General Pharmaceutical Council

# Regulating healthcare professionals, protecting the public: GPhC response to the DHSC consultation

We welcome the significant and continued progress made in relation to reforming healthcare regulators' legislation, particularly in the context of the ongoing pandemic. This consultation is a real opportunity to improve health professional regulation, so we can best protect patients and the public and support health services and health professionals to provide high-quality care.

We have also encouraged patients and the public and the pharmacy professionals and pharmacy owners we regulate to respond. The voices of patients and health professionals need to be at the heart of this consultation, to help make sure that health professional regulation is fit for the future.

We share the UK Government's and Devolved Administrations' aim of ensuring healthcare regulation is faster, fairer and more flexible. Whilst we support the proposals to bring about a more consistent set of powers across all of the health professional regulators, we have a unique statutory role in relation to both 'system' regulation of registered pharmacies, as well as professional regulation of individual pharmacists and pharmacy technicians.

The COVID-19 pandemic has clearly demonstrated why we need the powers to enable us to quickly change the way we work, in response to external challenges and opportunities in and for pharmacy. And we support the proposals to strengthen the oversight of the GPhC and other regulators, to make sure we are using this flexibility appropriately on behalf of patients and members of the public.

Thank you for the opportunity to engage with the proposals, along with other regulators, in the initial development stages. The individual and roundtable meetings were important in getting us to where we are with the proposals. Discussions highlighted broad agreement on the direction of travel and this consultation provides an opportunity to further explore areas where there was some divergence, for example, grounds for action in fitness to practise.

We welcome the scope of the approach to regulatory reform as it captures education, registration and governance as well as fitness to practise. This will help build a clear narrative and case for legislative reform. We also support the drivers behind the legislative change in fitness to practise including the need for regulators to look further upstream at professionalism and prevention. This is something we hope to achieve through our managing concerns strategy.

Our **detailed responses to the specific consultation questions are set out at Appendix 1 below** and we hope you find this response helpful.

We note that a number of the proposals relate to powers that we already hold, including in relation to registration and training, and we would be seriously concerned about any unintended or negative impact on our existing powers. However, we understand that this is not the policy intention.

We look forward to the next stage and making further progress to implement the future changes.

16 June 2021

## Appendix 1: Response to consultation questions

| Question No. | Question | GPhC response |
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| **1** | Do you agree or disagree that regulators should be under a duty to co-operate with the organisations set out above? | **Agree.** This reflects our current approach and we regularly co-operate with other regulators, agencies and organisations to support the delivery of our statutory objectives; to promote a transparent and collaborative culture; and, to provide public protection. This is carried out in line with relevant legislation, guidance, MOUs and information sharing agreement and other protocols. Although this is reflected in our existing approach, we support the introduction of this duty to ensure consistency across the sector. |
| **2** | Do you agree or disagree that regulators should have an objective to be transparent when carrying out their functions and should have these related duties? | **Agree.** This reflects our current approach and we already publish the information listed under this provision. This includes publishing annual information about regulatory functions, holding Council meetings and hearings in public unless confidential matters are being discussed, publishing records of Council meetings and hearings save for confidential matters and publishing public consultations on significant changes. Although this is reflected in our existing ways of working, we support the introduction of this duty to ensure consistency across the sector. The GPhC operates from the principle that effective regulation requires the confidence of both the public we serve and those we regulate, and transparency underpins this principle. |
| **3** | Do you agree or disagree that regulators should be required to assess the impact of proposed changes to their rules, processes and systems before they are introduced? | **Agree with caveats.** We consider that this proposal (i.e. assessing the proportionality of significant policy or process change) is aligned with our existing approach. We consider each of our regulatory interventions and their impact carefully and on a case by case basis. This determines, for example, the extent and duration of the consultations we undertake, as well as the range of stakeholders we consult on our proposals.<br><br>Whenever we propose to implement a new policy or process, we objectively analyse the qualitative and quantitative evidence we gather through surveys, focus group discussions and one-to-one meetings with key stakeholders. We |

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| | | produce Equality Impact Assessments (EIAs), exploring any impacts of our proposals on people who share any of the protected characteristics, and we ask additional questions about the wider impact of proposals on any other groups and individuals. This allows us to see if there are any adverse unintended consequences on anyone. The analysis of these findings is captured in a report produced as a result of every consultation we carry out and published on our website. In some cases, we will also carry out regulatory or business impact assessments.<br><br>We believe that assessing the impact / proportionality should be considered as part of existing processes. We currently consider proportionality in the context of our existing equality or regulatory impact assessments, and this is reflected in our consultation reports. We also commission external reports where this is necessary to help us assess and consider proportionality. For example, we recently commissioned an external business impact assessment of pharmacy registration fees on registered pharmacies in Great Britain.<br><br>We think that it would be disproportionate to expect a separate or standalone proportionality impact assessment to be carried out every time we develop or review our policies or processes. We would strongly encourage that this process does not become an over-burdensome and over-bureaucratic practice, placing an onerous demand on the resources of the regulators.<br><br>The consultation discusses the need to assess cost impact. We would welcome more information about the extent to which cost impact will need to be assessed in respect of the three groups mentioned in the consultation: patients, service users and the public; current and prospective health and care professionals; and other relevant stakeholders across the health and care system. There should be flexibility here, as cost impact may not be relevant to every proposed policy or process change and, in some cases, costs impact may be difficult or impossible to quantify. |

