Fees) (Amendment) Rules 2019.

(2) These Rules come into force on [1st July 2019].

Amendments to the General Pharmaceutical Council (Registration and Renewal Fees) Rules 2015

2. The Schedule to these Rules amends the General Pharmaceutical Council (Registration and Renewal Fees) Rules 2015—

- (a) to increase the amount of the fee payable on the grant of an application for the entry of a person in Part 1, 2 or 3 of the Register;
- (b) to increase the amount of the fee payable on the renewal of any such entry; and
- (c) to remove the additional fee for the processing of any payment made by credit card.

Given under the official seal of the General Pharmaceutical Council [insert date].



Nigel Clarke
Chair
Duncan Rudkin
Chief Executive and Registrar

(a) S.I. 2010/231.

(b) Article 66(3)(a) was amended by S.I. 2013/235.

SCHEDULE

Rule 2

Amendments to the General Pharmaceutical Council (Registration and Renewal Fees) Rules 2015

General

Amendment of rule 2

1. In rule 2(1) (interpretation), omit the definition of “credit card”.

Registered pharmacists

Amendment of rule 5

2. In rule 5 (entry in Part 1 of the Register following grant of an application), for “£250” substitute “£257”.

Amendment of rule 9

3. In rule 9(1) (renewal of an entry in Part 1 of the Register), for “£250” substitute “£257”.

Amendment of rule 14

4. In rule 14 (administration), omit paragraph (3).

Registered pharmacy technicians

Amendment of rule 16

5. In rule 16 (entry in Part 2 of the Register following grant of an application), for “£118” substitute “£121”.

Amendment of rule 19

6. In rule 19(1) (renewal of an entry in Part 2 of the Register), for “£118” substitute “£121”.

Amendment of rule 23

7. In rule 23 (administration), omit paragraph (3).

Premises

Amendment of rule 26

8. In rule 26 (entry in Part 3 of the Register following the grant of an application), for “£241” substitute “£262”.

Amendment of rule 29

9. In rule 29(1) (renewal of an entry in Part 3 of the Register), for “£241” substitute “£262”.

Amendment of rule 33

10. In rule 33 (administration), omit paragraph (4).

Meeting paper

Council meeting on Thursday, 07 March 2019

Public business

Consultation on guidance for pharmacist prescribers

Purpose

To present to Council the consultation on draft guidance for pharmacist prescribers.

Recommendations

The Council is asked to approve for consultation the draft guidance for pharmacist prescribers.

1. Background

- 1.1. From time to time, the GPhC publishes guidance to support the standards for pharmacy professionals. Given the increase in the number of pharmacist prescribers, and other influencing drivers (for example new technologies being used for prescribing (remote and online)), we believe it is necessary to issue guidance to help ensure pharmacist prescribers are meeting our standards.
- 1.2. Over the past three years we have carried out research to better understand the issues pharmacist prescribers face when carrying out their prescribing role. This included looking at information received through our prescribers' survey (2016), the enquiries received through the education and standards teams and our inspectors, fitness to practise cases, our discussion paper on *making sure patients and the public obtain medicines and other pharmacy services safely online* (June 2018), recent reports and consultations and guidance produced by other regulators and professional bodies.
- 1.3. In September 2018, we provided Council with an overview of the regulation of pharmacist independent prescribing, and the work planned in this area. This included providing guidance for pharmacist prescribers to help ensure patients and the public receive safe and effective care.
- 1.4. In January 2019 we published revised standards for the education and training of pharmacist independent prescribers. We are currently consulting on our initial education and training

for pharmacists revising the learning outcomes so that they are more focused on developing clinical skills and communication skills, and making sure that students learn skills relating to prescribing such as consultation and physical examination.

- 1.5. We have produced guidance for pharmacist prescribers to help ensure they provide safe and effective care to patients and the public and to help them understand their obligations as a prescriber and the importance of prescribing safely. It supports the standards for pharmacy professionals which all pharmacy professionals must meet, including pharmacist prescribers regardless of their area of prescribing or scope of practice. We are planning to consult and engage on this guidance for twelve weeks, subject to Council approval.

2. Objectives

- 2.1. Our proposals were developed to meet our regulatory aims, as set out in our Strategic plan (2017–20):
 - to support and improve the delivery of safe, effective care and to uphold trust in pharmacy
 - to promote patient safety and ensure pharmacy professionals provide safe and effective care
 - to assure the public by making sure that pharmacist prescribers have the necessary knowledge and skills.

3. Key considerations

- 3.1. Pharmacists working as independent prescribers are part of a wider change in which pharmacy is playing a more significant part in person-centred care, by using the pharmacist prescriber's knowledge and skills.
- 3.2. We have considered recent reports including the Gosport Panel review, and made sure that the key themes such as listening to patients, speaking up and patient safety are reflected in our guidance. We have not produced separate guidance on anticipatory prescribing as it is covered in the section taking responsibility for prescribing safely.
- 3.3. We continue to work collaboratively with other regulatory agencies, for example the MHRA, CQC, and the Joint Council of Cosmetic Practice to help identify issues that affect patient safety, and to make sure pharmacist prescribers provide safe and effective care.

4. Other regulators

- 4.1. Several of the other regulators have adopted the Royal Pharmaceutical Society's competency framework for all prescribers, as their Standards for Prescribing. This includes

the Nursing and Midwifery Council, who adopted it from January 2019, the Health and Care Professions Council who recently consulted to adopt it as their Standards for prescribing and the Pharmacy Council of New Zealand. (See table below).

Regulator	Standards underpinning prescribing	Guidance
General Medical Council	Good medical practice	Good practice in prescribing and managing medicines and devices
General Dental Council	Standards for the dental team	Guidance on prescribing medicines, Guidance on prescribing antimicrobials
Nursing and Midwifery Council	Adopted RPS competency framework (Jan 2019)	
The Health and Care Professions Council	HCPC standards for prescribing Consultation to adopt RPS competency framework ended Jan 2019.	Physiotherapists, dieticians, radiographers, paramedics have their own practice guidance for prescribers
Pharmaceutical Society of N Ireland	Standards and Guidance for pharmacy prescribers (based on their Code of Ethics and further guidance) – refers to the prescribing competency framework	
Pharmacy Council of New Zealand	Safe and effective pharmacy practice-Standards and Guidance for pharmacist prescribers - based on RPS prescribing competency framework	

- 4.2. Our guidance reflects themes from the Royal Pharmaceutical Society's competency framework for all prescribers and guidance from the **General Medical Council**, but has been tailored to pharmacy specific issues that we have seen or have been raised with the GPhC, as described in 1.2 above.

5. Our guidance

- 5.1. The draft guidance for pharmacist prescribers reflects the themes of our standards for pharmacy professionals and our standards for registered pharmacies, to ensure patients receive safe and effective care.
- 5.2. The guidance sets out the key areas pharmacist prescribers should consider when prescribing to ensure safe and effective care, including:
 - taking responsibility for prescribing safely
 - keeping up to date and prescribing within their level of competence
 - working in partnership with people seeking care and other healthcare professionals
 - prescribing in certain circumstances
 - prescribing non-surgical cosmetic medicinal products
 - remote prescribing
 - safeguards for remote prescribing for certain categories of medicines
 - raising concerns
 - information for pharmacy owners and employers of pharmacist prescribers.
- 5.3. This consultation asks for views on our draft guidance. More specifically we are asking for views on:
 - the key areas for safe and effective prescribing (as described in section 5.4 below).
 - the circumstances to consider when it is appropriate to prescribe safely
 - prescribing and supplying
 - safeguards for remote prescribing of certain categories of medicines, and
 - the impact this guidance may have on various stakeholder groups.
- 5.4. Our guidance includes safeguarding issues when prescribing remotely, information for pharmacy owners and employers of pharmacist prescribers and safeguards for remote prescribing of certain medicines, prescribing and supplying which the GMC guidance does not have. We have also included a section on non-surgical cosmetic medicines within our guidance document.
- 5.5. The GMC are currently updating their *Good practice in prescribing and managing medicines and devices* guidance. They have a separate document *Guidance for doctors who offer cosmetic interventions*. Their current guidance has separate sections on unlicensed medicines, sports medicines, repeat prescriptions and reviewing medicines, but we have included these in our taking responsibility for prescribing safely.
- 5.6. Both the GMC's and our guidance on prescribing contains sections on prescribing safely, keeping up to date, consent, sharing information with the person's regular prescriber (such

as their NHS or independent GP), raising concerns, working in partnership and prescribing for themselves, family and friends.

- 5.7. When we consulted on the discussion paper for our guidance for registered pharmacies providing pharmacy services at a distance, including on the internet, we received comments about adding clarity regarding the responsibilities of prescribers who work for online prescribing services. Our prescribing guidance includes principles for safe and effective prescribing and other areas including, but not exclusively, remote prescribing.
6. There is some overlap between our draft guidance for pharmacist prescribers and our guidance for registered pharmacies providing pharmacy services at a distance, including on the internet (which is being presented to Council in April for noting.) They support our standards for pharmacy professionals and registered pharmacies. The guidance in both documents is aligned and consistent.

7. Timetable

- 7.1. The consultation, subject to Council approval, will run for 12 weeks from 26 March to 18 June 2019. We expect to provide Council with an analysis of the responses in late 2019, to inform a decision on the new guidance for pharmacist prescribers.

8. Equality and diversity implications

- 8.1. In all stages of our development work we have considered whether there are any significant equality implications, either positive or negative, for registrants or members of the public. We have not identified any significant negative equality or diversity implications of our proposals and expect there to be a positive benefit for patients and the public. However, we have asked a specific question in the consultation to ensure we receive feedback on any relevant issues.
- 8.2. Throughout the development of this work, a detailed analysis of the equality and diversity implications of the proposed changes continues to be updated as any new aspects are identified.

9. Communications

- 9.1. We will signpost to other available prescribing resources during the twelve-week consultation period. However, it is important to point out that our guidance consolidates the existing available resources.
- 9.2. We are committed to a process of consultation and engagement with key stakeholders, including pharmacist prescribers, other pharmacy professionals, employers and

organisations representing pharmacy owners, professional representative bodies, pharmacy service users, patients' representative bodies and others with an interest in this area.

- 9.3. The consultation will be published on the GPhC website and in Regulate, and targeted emails will be sent to our stakeholders. We will also arrange or attend a series of meetings and events to seek feedback on our proposals.

10.Resource implications

- 10.1. The resource implications for this work have been accounted for in existing budgets.

11.Risk implications

- 11.1. It is important, as prescribing within pharmacy grows, that the GPhC identifies and mitigates any potential risks associated with pharmacist prescribing. The GPhC must continue to understand and regulate pharmacist prescribing in way that ensures patients and the public continue to receive safe and effective care from pharmacy professionals.

12.Monitoring and review

- 12.1. The work outlined in the paper will be taken forward and Council will be kept updated on progress as part of ongoing Council business.
- 12.2. If there are significant changes regarding the practice of pharmacist prescribing in the future we will review our guidance to make sure it continues to be up to date.

Recommendations

The Council is asked to approve for consultation the draft guidance for pharmacist prescribers.

Mark Voce, Director of Education and Standards

In practice: Guidance for pharmacist prescribers

DRAFT

March 2019 v1.9

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Guidance for pharmacist prescribers

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Questions to ask yourself

Other sources of information

About this guidance

This guidance should be read alongside the [standards for pharmacy professionals](#) which all pharmacy professionals must meet.

It should also be read alongside our [standards for registered pharmacies](#), which all pharmacy owners are responsible for meeting to ensure the safe and effective provision of pharmacy services from the registered pharmacy.

This guidance cannot cover every situation and does not give legal advice, as all pharmacy professionals must keep to the relevant laws.

It gives guidance to pharmacist prescribers in applying the standards when prescribing whether they work privately or under the NHS, and sets out the key areas pharmacist prescribers should consider when applying the standards when prescribing. It also applies to pharmacist prescribers who work remotely, (including those who prescribe online), and where pharmacy owners employ or contract with a pharmacist prescriber or service provider to provide online prescribing services.

We want this guidance to support appropriate and effective access to pharmaceutical care and medicines, which complies with the law¹ and meets our standards. We believe this guidance will be helpful for other organisations who employ pharmacist prescribers or provide pharmacy prescribing services across a range of settings.

Pharmacist prescribers should be able to justify their decisions and use their professional judgement in applying this guidance in practice²

All pharmacy professionals should be familiar with the areas raised within this guidance and understand their own responsibilities in relation to prescribers.

Pharmacist prescribers should also comply with other relevant standards³ and guidance, which apply to their place of work and role, such as from the CQC, HIW, HIS and the ASA on

¹For information on writing prescriptions and using electronic prescriptions refer to the prescribing hub [Royal Pharmaceutical Society](#) and the BNF

²The [Committee of Advertising Practice Marketing of cosmetic interventions](#) for guidance on advertising of non-surgical cosmetic procedures. Treatments you can trust? MHRA guidance for providers that offer medicinal treatment services in [Appendix 6](#) of the [MHRA Blue Guide](#)

³ The GPhC sets standards for the education and training of pharmacists to become PIPs. https://www.pharmacyregulation.org/sites/default/files/document/standards_for_the_education_and_training_of_pharmacist_independent_prescribers_january_2019.pdf

advertising⁴. This guidance should also be read alongside any relevant regulatory and NHS documents for England, Scotland and Wales, and any relevant guidance published by other organisations⁵, including professional leadership bodies and other regulators.

We have a range of **guidance** on our website to help pharmacy professionals apply our standards.

Pharmacist prescribing

Pharmacist prescribers play a vital role in the delivery of high quality healthcare services and the variety of these roles are increasing. Pharmacist prescribers are responsible for creating a culture of person-centred professionalism wherever they work and ensuring prescribing services are delivered safely and effectively.

A pharmacist prescriber may be a pharmacist supplementary⁶ prescriber (PSP) or a pharmacist independent⁷ prescriber (PIP). Both can prescribe, supply and administer medicines.

Commented [CGI]: Will have footnote info boxed out.

An independent pharmacist prescriber (PIP) is responsible and accountable for the clinical assessment and management of people with undiagnosed or diagnosed conditions, without needing to consult another prescriber, for the prescribing decisions they make, and for the appropriateness of the prescriptions they sign. Consultations with PIPs can frequently involve the provision of advice without a prescription being provided.