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| **4** | Do you agree or disagree with the proposal for the constitution on appointment arrangements to the Board of the regulators? | **Disagree.** In our response to the earlier DHSC consultation in 2017 we stated:<br><br>*"6.17 Given the clear effectiveness of our current arrangements we will continue to value clear lines of accountability and a balance of professional and lay perspectives. The professional members are important and necessary members of the Council, who ensure that the context in which regulated professionals practice is understood, and whose presence on Council also enhances the confidence of the regulated professions in the deliberations and decisions made. It is for these reasons that a professional and lay Council is most valuable. When considering the number of Council members, it is important that the size is not so small that it precludes effective decision making and continues to ensure that the context of the regulated is considered. Decisions in the past have resulted in a reduction in the size of the Councils of regulatory bodies, and there is no doubt that this has improved governance overall; but the case for a further reduction is not made, in our view.*<br><br>*6.18 The breadth of the structure of our Council enables us to draw upon a wealth of experience of different models of governance, and we remain unconvinced of the potential benefits of a unitary board where the executive do not have any clear lines of accountability within the organisation. Such an arrangement compromises the accountability of the Chief Executive – who is then playing two roles of blurred identity, which have the potential to conflict".*<br><br>Although we recognise the preferred direction of travel in this area, we remain of the view as expressed above. |
| **5** | Do you agree or disagree that regulators should be able to set their own fees in rules without Privy Council approval? | **Agree.** We already have these powers under our existing legal framework as set out in the Pharmacy Order 2010. We understand that three other regulators also have these powers. We would be seriously concerned if the outcome of the consultation had any negative or unintended impact on those who already have these powers. |

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| **6** | Do you agree or disagree that regulators should be able to set a longer-term approach to fees? | **Agree**. We have this provision in article 36 of the Pharmacy Order 2010 which provides that fees may be charged in relation to the entry of registered pharmacies in the Register by reference to different periods. Like our answer to question 5 above, should the outcome of the consultation result in the loss of this provision we would be very concerned. |
| **7** | Do you agree or disagree that regulators should be able to establish their own committees rather than this being set out in legislation? | **Agree.** At present, we are required, under the Pharmacy Order 2010 (the Order), to have three statutory Committees. We also have broader power to establish any such other committees as the Council considers appropriate in connection with the discharge of its functions and may delegate any of its functions to them, except any power to make rules. And, we currently use this power. Overall, we support this proposal to enable us to operate more flexibly in the future. |
| **8** | Do you agree or disagree that regulators should be able to charge for services undertaken on a cost recovery basis, and that this should extend to services undertaken outside of the geographical region in which they normally operate? | **Agree.** We have powers under article 42 of the Order to approve, or arrange with others to approve, courses of education or training run both inside and outside of Great Britain. We have powers under article 54 of the Order to charge fees. |
| **9** | Do you agree or disagree that regulators should have the power to delegate the performance of a function to a third party including another regulator? | **Agree.** We consider that this will support the regulators to work together more closely where it is appropriate for them to do so. This system should work on the basis of consent and there should be no delegation without express agreement of each regulator or third party.<br><br>We note that the consultation now includes a proposal that core functions such as maintaining a register, setting standards, giving advice and administering fitness to practise procedures (previously excluded from delegation) could be delegated to another regulator, but not to a third party. |

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| | | We recognise that this approach may enable flexibility in how functions are delivered in the future. However, we agree that this should be framed in terms of a permissive power to delegate and not a duty to delegate, to ensure that any delegation is only considered and taken forward, where appropriate in all the circumstances. We agree that if a regulator chooses to delegate the performance of a function or part of a function to another regulator, the delegating regulator should retain accountability for the delivery of that function and conduct appropriate due diligence and checking to ensure that any delegation and carrying out of the function is done so appropriately and in line with relevant legal or other requirements.<br><br>We also believe that it is important that core functions are working in tandem. This is a key part of our Vision and Strategic Plan to make sure we adopt the right regulatory interventions in the interests of patient safety with registration, standards and fitness to practise (and inspection) working together. This includes being able to quickly and clearly identify trends and issues across their core regulatory functions in the interests of patient safety. This would remain relevant in the context of any potential delegation. |
| **10** | Do you agree or disagree that regulators should be able to require data from and share data with those groups listed above? | **Agree**. It is important that regulators are able to obtain and share information that is necessary to carry out their statutory functions and meet their objectives. Extending these powers to other statutory functions would support thorough risk assessment, in particular of people seeking to join the register, and be likely to assist with timeliness of responses from other parties. We note that any requests for or sharing of data under an extension of these powers must be done in accordance with the GDPR and Data Protection Act and that the rights of data subjects would therefore be protected. |