Prescribing can be applied in different ways and in different contexts but may also involve the supply of a prescription for a prescription only medicines or medical device, advising people on the supply of an over the counter medicine and giving advice or information.

⁴ Advertising Standards Authority - **Cosmetic interventions**

⁵ Royal Pharmaceutical Society **A competency framework for all Prescribers (July 2016)**. The Single competency framework for all prescribers sets out a common set of competencies that should underpin all prescribers, For Scotland

⁶ A supplementary prescriber works with a medical or dental practitioner within a specific clinical management plan (CMP). The law sets out what the CMP must include, the limitations of what the PSP can prescribe and under what circumstances. A PSP may become a PIP by further training and converting their qualification, and work as both a PSP and a PIP.

⁷ A pharmacist independent prescriber is a pharmacist who has completed the relevant approved education and training to add an annotation to their entry in the register. A PIP may prescribe all medicines autonomously for any condition within their scope of practice and clinical competence, excluding three controlled drugs for the treatment of addiction (cocaine, dipipanone and diamorphine) and unlicensed cannabis based medicinal products (CBMPs). A change in the law in November 2018, made cannabis and certain cannabis based medicinal products (CBMPs) a Schedule 2 under the Misuse of Drugs Regulations 2001. However, CBMPs can only be prescribed by a Specialist doctor registered on the General Medical Council (GMC) Specialist Register. Once a substance receives a marketing authorisation this prescribing restriction will no longer apply and the product will be available for patient use as other schedule 2 drugs. The GPhC sets standards for the education and training of pharmacists to become PIPs. Pharmacist prescribers can also prescribe veterinary medicines classified as prescription-only medicine – veterinarian, pharmacist, suitably qualified person (SQP), POM-VPS, in accordance with the current Veterinary Medicines Regulations.

A supplementary prescriber works with a medical or dental practitioner within a specific clinical management plan (CMP), but does not prescribe independently.

In this guidance we use the term 'pharmacist prescriber' to include both, as they can both work in the same settings.

1. Taking responsibility for prescribing safely

People receive safe, effective and person-centred care when pharmacy professionals treat every person as an individual with their own values, needs and concerns.

Pharmacist prescribers are responsible and accountable for their decisions and actions. This will include when they prescribe and for the prescriptions they sign. To minimise patient risk and improve patient safety, pharmacist prescribers must make sure prescribing is evidence based, safe and appropriate. Any prescribing decision must be made in partnership with the person being assessed to make sure the care meets their needs and the pharmacist prescriber has consent⁸ to prescribe. Pharmacist prescribers should be empowered to exercise their professional judgement, so that they act in the person's best interest and only prescribe medicines they know to be safe and effective for the condition they are treating.

Pharmacist prescribers must effectively communicate with the person to understand their needs, to make sure there is a genuine clinical need for treatment and come to a shared decision about the care they provide. This includes getting all the relevant information from the person, and giving the person all the relevant information in a way they can understand so the person can make an informed decision and choice. Pharmacy professionals must take responsibility for ensuring person centred care is not compromised by personal values and beliefs, including in the context of prescribing. Additionally, people also receive safe and effective care when they recognise and value diversity and respect cultural differences.

To safeguard people, particularly children and vulnerable adults, it is important that pharmacist prescribers know who to refer to, and act when necessary. This is also important when prescribing remotely.

Pharmacist prescribers must manage incentives or targets and make sure the care they provide reflects the needs of the person and does not compromise the health, safety and wellbeing of patients and the public.

When prescribing, pharmacy professionals should:

- consider whether they have sufficient information and knowledge of the person's health and medical history⁹, including using medical records, such as the summary care record (SCR) (in England), where available

⁸ GPhC In practice guidance on consent

⁹ This may include: any previous adverse reactions or allergies to medicines or allergies, or allergies to flavouring and food products, recent use of other medicines, including but not limited to regular medicines, acute medicines (e.g. short course antibiotics) OTC medicines, herbal medicines, alternative medicines and others bought online, other medical conditions, encouraging the person to be open about the way they take their medicines, their adherence to medicines prescribed,

- fully assess the person, and carry out an examination in cases where it is necessary in an appropriate environment which ensures the person's privacy and confidentiality
- take account of and prescribe in line with clinical¹⁰, national and local guidelines, which are evidence based, where possible
- where they consider prescribing to be inappropriate explain their reasons to the person and explain any other options available to them
- consider the risks of prescribing for different groups of patients, (for example children, young people, women and girls able to have children, pregnant and lactating women and older people)
- consider the risks of prescribing certain categories of medicines and in certain circumstances, and do everything they can to keep those risks as low as possible
- consider whether it is appropriate to withdraw medicines, stop prescribing a medicine or alter the prescribed dose of a medicine
- only prescribe within the limits of their knowledge and skills and their area of competence
- prescribe and review the person's medicines, and promptly make any changes to the person's medical record. This should include a record of discussions, particularly where prescribing is outside the national guidelines or is an unlicensed medicine^{11,12}, reasons for their prescribing decisions and arrangements for follow up and monitoring, so there is a complete audit trail
- consider reporting mechanisms for suspected adverse drug reactions (ADRs), and whether there is a need for urgent referral to another healthcare professional. They should also make sure the person seeking care knows how to report ADRs
- make prescribing decisions on the needs of the individual person and not on commercial interests or pressure from people, colleagues or pharmaceutical companies
- consider the impact of their prescribing on the person who is being prescribed for
- provide information, including patient information leaflets, in a way the person can understand and check they have understood them
- refer the person to an appropriate healthcare professional when further examination or assessment is required
- in the case of unlicensed or off label medicines, make sure there is no licensed medicine available to meet the needs of the person. They should have sufficient evidence of the safety, effectiveness and appropriateness on the use of the unlicensed or off label medicine. Some medicines are routinely used outside the terms of their licence, for example in paediatrics
- review repeat prescriptions as part of the NHS repeat prescribing service¹³, or when reviewing a person's medicines, check whether there have been any changes in their

¹⁰ NICE (England), Scottish Medicines Consortium and Health Improvement Scotland, Department for Health, Social Services and Public Safety (Northern Ireland), All Wales Medicines Strategy Group (Wales) and medical colleges and other authoritative sources

¹¹ The term unlicensed medicine is used to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK. They are commonly used in paediatrics and palliative care. Prescribing unlicensed medicines may be necessary where there is no suitably licensed medicine that will meet the patient's need, for example where there is no licensed medicine applicable to the particular patient and only an adult formulation is licensed and the patient is a child, or the suitably licensed medicines is not available due to medicines shortages. In emergencies it may not always be appropriate to explain the unlicensed nature, when this is likely to cause distress to the patient or the carer.

¹² See our Guidance for registered pharmacies preparing unlicensed medicines

¹³ the NHS repeat prescribing service is where several prescriptions are issued without the need for referral back to the prescriber, only applies in England and Wales

circumstances such as a hospital stay or changes to their medicines following a hospital or home visit

- make sure repeat prescriptions are securely and safely generated by staff who are competent to prepare the repeat prescription authorisation
- make sure the person knows who to contact if they have any questions or concerns.

2. Keeping up to date and prescribing within your level of competence

Pharmacist prescribers can prescribe in many different clinical and therapeutic areas, which may be either as a specialist or generalist. These roles continue to develop and expand and so pharmacist prescribers must maintain, develop and use the professional knowledge and skills relevant to their role and prescribing area. They should use the GPhC standards of initial education and training for pharmacist prescribers¹⁴ and the learning outcomes, as well as the various reference sources¹⁵, to help identify any gaps and needs in their knowledge.

With regards to the patient's condition and the medicines available to manage their health care, pharmacist prescribers must only prescribe within the limits of their knowledge, skills and clinical competence. They must maintain the competencies specific to their role as a prescriber and the scope of their practice and reflect on the application of their knowledge and skills to keep themselves up-to-date. When prescribing in a new area, they should undertake any necessary additional training and be familiar with the relevant resources to ensure that they are competent. When a person's presenting condition is outside a prescribing pharmacist's scope of competence, they must refer the person to another appropriate prescriber.

Pharmacist prescribers should make sure that some of their revalidation records directly address their role as a pharmacist prescriber. This includes keeping up to date with relevant changes in the law as well as the therapeutic areas in which they prescribe. Pharmacist prescribers should use the revalidation framework¹⁶ to plan and demonstrate they remain up to date when prescribing.

To continually improve their prescribing skills and the care they give, pharmacist prescribers should regularly audit and monitor their prescribing. If they work outside NHS settings where clinical governance systems may be different or not be applied in the same way, pharmacist prescribers must ensure they are competent to practise. They must show how they audit their practice, keep up-to-date with current guidelines, and how they safeguard the people in their care.

Pharmacist prescribers must regularly check they are covered for any additional or different prescribing roles they undertake with their professional indemnity provider and review their cover as appropriate.

¹⁴ GPhC website

¹⁵ MHRA Drug safety updates, NHS Central alert system, National electronic Library for medicines, the National Institute for Health and Clinical excellence, (NICE), Medicines and prescribing community, the electronic medicines compendium and patient information leaflets (PILs), British National Formulary (BNF) and British National Formulary for Children (BNFC)

¹⁶ Revalidation framework [Jan 2018](#)

3. Working in partnership with people seeking care and other healthcare professionals

Pharmacist prescribers must communicate effectively and work in partnership, with other health professionals and the people seeking care, to deliver safe and effective care.

They must be open and honest with the person seeking care and those they prescribe for. They should make sure people are aware in what capacity they are prescribing, either as part of an NHS or private arrangement, and any charges that apply.

Pharmacist prescribers must make sure they maintain a person's confidentiality¹⁷ and privacy as this is a vital part of the relationship between the pharmacist prescriber and the person seeking care.

3.1 Working with people seeking care and sharing information with their prescribing doctor

Pharmacist prescribers must ask for consent from the person to access their medical records or other reliable information about the person's health and medicines from their regular prescriber, where they have one, so they can prescribe safely. They should give the person clear information so they can make an informed decision to make sure person-centred care is not compromised, and discuss other available options when it is not appropriate to prescribe. They should make a record of all decisions including when they decide not to issue a prescription and the reason why.

Pharmacist prescribers must consider whether they can prescribe safely where:

- they do not have access to the person's medical records,
- the person refuses to give consent to contact their prescriber for more information,
- the person has not been referred to the pharmacist prescriber by their prescriber or
- the person does not have a regular prescriber (such as a GP).

Prescribing information should be shared with the person's regular prescriber or others involved in their care so the person receives safe and effective care. The pharmacist prescriber should give the other prescriber all relevant information, (for example, information on all medicines prescribed, the reasons for any changes and any further monitoring requirements) accurately and in a timely manner. It should be clearly recorded.

Where carers seek information about medicines on behalf of a person, pharmacist prescribers should make sure they have the person's consent to disclose this information or, if the person lacks capacity to consent, whether it is in their best interests to share the information.

3.2 Working in partnership with other healthcare professionals

¹⁷ In Practice: Guidance on confidentiality

Pharmacist prescribers must take responsibility for their practice and provide leadership to the people they work with.

Pharmacist prescribers who prescribe for people in environments such as a care home, nursing home or a hospice should communicate with the person or their carer and provide the necessary information and advice. They should make sure any information is understood by the person and carer.

Where a pharmacist prescriber prescribes at the recommendation of another healthcare professional, they are still professionally accountable and responsible for all prescriptions they sign. They must make sure the prescription is appropriate and meets the person's needs and allows continuity of care for the person concerned.

Where a person transfers¹⁸ between care settings, pharmacist prescribers should check the information provided and make sure all necessary information about the person's medicines is accurately recorded and transferred with that person.

Where they share responsibility for a person's care with a colleague, they must make sure there are clear lines of accountability and they are competent to share their part of the clinical responsibility. They must elicit all the necessary information to prescribe, if they are responsible for the initial diagnosis or assessment of a person. Any decisions made regarding who is then responsible for follow up and monitoring, should be in the person's best interests, and clearly communicated to those involved in the arrangement.

Where a pharmacist prescriber is supervising another prescriber in training, as a designated prescribing practitioner (DPP), they must exercise oversight.

4. Prescribing in certain circumstances

4.1 Prescribing for themselves, family and friends

Wherever possible, pharmacist prescribers should avoid prescribing for themselves or anyone with whom they have a close personal relationship, (such as family members, friends or colleagues), other than in exceptional circumstances. This is particularly important where controlled drugs and drugs of abuse are prescribed.

Pharmacist prescribers may, in exceptional circumstances, prescribe where:

- there is no other prescriber available to assess the person's clinical condition and to delay prescribing would put the person's life or health at risk or cause unacceptable pain or distress
- the treatment is immediately necessary to:
 - o save a life
 - o avoid serious deterioration in the person's health and well-being
 - o alleviate otherwise uncontrollable pain or distress.

¹⁸ Keeping patients safe when they transfer between care providers –getting the medicines right RPS 2012

Pharmacist prescribers, when prescribing for themselves or anyone they have a close relationship with must:

- be able to justify their decision to prescribe
- make a clear record, including the nature of their relationship with the person and the reasons it was necessary to prescribe, so there is a robust audit trail.

They should also consider whether the person needs an independent clinical assessment by another prescriber, to make sure their professional judgement is not influenced or impaired by the person they are prescribing for.

4.2 Prescribing and supplying

Pharmacist prescribers should normally keep the initial prescribing and supply of medicines prescribed as separate functions to protect the person's safety. There may be circumstances where the person needs the medicine urgently and person-centred care or the safety of the person would be compromised if the medicine was not supplied at that point, and alternative options are unavailable, such as referring to another pharmacy.

Where a pharmacist prescriber both prescribes and supplies a prescription it must be within their scope of practice and the pharmacist prescriber should have robust governance arrangements in place. Where possible, a second suitably competent person should be involved in carrying out the final accuracy check and the check for clinical appropriateness.

The pharmacist prescriber must make a record of their prescribing and the reasons for their prescribing decision.

4.3 Prescribing, supplying and administering

Where a pharmacist prescriber prescribes, supplies and administers, for example in the case of non-surgical cosmetic medicines or travel vaccines, they should make sure person-centred care is delivered, making the care of the person their priority. Where a pharmacist prescriber delegates the administering of these medicines to another person, they must make sure the other person has the necessary training and skills to administer safely.