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| **11** | Do you agree or disagree that regulators should produce an annual report to the Parliament of each UK country in which they operate? | **Agree**. The importance of the reporting requirements as a means of focusing the minds of members of the governing body and executives on having good progress on which to report, should not be under-estimated as a tool for strengthening the accountability of the regulators. We would strongly favour all the regulators being obliged to submit their statutory reports for laying before all four (or in our case three) legislatures. The current inconsistent laying arrangements seem to be essentially an accident of history and timing with respect to devolution. |
| **12** | Do you agree or disagree that the Privy Council's default powers should apply to the GDC and GPhC? | **Agree.** To date, there have been no concerns or issues raised about the lack of Privy Council default powers in respect of the GPhC. Having said which, we can see the case for consistency across all of the regulators. However, it is important to be clear that this is not being introduced in response to a specific issue or problem arising from the current lack of powers. |
| **13** | Do you agree or disagree that all regulators should have the power to set:<br>• standards for the outcomes of education and training which leads to registration or annotation of the register for individual learners;<br>• standards for providers who deliver courses or programmes of training which lead to registration;<br>• standards for specific courses or programmes of training which lead to registration;<br>• additional standards for providers who deliver post-registration courses of programmes of training which lead to annotation of the register; and<br>• additional standards for specific courses or programmes of training which lead to annotation of the register? | **Agree.** We agree that all regulators should have the power to set standards and additional standards as set out in the consultation. In particular, we agree that the standards should be linked clearly to registration or annotation of the register to maintain and reinforce the primary regulatory focus on patient safety. |

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| | Please give a reason for your answer. | |
| **14** | Do you agree or disagree that all regulators should have the power to approve, refuse, re-approve and withdraw approval of education and training providers, qualifications, courses or programmes of training which lead to registration or annotation of the register? Please give a reason for your answer. | **Agree.** We believe it is right that these powers are available in relation to education and training providers, qualifications, courses or programmes. Without this, there are potential gaps in regulatory action which could reduce public assurance. |
| **15** | Do you agree that all regulators should have the power to issue warnings and impose conditions? Please give a reason for your answer. | **Agree.** We agree that all regulators should have the power to issue warnings and impose conditions. This will allow regulators to choose the most appropriate and proportionate intervention, depending on the particular circumstances of the issue relating to the education and training provider, qualifications, courses or programmes. |
| **16** | Do you agree or disagree with the proposal that education and training providers have a right to submit observations and that this should be taken into account in the decision-making process? Please provide a reason for your answer. | **Agree.** We agree that education and training providers should have the right to submit observations and that this should be taken into account in the decision-making process. This is important in ensuring the factual accuracy of decisions and that decisions take account of all relevant evidence and views. |
| **17** | Do you agree that:<br>• education and training providers should have the right to appeal approval decisions;<br>• that this appeal right should not apply when conditions are attached to an approval;<br>• that regulators should be required to set out the grounds for appeals and appeals processes in rules? Please provide a reason for your answer. | **Agree.** Education and training providers should have the right to appeal approval decisions i.e. when approval is refused or withdrawn. We also agree that this right should not apply when conditions are attached to an approval because providers will be able to demonstrate whether or not these conditions are met before any decision is taken to refuse or withdraw approval. And we agree that the grounds for appeals and appeal processes should be set out in rules to provide clarity and transparency. |

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| **18** | Do you agree or disagree that regulators should retain all existing approval and standard setting powers? Please provide a reason for your answer. | **Agree.** We believe this provides the appropriate flexibility ensuring regulators are addressing the issues specific to their area of healthcare. |
| **19** | Do you agree or disagree that all regulators should have the power to set and administer exams or other assessments for applications to join the register or to have annotations on the register? Please provide a reason for your answer. | **Agree**. All regulators should have the power to set and administer exams or other assessments for applications to join the register or to have annotations on the register. This reflects current powers operated by the GPhC and will enable all regulators to maintain, or introduce, exams or other assessments depending on the structure and standards of education and training in their own area of healthcare. In particular, this provides the necessary flexibility in the future taking account of any particular patient safety issues that may arise and/or related changes to the structure of education and training in future. |
| **20** | Do you agree or disagree that this power to set and administer exams or other assessments should not apply to approved courses or programmes of training which lead to registration or annotation of the register? Please provide a reason for your answer. | **Agree.** We agree that this is not necessary in relation to approved courses or programmes of training given that powers will exist for regulators to set the standards necessary in relation to the outcomes required. |
| **21** | Do you agree or disagree that regulators should be able to assess education and training providers, courses or programmes of training conducted in a range of ways? Please provide a reason for your answer. | **Agree.** This provides the appropriate flexibility for regulators to take full account of the learning from the pandemic and to utilise different methods depending on an assessment of the level of risk, proportionality and availability of resources. |
| **22** | Do you agree or disagree that the GMC's duty to award CCTs should be replaced with a power to make rules setting out the procedure in relation to, and evidence required in support of, CCTs? Please give a reason for your answer. | We do not have a view on this particular question. |