5. Prescribing non-surgical cosmetic medicinal products

We are aware that an increasing number of aesthetic pharmacists are now prescribing non-surgical cosmetic medicinal products. Pharmacist prescribers have an important role in making sure prescribing is safe and effective in this area, and any risks to the person are minimised. They must use their professional judgement so they act in the person's best interest and only prescribe medicines which are appropriate, taking extra safeguards where necessary.

Pharmacist prescribers who prescribe and administer non-surgical cosmetic medicinal products must be appropriately trained¹⁹ and only prescribe and administer non-surgical cosmetic medicinal products in line with good practice guidelines,^{20,21} and only after a physical examination of the person has taken place. For this reason, a remote consultation for non-surgical cosmetic medicinal products is not appropriate.

Pharmacist prescribers must be satisfied that any services they prescribe for complies with any relevant registration and regulatory requirements. They must make sure any procedures are carried out in an appropriate and professional manner in a safe and appropriate environment for the procedures being carried out. Pharmacist prescribers must make sure that any person they delegate the administration to has the necessary training and skills to administer and carry out the procedure.

Before prescribing and/or administering non-surgical cosmetic medicines, pharmacist prescribers should:

- have the necessary training and experience to practise safely and know whether the medicines being prescribed meet approved guidelines
- have professional indemnity insurance to cover both NHS and private activities
- have consent from the person to carry out the procedure
- be familiar with the procedure including what it involves, how long it will take and also if the products are appropriately licensed
- consider whether the person has capacity to consent to having the procedure carried out
- consider the psychological needs of the person
- be prepared not to carry out the prescribing or procedure if they think it is not appropriate or the person wants more time to consider the procedure. In this case the pharmacist prescriber should explain why, discuss alternative options and record the decisions
- be able to show that all prescribing arrangements are transparent, and do not cause conflicts of interest, restrict a person's choice, or unduly influence or mislead people requesting prescribing services deliberately or by mistake
- make sure if they administer or delegate the administration, they only delegate to people who are competent and appropriately trained.

Pharmacist prescribers should work with the individual person to make sure the person has all the relevant information to make an informed decision and choice, to make sure they:

- have realistic expectations
- are clear about the potential risks and complications of the procedure and the outcomes

¹⁹ JCCP/CPSA Guidance for practitioners who provide cosmetic interventions, Health Education England was commissioned by the Department of Health to develop **qualification requirements** (2015) for the delivery of non-surgical cosmetic interventions with the aim of improving and standardising the training available to practitioners. Necessary training depends on prior experience, adequate insurance provision.

²⁰ [Guidance for doctors who offer cosmetic interventions \(June 2016\)](#)

²¹ [Professional Standards for Cosmetic Surgery RCS 2016](#), [Qualifications requirements for delivery of cosmetic procedures NHS HEE 2015](#), [Report on implementation for qualifications requirements for cosmetic procedures NHS HEE 2015](#); [Code of Practice-British Association of Aesthetic Plastic surgeons](#), [Code of practice-British Association of Plastic reconstructive and aesthetic surgeons 2016](#)

- have all the information to decide whether to have the procedure
- have all the information to support continuity of care and their GP is kept informed
- know what follow up and after care is provided, and
- know when and how to seek further help should there be a negative reaction or something goes wrong.

6. Remote prescribing

[N.B. The draft guidance for pharmacist prescribers references future guidance which will be published in the next few months and may be subject to change.]

Increasingly people are accessing pharmacist prescribers not in the traditional face to face way, but remotely,²² either by telephone or video link or more commonly online through prescribing services. In these cases, pharmacist prescribers should make sure they can make an adequate and safe clinical assessment, communicate effectively and obtain the person's consent.

Prescribing medicines remotely, either as part of an online prescribing service or independently on the internet, brings different risks than those when there is a face to face consultation.

Pharmacist prescribers are accountable for their decisions to prescribe and should only prescribe where they have the relevant knowledge of the person's health and medical history, and are satisfied that the care meets the needs of the person, including when prescribing remotely.

Where pharmacist prescribers do not have access to a person's medical records or have not carried out a previous consultation face to face with the person, they should explain to the person how the remote consultation will be carried out.

Pharmacist prescribers who prescribe for people in other countries must keep to any other laws that apply. Countries have different restrictions and some do not allow the online supply of medicines at all. Pharmacist prescribers should make sure the medicine they prescribe has the marketing authorisation needed for it in the country of destination²³. They should make sure the person can obtain the medicine and that they have considered the product's licensed name, indications and recommended dosage regimen in that country.

Regardless of who they are prescribing for and where that person is located, pharmacist prescribers must assess and manage any risks related to their prescribing and the care they provide. Before carrying out a remote consultation, pharmacist prescribers should consider:

- the limitations of effective communication with the person through the remote consultation (not being able to see physical symptoms or read their body language, not being able to ask follow up questions)
- the complexity of the clinical need and whether the medicine requested requires further safeguards before being prescribed
- how they can verify the person's identity

²² See our Guidance on registered pharmacies providing pharmacy services at a distance including on the internet.

²³ Regulation 28 of the Human Medicines (Amendment) Regulations 2013

- whether a physical examination is required
- whether the prescriber can assess whether the person has capacity to decide about their medicines
- whether there are any safeguarding issues that need to be addressed
- any follow up or further monitoring required, either by themselves or a local healthcare professional
- whether the person has all the necessary information they want and need about the medicine options
- whether their professional indemnity insurance covers these activities
- whether they need to be registered with a regulatory body in the country in which the prescribed medicines are to be dispensed, and any import/ export requirements of the MHRA and safety of delivery²⁴.

7. Safeguards for remote prescribing of certain medicines

[N.B. The draft guidance for pharmacist prescribers references future guidance which will be published in the next few months and may be subject to change.]

Pharmacist prescribers should be aware that some categories of medicines are not suitable to be prescribed or supplied remotely unless further safeguards have been put in place to make sure that they are clinically appropriate. The categories include:

- **Antimicrobials (antibiotics)**, where it is important to effectively manage their use, to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection. These should only be supplied if in line with good practice guidance, taking into account antimicrobial stewardship guidelines relevant for the person and their location.
- **Medicines liable to abuse, overuse or misuse, or where there is a risk of addiction and ongoing monitoring is important.** For example, opiates, sedatives, laxatives, pregabalin, gabapentin.
- **Medicines that require ongoing monitoring or management.** For example, medicines with a narrow therapeutic index²⁵, medicines used to treat diabetes, asthma, epilepsy and mental health conditions. A particular example of this is sodium valproate which is used for the treatment of epilepsy and bipolar disorder but which puts babies in the womb at high risk of malformations and developmental problems.

²⁴ See our Guidance for registered pharmacies providing pharmacy services at a distance including on the internet

²⁵ Drugs with a narrow therapeutic index are drugs with small differences between therapeutic and toxic doses. For example, lithium, warfarin, digoxin.

- **Non-surgical cosmetic medicinal products.** In line with good practice guidelines, these should only be prescribed and supplied once a physical examination of the person has taken place.

If pharmacist prescribers decide to prescribe remotely or work with an online prescribing service, the above categories of medicines should not be prescribed unless they have made sure the following safeguards have been put in place:

- the prescriber has robust processes in place to check the identity of the person to ensure the medicines prescribed go to the right person
- the prescriber has asked the person for the contact details of their regular prescriber such as their GP and for their consent to contact them regarding the prescription
- the prescriber will proactively share all relevant information about the prescription with other health professionals involved in the care of the person (for example their GP)
- the prescriber has systems in place so that the pharmacy team can clearly document the prescriber's decision to issue a prescription if the person does not have a regular prescriber such as a GP or there is no consent to share information
- the prescriber is working within national prescribing guidelines for the UK and good practice guidance.²⁶

8. Raising concerns²⁷

All pharmacy professionals must speak up when they have concerns or when things go wrong including pharmacist prescribers. The quality of care people receive is improved when pharmacist prescribers learn from feedback and incidents, and challenge poor practice and behaviours, which include speaking up when they have concerns.

Where any pharmacy professional, including pharmacist prescribers, consider the prescribing of a colleague is unsafe for the person, they should question the decision or action, and raise concerns where it is likely to affect the health and wellbeing of the person. Where pharmacist prescribers pick up concerns about prescribing data, they must also raise these.

Pharmacist prescribers must reflect on feedback or concerns raised by colleagues, people or carers about their own practice and act when appropriate, to prevent the same thing happening again.

9. Information for pharmacy owners and employers of pharmacist prescribers

²⁶ <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors#prescribing>;
<https://www.rpharms.com/resources/frameworks/prescribers-competency-framework>;
<https://www.cqc.org.uk/guidance-providers/online-primary-care#care-standards>; www.nice.org.uk/guidance
<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/sharing-information-with-colleagues>
<https://www.gov.uk/government/news/valproate-banned-without-the-pregnancy-prevention-programme>

²⁷ In practice: Raising concerns

Pharmacy owners must have governance arrangements in place which safeguard the health, safety and wellbeing of patients and the public. Pharmacy owners must identify and manage the risks involved in providing and managing pharmacy services, including a prescribing service which may be online.

Pharmacy owners who employ pharmacist prescribers must make sure that:

- they identify and manage the risks of providing prescribing services remotely (including online), and to ensure the safe and effective practice of pharmacy
- all members of the pharmacy team are familiar with the areas raised within this guidance and understand their own responsibilities in relation to pharmacist prescribers
- where pharmacist prescribers carry out assessments and provide diagnostic testing to assess a person's condition, the equipment and facilities in the pharmacy are safe to use and appropriately maintained
- pharmacy professionals can meet their own professional and legal obligations, and are able to exercise their professional judgement in the interests of patients and the public
- they have systems in place so that the pharmacist prescriber can clearly document their decision to issue a prescription if the person does not have a GP or there is no consent to share information
- incentives or targets do not compromise the health, safety and wellbeing of patients and the public, or the professional judgement of staff.

9.1 Working with online prescribing services

Pharmacy owners should not work with online providers who are seeking to circumvent the regulatory oversight put in place within the UK to ensure patient safety throughout the healthcare system. Working with prescribers who are not appropriately registered with the relevant UK professional regulator, and prescribing services not based in the UK, could create significant additional risks for patients and the public. If pharmacy owners decide to work with prescribers or prescribing services operating outside the UK, they should make sure that:

- they successfully manage the additional risks that this may create
- they have sufficient indemnity insurance in place to cover the service that uses prescribers or prescribing services based outside the UK and pharmacy staff supplying medicines against prescriptions issued by such prescribers or prescribing services
- the prescriber is registered in their home country where the prescription is issued and can lawfully issue prescriptions online
- the prescriber is working within national prescribing guidelines for the UK

Questions to ask yourself

Below are some key questions that pharmacist prescribers should ask themselves when thinking about how they can ensure and demonstrate that they have provided person-centred care in this context:

Commented [CG2]: Suzannah, please can the questions be in a SmartArt format/mind map, including the ones below which I couldn't fit in.



Have I made the care of the person my priority?
Can I check the requesting person's identity?
Am I concerned about the quantity of medicines being requested?
Have I considered what extra safeguards need to be in place for the medicines being prescribed?
Have I made a record of any decisions where prescribing is outside the guidelines?
Does the patient have capacity to consent?
Am I concerned about the frequency of requests?

Other sources of information

Pharmacist prescribers can get more information and guidance from professional bodies, indemnity insurance providers, and from other independent bodies such as those listed below:

Royal Pharmaceutical Society - **A Competency Framework for all prescribers**

Royal Pharmaceutical Society – **Prescribing_Specials**

Royal Pharmaceutical Society - **a practical guide to support pharmacist independent prescribers** (Nov 2018)

Health Education England **Qualification requirements for delivery of cosmetic procedures: Non-surgical cosmetic interventions and hair restorative surgery** Nov 2015

General Medical Council- **Good practice in prescribing and managing medicines and devices** (March 2013)

General Medical Council – **Guidance for doctors who offer cosmetic interventions** June 2016

General Medical Council **Cosmetic procedures-what do I need to consider** June 2016

The All Wales Medicines Strategy Group (AWMSG) - **Non-Medical Prescribing in Wales** (May 2017),

GPhC – **Standards for education and training standards for pharmacist independent prescribers**

CPPE **Prescribing: maintaining competence and confidence**

JCCP/CPSA **guidance for practitioners who provide cosmetic interventions**

Consultation on guidance for pharmacist prescribers

March 2019 v 1.5

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About the GPhC

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 main work includes:

- setting standards for the education and training of pharmacists, pharmacy technicians, and approving and accrediting their qualifications and training
- maintaining a register of pharmacists, pharmacy technicians and pharmacies
- setting the standards that pharmacy professionals have to meet throughout their careers
- investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public
- setting standards for registered pharmacies which require them to provide a safe and effective service to patients
- inspecting registered pharmacies to check if they are meeting our standards.

Overview

We are consulting **from 26 March -18 June 2019** on our draft guidance for pharmacist prescribers.

This consultation is about draft guidance to support pharmacist prescribers in meeting our standards for pharmacy professionals and to ensure they provide safe and effective care when prescribing.

The draft guidance sets out the key areas pharmacist prescribers should consider when prescribing, whether within the NHS or privately, including primary care and secondary care, as well as healthcare roles within the armed forces and prisons.

This consultation asks for views on our draft guidance. More specifically we are asking for views on:

- the key areas for safe and effective prescribing
- what pharmacist prescribers must do in order to safely prescribe
- prescribing and supplying
- safeguards for remote prescribing of certain categories of medicines, and
- the impact this guidance may have on various stakeholder groups.

We welcome responses from anyone with an interest in pharmacist prescribing. We are particularly interested to hear views about the impact of our proposals on patients and the public, pharmacist prescribers, pharmacy professionals, pharmacy owners and employers.

The consultation process

The consultation will run for 12 weeks and will close on 18 June 2019. During this time, we welcome feedback from individuals and organisations. We will send this document to a range of stakeholders, including pharmacy professionals, pharmacist prescribers, pharmacy owners, patients' representative bodies and others with an interest in this matter.

We hope you will read this paper and consider responding. You can get more copies of this document on our website www.pharmacyregulation.org/xxxx or you can contact us if you would like a copy of the document in another format (for example, in larger type or in a different language).

How to respond

You can respond to this consultation in a number of ways.

You can fill in the questionnaire at the end of this document or go to www.pharmacyregulation.org/ADDLINK and fill in an online version there.