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| **23** | Do you agree or disagree that regulators should be able to set out in rules and guidance their CPD and revalidation requirements? Please give a reason for your answer. | **Agree**. Regulators should have flexibility, through rules and guidance, to set out the requirements for CPD and revalidation. As the pandemic has demonstrated, there may be a need for requirements to be changed at short notice. In addition, this will provide flexibility to ensure that requirements can be updated swiftly (after appropriate consultation) in response either to emerging patient safety issues or through changes to the roles that healthcare professionals are undertaking. We would welcome confirmation that the proposed powers allow regulators to identify themselves whether rules or guidance, or a combination of the two, are needed. |
| **24** | Do you agree or disagree that the regulators should hold a single register which can be divided into parts for each profession they regulate? Please give a reason for your answer. | **Agree.** We agree that holding a single register divided into parts is the most effective way to provide greater consistency across all regulators and provides the flexibility to add new regulated professions in the future. It is essential that the register is clear and comprehensible to all those who may use it, including the public, registrants and other stakeholders. |
| **25** | Do you agree or disagree that all regulators should be required to publish the following information about their registrants:<br>• Name<br>• Profession<br>• Qualification (this will only be published if the regulator holds this information. For historical reasons not all regulators hold this information about all of their registrants)<br>• Registration number or personal identification number (PIN)<br>• Registration status (any measures in relation to fitness to practise on a registrant's registration should be published in accordance with the rules/policy made by | **Agree**. We agree that these requirements provide the information essential for public assurance. We would simply caveat our answer that any new provision(s) envisaged needs to take account of what is fair, reasonable, and proportionate to publish in terms of historic registration history. Care would need to be taken to ensure that registrants' age or other personal (including protected) characteristics are not inadvertently available by virtue of piecing together information published, e.g. registration history, periods not on the Register etc, so as to protect against a potential risk of discrimination.<br><br>We would envisage regulators would still need to prepare and publish their own publication and disclosure policies, taking account of the circumstances and context of those they regulate. |

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| | a regulator)<br>• Registration history<br>Please provide a reason for your answer. | |
| **26** | Do you agree or disagree that all regulators, in line with their statutory objectives, should be given a power allowing them to collect, hold and process data? Please give a reason for your answer. | **Agree.** We agree that a power of this nature provides additional flexibility for regulators and agree that it must be linked explicitly to regulators' statutory functions. Any data collected, held and processed would need to be justifiable and compatible with regulators responsibilities under the Data Protection Act 2018 and the UK GDPR. In practical terms, this may require lengthy retention periods to ensure public protection and safety over the course of a registrants' careers. |
| **27** | Should they be given a discretionary power allowing them to publish specific data about their registrants? Please give a reason for your answer. | **Agree.** We agree that this power can provide additional public assurance where regulators identify a need to publish specific data relating to their particular healthcare profession(s). |
| **28** | Do you agree or disagree that all regulators should be able to annotate their register and that annotations should only be made where they are necessary for the purpose of public protection? Please give a reason for your answer. | **Agree.** Annotation of the register, rather than separate registers or lists, provides the most effective way for the public to identify particular specialties. We also agree that the purpose of annotation is public protection and, as such it would not be appropriate to include lists of all qualifications that a healthcare professional may achieve in the course of their career. |
| **29** | Do you agree or disagree that all of the regulators should be given a permanent emergency registration power? Please give a reason for your answer. | **Agree.** This reflects the current powers available to the GPhC. Having the power available to all regulators will ensure that action can be taken quickly across all healthcare professions when the Secretary of State declares an emergency. |
| **30** | Do you agree or disagree that all regulators should have the same offences in relation to protection of title and registration within their governing legislation? | **Agree**. The use of title by non-registered people carries the same risks across all professions as, by definition, they are not registered or qualified. We agree that all regulators should have the same offences in relation to protection of |