If you fill in the questionnaire in this document, please email it to: consultations@pharmacyregulation.org with the subject line 'In practice: Guidance for pharmacist prescribers' or post it to us at:

Guidance for pharmacist prescribers consultation response
General Pharmaceutical Council
25 Canada Square
London
E14 5LQ

Comments on the consultation process itself

If you have concerns or comments about the consultation process itself, please send them to: feedback@pharmacyregulation.org or post them to us at:

Governance team
General Pharmaceutical Council
25 Canada Square
London
E14 5LQ

Please do not send consultation responses to this address.

Our report on this consultation

Once the consultation period ends we will analyse the responses we receive. Our governing council will receive the analysis at a meeting in Autumn 2019 and will take the responses into account when considering the proposed changes, we make to the final guidance.

We will also publish a summary of the responses and an explanation of the decisions taken. You will be able to see these on our website www.pharmacyregulation.org

1. Background

Pharmacist prescribers play a vital role in the delivery of high-quality healthcare services. Pharmacist prescribers are responsible for creating a culture of person-centred professionalism wherever they work and ensuring prescribing services are delivered safely and effectively.

Government policies and the changing demands from health services and patients across Great Britain have significantly influenced and developed the role and use of pharmacist prescribers over the last few years. Simultaneously, the number of annotated pharmacist prescribers has significantly increased. While national pharmacy strategies vary across the countries in Great Britain, what is consistent is a recognition that employing pharmacist prescribers across healthcare settings makes the best use of pharmacists' prescribing knowledge and skills, and complements the skills of other members of the healthcare team.

Our Strategic plan (2017–20) sets out our aim to use our regulatory powers to support and improve the delivery of safe, effective care and to uphold trust in pharmacy. One of the ways we do this is and assure the public is by making sure that pharmacist prescribers have the necessary knowledge and skills.

We have carried out research over the past three years, and from this and information received through our prescriber's survey (2016), the enquiries received, FtP cases, our discussion paper and consultations^{1,2} we have better understood the issues pharmacist prescribers face when carrying out their prescribing role. This includes prescribing remotely or online and prescribing certain categories of medicines. We have also taken account of other prescriber guidance when drafting ours. In particular, we looked at the GMC prescribing guidance and that of the Joint Council of Cosmetic Practice.

We are working collaboratively with other regulatory agencies, for example the MHRA and CQC, to help identify issues that affect patient safety, and to make sure pharmacist prescribers provide safe and effective care.

Who are pharmacist prescribers?

A pharmacist independent prescriber (PIP) is a pharmacist who has completed the relevant approved education and training to add an annotation to their entry in the register. A PIP may prescribe all medicines autonomously for any condition within their scope of practice and clinical competence, excluding three controlled drugs for the medicine of addiction (cocaine, dipipanone and diamorphine) and unlicensed cannabis based medicinal products (CBMPs).

A supplementary prescriber (PSP) works with a medical or dental practitioner within a specific clinical management plan (CMP). The law sets out what the CMP must include, the limitations of what the PSP can prescribe and under what circumstances. A PSP may become a PIP through further training and converting their qualification, and can then work as both a PSP and a PIP.

¹ Discussion paper: Making sure patients and the public obtain medicines and other pharmacy services safely online

² Consultation on education and training standards for pharmacist independent prescribers

Our **standards for pharmacy professionals** apply to all pharmacy professionals in Great Britain including pharmacist prescribers. Given the increase in the number of pharmacist prescribers, and other influencing drivers for example new technologies being used for prescribing (remote and online), we felt it was timely to look again at how we can support pharmacist prescribers to provide safe and effective care in their prescribing role.

We have developed guidance to support our standards for pharmacy professionals which all pharmacy professionals must meet, which includes pharmacist prescribers regardless of their area of prescribing. It provides guidance to pharmacy professionals who are pharmacist prescribers on applying our standards.

The guidance sets out the nine key areas pharmacist prescribers should consider when prescribing to ensure safe and effective care, including:

- taking responsibility for prescribing safely
- keeping up to date and prescribing within their level of competence
- working in partnership with people seeking care and other healthcare professionals
- prescribing in certain circumstances
- prescribing non-surgical cosmetic medicinal products
- remote prescribing
- safeguards for remote prescribing for certain categories of medicines
- raising concerns
- information for pharmacy owners and employers of pharmacist prescribers.

Please read the draft guidance in the next section for more information on how to apply the standards for pharmacy professionals.

2. In practice: Guidance for pharmacist prescribers

add draft guidance document here xxx

3. Responding to the consultation

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

If you respond as a private individual, we will not use your name or publish individuals' responses. If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to. If you want any part of your response to stay confidential, you should explain why you believe the information you have given is confidential. The GPhC may need to disclose information under the laws covering access to information (the General Data Protection Regulation 2016/679). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it but we cannot guarantee that confidentiality can be maintained in all circumstances. If you email a response to the consultation and this is covered by an automatic confidentiality disclaimer generated by your IT system this will not, in itself, be binding on the GPhC.

4.Consultation questions

NB. Some of the guidance is based on requirements from the GPhC's standards for pharmacy professionals and therefore will not change as a result of this consultation. Some elements have already been consulted on in our discussion paper on the safe and effective delivery of online services, so we have not asked further questions regarding this. This means that not all feedback will result in change where it directly relates to our standards or a previous consultation.

We welcome your views on the following questions. Please visit www.pharmacyregulation.org/xxx to complete the online survey.

Views on the proposals

Key areas for safe and effective prescribing

In developing this guidance, we have identified nine core areas that relate to the provision of safe and effective prescribing.

1. Have we have identified all the necessary areas for ensuring safe and effective care is provided?

Yes

No

Don't know

2. For each of the nine core areas, do you agree or disagree with the guidance we have proposed?

Area	Agree	Disagree	Don't know
1. Taking responsibility for prescribing safely			
2. Keeping up to date and working within your level of competence			
3. Working in partnership with people seeking care and others healthcare professionals			
4. Prescribing in certain circumstances			
5. Prescribing non-surgical cosmetic medicinal products			
6. Remote prescribing			
7. Safeguards for remote prescribing of certain medicines			
8. Raising concerns			

9. Information for pharmacy owners and employers of pharmacist prescribers			
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3. Please explain your responses to questions 1 and 2 above.

Please note you will be asked questions about what pharmacist prescribers must do in order to safely prescribe, carry out both prescribing and supplying, and the safeguards for remote prescribing later in the consultation.

Prescribing safely

In section 3.1 of our proposals we provide guidance on what pharmacist prescribers must do in order to prescribe safely including asking for consent to access a person's medical record from their regular prescriber, giving the person clear information so they can make an informed decision, and discussing other available options when it is not appropriate to prescribe.

We also describe circumstances where pharmacist prescribers must consider whether they can prescribe safely, such as where:

- they do not have access to the person's medical records
- the person refuses to give consent to contact their prescriber for more information
- the person has not been referred to the pharmacist prescriber by their prescriber or
- the person does not have a regular prescriber (such as a GP)

4. Are there any other circumstances where a pharmacist prescriber should consider whether they can prescribe safely for a person?

Yes

No

Don't know

Please explain your reasons for this.

Prescribing and supplying

In section 4.2 of our proposals we say wherever possible pharmacist prescribers should normally keep the prescribing and supply of medicines as separate functions to protect the person's safety. We describe exceptional circumstances where it may be necessary to prescribe and supply and have also identified certain circumstances where a pharmacist prescriber may prescribe and supply on a regular basis, for example in travel clinics.