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| | | title and registration. This provides greater clarity for the public and reduces the opportunity for individuals to deceive the public. |
| **31** | Do you agree or disagree that the protection of title offences should be intent offences<br><br>Or<br><br>Do you think some offences should be non-intent offences (these are offences where an intent to commit the offence does not have to be proven or demonstrated)?<br><br>Please give a reason for your answer. | Regulators should focus on the use of title when a person is not registered and are passing themselves off as a registered professional and/or carry out activities restricted to registered professionals only. However, while the question of intent may well be fundamental in many cases, we should not be quick to restrict its applicability in ways that might limit our ability to take action in other, perhaps unanticipated, situations. These might include instances where specific intent cannot be proved, but the protection of title issue appears to be one of recklessness, or wilful disregard. Also, having intent and non-intent offences, the criminal penalties will better reflect the nature and scope of the intent. |
| **32** | Do you agree or disagree with our proposal that regulators should be able to appoint a deputy registrar and/or assistant registrar, where this power does not already exist? Please give a reason for your answer. | **We are neutral on this issue**. We already have provision for the appointment of a Deputy Registrar in article 18 of the Order. We are not currently using it. |
| **33** | Do you agree or disagree with our proposal that regulators should be able to set out their registration processes in rules and guidance? Please give a reason for your answer. | **Agree.** This provides the appropriate flexibility for regulators to set out their registration processes given the specific requirements that may exist in different regulated professions and to amend or update them swiftly should the need arise. |
| **34** | Should all registrars be given a discretion to turn down an applicant for registration or should applicants be only turned down because they have failed to meet the new criteria for registration? Please give a reason for your answer. | We believe the better course of action is for applicants to be turned down only where they have failed to meet criteria for registration. This provides greater transparency and ensures that decision-making is as objective as possible. Regulators should ensure that appropriate account is taken of examples such |

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| | | as an extended break in practice and incorporated in the criteria where necessary. |
| **35** | Do you agree or disagree that the GMC's provisions relating to the licence to practise should be removed from primary legislation and that any requirements to hold a licence to practise and the procedure for granting or refusing a licence to practise should instead be set out in rules and guidance? Please give a reason for your answer. | We do not have a view on this particular question. |
| **36** | Do you agree or disagree that in specific circumstances regulators should be able to suspend registrants from their registers rather than remove them? Please give a reason for your answer. | **Agree, but would like further information.** While we are not opposed to a power to suspend registrants rather than removing them, we are unclear about the particular benefits of this and the reasons why this is being proposed. We note that the examples cited such as failure to pay fees or failure to maintain contact details are also reasons for removal from the register as set out in paragraph 208. This creates the potential for regulators to adopt different approaches to the same failure which may create confusion for the public and scope for challenge from those who are suspended or removed. Therefore, we would welcome additional information on the policy reasons underpinning this proposal and how it is envisaged the new provision(s) would work in practice. We would be happy to discuss further. |
| **37** | Do you agree or disagree that the regulators should be able to set out their removal and readmittance processes to the register for administrative reasons in rules, rather than having these set out in primary legislation? Please give a reason for your answer. | **Agree**. Where possible we should avoid primary legislation becoming too heavy in detail. Therefore, this would be more of an operational matter for which the rules are more appropriate than primary legislation.<br><br>However, there would need to be some broad agreement for what the core processes should be. For example, what is the evidential test for the Registrar |

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| | | to make the initial decision to remove? Is there an initial review mechanism before an appeal right is triggered? How would a statutory committee determine an appeal and what test should it apply to allow an appeal. In the absence of an agreed framework or approach to any new provisions, there is a risk of a lack of uniformity of approach amongst the regulators as well as the risk of some having greater administrative/resource intensive processes. |
| **38** | Do you think any additional appealable decisions should be included within legislation? Please give a reason for your answer. | **No - disagree**. Regulators need to distinguish carefully between decisions which fundamentally impact on the professional's ability to register or renew their registration and other administrative decisions. The former can be and should be appealable decisions. The latter are better managed by the obligations on the regulator to act in accordance with well-established public law principles and if necessary, judicially reviewing the regulator. |
| **39** | Do you agree or disagree that regulators should set out their registration appeals procedures in rules or should these be set out in their governing legislation? Please give a reason for your answer. | **Agree**. Set out in rules, for the same reason as question 37 above on administrative removal. Once the appealable decisions are set out in legislation, the appeals procedures should be set out in rules with the same caveat about setting agreed frameworks for the Appeals Committee's powers, what tests they should apply and so on. Ultimately setting the procedures down in rules rather than in regulators' governing legislation allows for greater flexibility. |
| **40** | Do you agree or disagree with our proposal that the regulators should not have discretionary powers to establish student registers? Please give a reason for your answer. | **Agree.** There is no need for a discretionary power for regulators to establish student registers. As indicated in the consultation, students are not allowed to practise unsupervised and we do not see a reason in terms of public protection for holding and publishing a student register. |

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| **41** | Do you agree or disagree with our proposal that the regulators should not have discretionary powers to establish non-practising registers? Please give a reason for your answer. | **Agree.** Regulators should not have a discretionary power to establish non-practising registers. We do not see that such a register provides any additional public assurance and may create unnecessary confusion for the public. |
| **42** | Do you agree or disagree that the prescriptive detail on international registration requirements should be removed from legislation? Please give a reason for your answer. | **Agree.** The prescriptive detail on international registration requirements should be removed from legislation to ensure that each regulator has the necessary flexibility to adopt an appropriate and proportionate approach. |
| **43** | Do you agree or disagree with our proposal that regulators should be given powers to operate a three-step fitness to practise process, covering:<br>• 1: initial assessment<br>• 2: Case Examiner stage<br>• 3: fitness to practise panel stage?<br>Please give a reason for your answer. | **Agree**. It is important that there is consistency and uniformity in approach across all healthcare regulators and we particularly welcome the introduction of Case Examiners. The Case Examiner stage provides greater flexibility in statutory decision-maker resources, as compared to the overly procedural Investigating Committee. However, the term 'three-step' implies that each step will be followed when in reality a significant number will be concluded early in the process. The term three 'part' approach may be more appropriate.<br><br>With regards to terminology we would suggest 'assessment and investigation', rather than just 'initial assessment'. This better reflects the breadth of activity within this part and it avoids the appearance that concerns will go straight to Case Examiners simply if they meet some initial assessment type criteria. |
| **44** | Do you agree or disagree that:<br>• All regulators should be provided with two grounds for action – lack of competence, and misconduct?<br>• Lack of competence and misconduct are the most appropriate terminology for these grounds for action?<br>• Any separate grounds for action relating to health and English language should be removed from the | **Agree in part**. We agree with the reduction in the number of grounds for action. This simplifies the approach and removes those grounds that regulators currently have but rarely, if ever, use. We do, however, have some concerns with the terminology used in this proposal and how health concerns may be managed going forward. |

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| | legislation, and concerns of this kind investigated under the ground of lack of competence?<br>• This proposal provides sufficient scope for regulators to investigate concerns about registrants and ensure public protection?<br>Please give a reason for your answers. | The gateways to fitness to practise proceedings are important. We understand and accept the rationale for health not being a standalone ground for impairment. We want to manage health concerns differently and agree that the mere fact of a health condition should never on its own be grounds for regulatory action. The health issue itself isn't the risk, it's the extent to which the professional is managing it. What is important is how regulators establish the threshold for when action is required on a health concern. Therefore, removing health as a separate gateway could influence regulators and encourage a cultural shift.<br><br>We note that the proposals have a health component attached to lack of competence. We would argue that, although it should not be a standalone ground for action, health is also frequently a significant component in misconduct cases and should be applicable to that ground for action as well as competence. One way of doing this is to have only two gateways and where the health is a material or significant factor, this can be incorporated into the evidence and weighed accordingly.<br><br>Furthermore, a professional's poor health should not be termed 'lack of competence'. It has negative connotations and is contrary to the more person-centred approach being introduced across healthcare regulation. It is also something of a binary decision, either you are competent or not. Most recently SWE used lack of competence and capability to define this ground referral. This can be more succinctly referred to as deficient performance, a preferable alternative to 'lack of competence'. Or, although somewhat cumbersome as an alternative, 'the inability to practise safely'. This would be sufficient in scope to capture performance and health and misconduct would also capture health should it be a significant component of the concern. |
| **45** | Do you agree or disagree that:<br>• all measures (warnings, conditions, suspension orders | **Agree**. All measures ought to be available to both Case Examiners and FtP panels. This aligns with the move to a less adversarial model in fitness to |

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| | and removal orders) should be made available to both Case Examiners and Fitness to Practise panels; and<br>• automatic removal orders should be made available to a regulator following conviction for a listed offence? Please give a reason for your answers. | practise and should bring benefits for both the regulator, professionals and those that raise concerns.<br><br>We **agree** that automatic removal orders should be made available following a conviction for a listed offence. |
| **46** | Do you agree or disagree with the proposed powers for reviewing measures? Please give a reason for your answer. | **Agree**. It is important that measures are always consistent with the principle of proportionality, and this will include the actual restrictions but also the length and duration of the restrictions. As measures have the potential to be experienced as punitive, even if not intended to be so, it is important that measures can be reviewed at any point before their expiry. This would ensure that if a point is reached where the measure is no longer necessary or in the public interest, the registrant can be allowed back to unrestricted practice. |
| **47** | Do you agree or disagree with our proposal on notification provisions, including the duty to keep the person(s) who raised the concern informed at key points during the fitness to practise process? Please give a reason for your answer. | **Agree**. Notifying those that raised the concern on a regular basis is an important part of being person-centred and the very minimum that those investigating concerns should aim to achieve. |
| **48** | Do you agree or disagree with our proposal that regulators should have discretion to decide whether to investigate, and if so, how best to investigate a fitness to practise concern? Please give a reason for your answer. | **Agree**. Each regulator should consider the impact of the concern on the profession which they regulate and this may differ from profession to profession. Therefore, each regulator should be able to set their own threshold criteria. Additionally, each regulator is funded very differently and therefore modes of investigation will naturally differ to ensure value for money. |
| **49** | Do you agree or disagree that the current restrictions on regulators being able to consider concerns more than five years after they came to light should be removed? Please give a reason for your answer. | **Agree**. The rule should be removed. Its removal provides a broader discretion for investigating historical matters that are serious or exceptional and that may not come to light for some time. The retention of the rule is not compatible with outcomes from recently published independent reports. |