5. Are there any other circumstances where you think a pharmacist prescriber should be able to prescribe and supply?

Yes

No

Don't know

Please explain your reasons for this.

Safeguards for remote prescribing of certain categories of medicines

In section 7 of our proposals we describe prescribing remotely, including online for certain categories of medicines. We say that certain medicines are not suitable to be prescribed remotely unless further safeguards have been put in place to make sure they are clinically appropriate.

In our recent discussion paper on our *guidance for registered pharmacies providing pharmacy services at a distance, including on the internet*, respondents agreed that additional safeguards should be put in place to make sure the medicines are clinically appropriate for the person, before prescribing remotely.

We have proposed five safeguards for ensuring certain categories of medicines are prescribed safely.

- the prescriber has robust processes in place to check the identity of the person to ensure the medicines prescribed go to the right person
- the prescriber has asked the person for the contact details of their regular prescriber such as their GP and for their consent to contact them regarding the prescription
- the prescriber will proactively share all relevant information about the prescription with other health professionals involved in the care of the person (for example their GP)
- the prescriber has systems in place so that the pharmacy team can clearly document the prescriber's decision to issue a prescription if the person does not have a regular prescriber such as a GP or there is no consent to share information
- the prescriber is working within national prescribing guidelines for the UK and good practice guidance

6. Are there any other safeguards that should be put in place to make sure certain medicines are prescribed safely remotely?

Yes

No

Don't know

Please describe any additional safeguards you think there should be.

Impact of the proposals

We are keen to hear views about the impact of the draft guidance.

7. What kind of impact do you think our proposals will have on patients and the public?

Positive impact
Negative impact
Both positive and negative impact
No impact
Don't know

8. What kind of impact do you think our proposals will have on pharmacist prescribers?

Positive impact
Negative impact
Both positive and negative impact
No impact
Don't know

9. What kind of impact do you think our proposals will have on other pharmacy professionals?

Positive impact
Negative impact
Both positive and negative impact
No impact
Don't know

10. What kind of impact do you think our proposals will have on employers or pharmacy owners?

Positive impact
Negative impact
Both positive and negative impact
No impact
Don't know

Please give comments explaining your responses to the above.

We want to understand whether our proposals may discriminate against or unintentionally disadvantage any individuals or groups sharing any of the protected characteristics in the Equality Act 2010.

11. Do you think our proposals will have a negative impact on certain individuals or groups who share any of the protected characteristics listed below? Please tick all that apply.

Age
Disability

Gender reassignment
Marriage and civil partnership
Pregnancy and maternity
Race
Religion or belief
Sex
Sexual orientation
None of the above

We also want to understand whether our proposals may benefit any individuals or groups sharing any of the protected characteristics in the Equality Act 2010.

12. Do you think our proposals will have a positive impact on certain individuals or groups who share any of the protected characteristics listed below? Please tick all that apply.

Age
Disability
Gender reassignment
Marriage and civil partnership
Pregnancy and maternity
Race
Religion or belief
Sex
Sexual orientation
None of the above

Please describe the impact and the individuals or groups you have described in the two questions above.

3. Consultation response form

(These will not be included in the consultation document, but are here to be included in the sign off.)

Background questions for Guidance on prescribing consultation

Are you responding as:

An individual?

On behalf of an organisation?

Individuals

Where do you live?

England

Scotland

Wales

Northern Ireland

Other (please specify)

Are you responding as:

a member of the public

a pharmacist

a pharmacy technician

a pre-registration trainee pharmacist

a pharmacy student

Other (please give details):

Are you qualified as:

an independent prescriber

a supplementary prescriber
both a supplementary and independent prescriber
none of the above

What type of prescribing services do you provide?

NHS
Private
Both NHS and private

Do you prescribe remotely (including online and over the telephone)?

Yes
No

Are you a pharmacy owner/employer?

Yes
No

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

Community pharmacy
Hospital
Prison pharmacy
GP practice
Care Home
Primary care organisation
Pharmaceutical industry
Research, education or training

Other setting (please give details)

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

Independent pharmacy (1 pharmacy)

Independent pharmacy chain (2-5 pharmacies)

Small multiple pharmacy chain (6-25 pharmacies)

Medium multiple pharmacy chain (26-100 pharmacies)

Large multiple pharmacy chain (Over 100 pharmacies)

Organisations

Is your organisation a:

pharmacy organisation?

non-pharmacy organisation?

Please choose the option below which best describes your organisation:

Organisation representing patients or the public

Organisation representing pharmacy professionals or the pharmacy sector

Independent pharmacy (1 pharmacy)

Independent pharmacy chain (2-5 pharmacies)

Small multiple pharmacy chain (6-25 pharmacies)

Medium multiple pharmacy chain (26-100 pharmacies)

Large multiple pharmacy chain (Over 100 pharmacies)

NHS organisation or group

Research, education or training organisation

Government department or organisation

Regulatory body

Other (please specify):

4. Equality monitoring

The equality monitoring form will be added online

Consultation on In Practice: Guidance for pharmacist prescribers: Equality monitoring

1. Equality monitoring

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

We want to make sure everyone has an opportunity to respond to this consultation on the revised initial education and training standards for pharmacists. This equality monitoring form will provide us with useful information to check that this happens.

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

What is your sex? Please tick one box

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

What is your sexual orientation? Please tick one box

- ☐ Heterosexual/straight
- ☐ Gay woman/lesbian
- ☐ Gay man
- ☐ Bisexual
- ☐ Other
- ☐ Prefer not to say

Do you consider yourself disabled? Please tick one box Disability is defined in the Equality Act 2010 as "physical or mental impairment, which has a substantial and long term adverse effect on a person's ability to carry out normal day to day activities".

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

What is your age? Please tick one box

- ☐ 16-24 years
- ☐ 25-34 years
- ☐ 35-44 years
- ☐ 45-54 years
- ☐ 55-64 years
- ☐ 65+ years
- ☐ Prefer not to say

What is your ethnic group? Choose the appropriate box to indicate your cultural background. Please tick one box.

White

- ☐ British
- ☐ Irish
- ☐ Gypsy or Irish traveller
- ☐ Other white background (please fill in the box at the end of this section)
- ☐ **Black or Black British**
- ☐ Caribbean
- ☐ African
- ☐ Other black background (please fill in the box at the end of this section)
- ☐ **Mixed**
- ☐ White and Black Caribbean
- ☐ White and Black African
- ☐ White and Asian
- ☐ Other mixed background (please fill in the box at the end of this section)
- ☐ **Asian or Asian British**
- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi

- ☐ Other Asian background (please fill in the box at the end of this section)
 ? **Chinese or Chinese British**
- ☐ Chinese or Chinese British
 ? **Arab**
- ☐ Arab
 ? **Other**
- ☐ Other ethnic group background (please fill in the box at the end of this section)
- ☐ Prefer not to say

If you answered 'other' to any of the above, please give more information in the space below:

What is your religion? Please tick one box

- ☐ Buddhist
- ☐ Christian
- ☐ Hindu
- ☐ Jewish
- ☐ Muslim
- ☐ Sikh
- ☐ None
- ☐ Prefer not to say
- ☐ Other

If you selected 'other', please specify:

Appendix A: Collated consultation questions

(Add in questions)