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| **50** | Do you think that regulators should be provided with a separate power to address non-compliance, or should non-compliance be managed using existing powers such as “adverse inferences”? Please give a reason for your answer. | Lack of co-operation or non-compliance by pharmacy professionals is not a problem the GPhC often encounters and when it does occur it is often caused by ill-health or anxiety of being investigated by the regulator. Therefore, managing non-compliance through adverse inferences and current approaches remains appropriate and proportionate. This should be enough to secure public protection with a power being contrary to a less adversarial approach in fitness to practise and possibly reinforcing a more punitive perception.<br><br>The introduction of a separate power would not be used very often, could be viewed as heavy handed and is unlikely to encourage a positive relationship with the professionals we seek to regulate.<br><br>One area where we do encounter issues, particularly as a systems regulator, is the provision of information by professionals or other third parties who hold it. This can be a barrier to securing all the relevant information we need and our ability to discharge our overarching objective. Therefore, any power should distinguish between general non-compliance which can be managed through established process and the narrower non-compliance where information is retained or withheld. |
| **51** | Do you agree or disagree with our proposed approach for onward referral of a case at the end of the initial assessment stage? Please give a reason for your answer. | **Agree**. Although, as referenced above, we should speak of assessment and investigation, as opposed to 'initial assessment'. Onward referral, with the exception of Interim Orders, should be at the point at which a reasonable and proportionate investigation has been completed, not simply once initial criteria have been met. |
| **52** | Do you agree or disagree with our proposal that regulators should be given a new power to automatically remove a registrant from the Register, if | **Agree**. A number of fitness to practise concerns will inevitably attract a removal and, where possible, we should avoid a lengthy and costly process. This proposal is an efficient mechanism for managing the most serious concerns. |

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| | they have been convicted of a listed offence, in line with the powers set out in the Social Workers Regulations? Please give a reason for your answer. | This should however be subject to a right of appeal, e.g. where a conviction is subsequently overturned on the basis of compelling evidence of innocence. |
| **53** | Do you agree or disagree with our proposals that Case Examiners should:<br>• have the full suite of measures available to them, including removal from the register?<br>• make final decisions on impairment if they have sufficient written evidence and the registrant has had the opportunity to make representations?<br>• be able to conclude such a case through an accepted outcome, where the registrant must accept both the finding of impairment and the proposed measure?<br>• be able to impose a decision if a registrant does not respond to an accepted outcomes proposal within 28 days?<br>Please give a reason for your answers. | **Agree**. We agree to all elements of this proposal. There may be many cases where the key FtP questions are not, in fact, in dispute, and therefore do not present a need for issues to be contested at a hearing. Enabling Case Examiners the full range of options enables such cases to be dealt with efficiently, and avoids undue distress to the parties involved.<br><br>There are of course some associated risks with the proposals around decisions being made in a non-transparent way. The decisions made by Case Examiners need to be accompanied by clear publication requirements to ensure transparency of the process and avoid any impact on public confidence in fitness to practise.<br><br>Regulators also need to ensure parties are supported to be able to participate in the process, and understand it, so they're able to provide clear and full evidence as witnesses or as professionals. This is particularly important for unrepresented professionals to ensure they can make an informed decision about whether or not to accept a proposed outcome. |
| **54** | Do you agree or disagree with our proposed powers for Interim Measures, set out above? Please give a reason for your answer. | **Agree**. However, the test for imposing interim measures is not clear from the consultation. We would caution against the removal of the public interest limb of any agreed test. |
| **55** | Do you agree or disagree that regulators should be able to determine in rules the details of how the Fitness to | **Agree**. This aligns with the current approach and enables the primary legislation to include the main governing legislation with the more detailed aspects set out in Rules. |

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| | Practise panel stage operates? Please give a reason for your answer. | |
| **56** | Do you agree or disagree that a registrant should have a right of appeal against a decision by a Case Examiner, Fitness to Practise panel or Interim Measures panel? Please give a reason for your answer. | **Agree**. Provisions to challenge decisions are required by natural fairness, particularly in instances of decisions which may be materially flawed or if new evidence comes to light. The absence of such an appeal mechanism could lead to a number of judicial reviews. The right of appeal of Case Examiners outcomes are particularly important as they will be able to access the full range of measures and the testimonial of the professional may not be as powerful as in person hearings. |
| **57** | Should this be a right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland? Please give a reason for your answer. | **Agree**. The proposal appears to be the most logical approach. Ideally, there would be a referral to a central appeals panel that covers all healthcare regulators which would achieve parity across all healthcare regulators. Only then if this stage failed should the matter progress to the High Court. |
| **58** | Do you agree or disagree that regulators should be able to set out in Rules their own restoration to the register processes in relation to fitness to practise cases? Please give a reason for your answer. | **Agree**. This aligns with the current approach and enables the primary legislation to include the main governing legislation with the more detailed aspects set out in Rules. |
| **59** | Do you agree or disagree that a registrant should have a further onward right of appeal against a decision not to permit restoration to the register? Please give a reason for your answer. | **Agree**. This aligns with current processes and the principle of fairness that where a regulator makes a decision, the professional has a clear avenue for appeal. |
| **60** | Should this be a right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or | **Agree**. The consequences of a refused restoration decision are no different to the decision which led to the removal of the person. The guidance from the higher courts is consistent in making clear that at the heart of a restoration |

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| | the High Court in Northern Ireland? Please give a reason for your answer. | decision is an assessment of fitness to practise. We feel that a High Court appeal is the most appropriate forum for reviewing the refusal to restore. |
| **61** | Do you agree or disagree that the proposed Registrar Review power provides sufficient oversight of decisions made by Case Examiners (including accepted outcome decisions) to protect the public? Please provide any reasons for your answer. | **Agree**. This is an important aspect of the proposals. Transparency and the perception of decision making for the public are important issues. There is a challenge for regulators here when cases are concluded by accepted outcome and Case Examiners. One means of addressing it and maintaining confidence is an appropriate and accessible appeal mechanism. This review power could be an invaluable part of the statutory framework to safeguard and ensure oversight of what will be much earlier case conclusions. How it works in practice, including the roles that act as delegates and the roles undertaking the reviews will be important to ensure separation and transparency.<br><br>With the proposed move to agreed outcomes there needs to be a clear appeal mechanism that is accessible to everyone from the PSA to the person that raised the concern. This mechanism is equitable across all interested parties and it is also flexible in that the Registrar has a mechanism with which to initiate or reject a review. |
| **62** | Under our proposals, the PSA will not have a right to refer decisions made by Case Examiners (including accepted outcome decisions) to court, but they will have the right to request a registrar review as detailed above.<br>Do you agree or disagree with this proposed mechanism? Please provide any reasons for your answer. | **Agree**. The Registrar Review can be a very effective measure for all parties involved including the PSA as it can bring swift outcomes that may otherwise have gone through lengthy and expensive court proceedings. |
| **63** | Do you have any further comments on our proposed model for fitness to practise? | The proposals provide clear benefits for regulators and professionals through a more fair and efficient process. The legislation needs to ensure there are |

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| | | sufficient protections for those raising concerns and that there aren't any unintended outcomes that may dissuade anyone from raising a concern. |
| **Questions 64 – 69 relate to the regulation of physician associates and anaesthesia associates and are not relevant to the GPhC** | | |
| **64** | Do you agree or disagree with the proposed approach to the regulation of PAs and AAs? Please give a reason for your answer | n/a |
| **65** | In relation to PAs and AAs, do you agree or disagree that the GMC should be given a power to approve high level curricula and set and administer exams? Please give a reason for your answer. | n/a |
| **66** | Do you agree or disagree with the transitional arrangements for PAs and AAs set out above? Please give a reason for your answer | n/a |
| **67** | Do you agree or disagree that PAs and AAs should be required to demonstrate that they remain fit to practise to maintain their registration? Please give a reason for your answer. | n/a |
| **68** | Do you agree or disagree with the benefits identified in the table above? Please set out why you've selected your answer and any alternative | n/a |

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| | benefits you consider to be relevant and any evidence to support your views | |
| **69** | Do you agree or disagree with the costs identified in the table above? Please set out why you've chosen your answer and any alternative impacts you consider to be relevant and any evidence to support your views. | n/a |
| **70** | Do you think any of the proposals in this consultation could impact (positively or negatively) on any persons with protected characteristics covered by the general equality duty that is set out in the Equality Act 2010, or by Section 75 of the Northern Ireland Act 1998? | We have highlighted some specific points in relation to protected characteristics in response to certain questions above. However, as we said at the outset of our response, we have also encouraged patients and the public and the pharmacy professionals and pharmacy owners we regulate to respond. The voices of patients and health professionals need to be at the heart of this consultation, to help make sure that health professional regulation is fit for the future. This should also help ensure that equality impacts are highlighted, understood and addressed. |