ROYAL PHARMACEUTICAL SOCIETY

66 East Smithfield
London, E1W 1AW

T: 020 7572 2737
E: support@rpharms.com
W: rpharms.com

Regulating healthcare professionals, protecting the public Consultation questions

Submitted by Jonathan Lloyd Jones Policy and Engagement Lead RPS Wales on the 15th June 2021. Jonathan.lloydjones@rpharms.com

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain. The RPS leads and supports the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession's policies and views to a range of external stakeholders in several different forums.

1. Do you agree or disagree that regulators should be under a duty to co-operate with the organisations set out above? Please give a reason for your answer.

Yes, we agree. This provides transparency and ensures public safety. It is also part of the Cumberledge recommendations which we fully endorse.

2. Do you agree or disagree that regulators should have an objective to be transparent when carrying out their functions and these related duties? Please give a reason for your answer.

Yes, we agree. Greater transparency on the functions the regulator undertakes and around how it does so will help to maintain public and professional confidence in the regulation of healthcare professionals.

For example, In our January 2021 response to the GPhC consultation on their fitness to practice strategy we called for the General pharmaceutical Council (GPhC) to be more transparent by publishing more data on how it processes fitness to practice concerns. Publishing additional metrics on the protected characteristics of the cases it is dealing with at every stage, including those triaged and concluded before reaching the Investigating Committee, would help to identify potential barriers.

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? Please give a reason for your answer

Yes, we agree. However, once the impact assessment has been undertaken, a report should be published by the regulator and any changes consulted on within a specified time frame. An established time frame as to when this will apply, in terms of regulators setting their own rules and standards, needs to be made explicit. Having the ability as a regulator to set out how they operate, and what their own governance structure should be, enables flexibility in times of emergency and this has been demonstrated with some of the changes enabled during the coronavirus-19 pandemic e.g., revalidation. There is a case for assessing the impact of not making a change, we believe that these powers could have been used more effective to support students completing the pre reg exam during the pandemic.

4. Do you agree or disagree with the proposal for the constitution on appointment arrangements to the Board of the regulators? Please give a reason for your answer.

Board members should be appointed on merit, but we do not fully support this proposal.

It is important that at least one board member, wholly or mainly, works or lives in each of the countries of the UK in which the regulator operates. However, we believe that having current or former registrants is important to ensure the wider context is considered. Without this experience it may be difficult to appreciate and fully understand the intended and unintended consequences of strategic directions.

We are concerned that the requirement to appoint a professional will no longer be in place. This would undermine confidence in, and support for, regulation among registrants. Also, registrants may not feel happy paying their registration fees without being properly represented.

Taking account of context is going to become increasingly important with pharmacists working in more complex roles in multidisciplinary teams (MDT). The expectations placed on pharmacists by other members of the MDT may lead to individuals being put under pressure to complete tasks that they may not feel confident doing.

The Cumberledge report found that: *'The healthcare system is not good enough at spotting trends in practice and outcomes that give rise to safety concerns. Listening to patients is pivotal to that'.* It could be argued that the removal of a lay person could have a negative effect on listening to patient voices.

As well as representation from each country it is also important that culture is considered as part of the wider context. In order to do this, board members must be culturally competent. There is an opportunity for the regulators to work with wider stakeholders such as, for

pharmacy professionals, the RPS ABCD group, UKBPA, The Black pharmacist collective, the PDA networks and others to ensure this competence.

5. Do you agree or disagree that regulators should be able to set their own fees in rules without Privy Council approval? Please give a reason for your answer

Yes, we agree. We recommend that each regulator provides an annual report so comparisons can be made between regulators as to how they set their fees.

We recently responded to a GPhC consultation about introducing multi -year fees cycles . We agree with the principle of introducing multi-year fees cycles but more information is required about how these fees will be projected.

6. Do you agree or disagree that regulators should be able to set a longer-term approach to fees? Please give a reason for your answer.

Setting fees for all registrant groups over a longer period would offer certainty and better forward financial planning for the regulator, professionals and contractors. However, the regulator would need to ensure that any proposed fee increases reflect a similar increase in income.

More information is needed on how and who would be responsible for projected costs of regulation for professionals over these fixed periods. If projected costs were inaccurate and 'exceptional' fees were charged on a regular basis during a multi-year cycle the benefits of better forward planning is lost.

We recently responded to a GPhC consultation about introducing multi -year fees cycles .

7. Do you agree or disagree that regulators should be able to establish their own committees rather than this being set out in legislation? Please give a reason for your answer.

Yes, we agree. Different professions will potentially require different committees. However, there may be some opportunities to work across the professions in some instances. For example, across all healthcare professional regulators, the rates at which registrants are referred into the Fitness to Practice processes are higher for Black Asian and Minority Ethnic registrants than they are for white registrants. We would encourage regulators to tackle issues such as this in a collaborative way.

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? Please give a reason for your answers.

Yes, we agree. It seems reasonable for these costs to be paid by the institution requiring the assessment rather than being paid for by registrants. A caveat to this is that this process should ensure a reasonable fee structure which is made publicly available, and that it should not lead to a significant decrease in the number of courses available for registrants if the courses meet the required standards.

The role of pharmacy teams is evolving quickly and there is a great need for comprehensive and accessible post graduate education. The GPhC are currently only involved in prescribing courses at a post graduate level. If this were to change it would be important that any charges can be absorbed by providers and charges do not become a barrier to offering this vital training for pharmacy teams.

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? Please give a reason for your answer.

We do not fully agree with this. In terms of holding a register, this is mainly an administrative task, although complex, and could be done centrally for all healthcare professionals, although different criteria will apply for the different professions.

In terms of the other three functions of determining standards of education and training for registration; providing advice about standards of conduct and performance; and administering procedures relating to misconduct and fitness to practise, we would be concerned if these were undertaken by a regulator other than the GPhC for the pharmacy profession as other regulators would not have the thorough understanding of the pharmacy profession that the GPhC have.

10. Do you agree or disagree that regulators should be able to require data from and share data with those groups listed above? Please give a reason for your answer.

Yes, we agree. However, it would have to be made explicitly clear what information could be requested, by who, and for what purpose. If it would be purely for research that should be

specified. It is vital personal information is kept safely and used appropriately. Sharing of information is important for ensuring the safety officers etc have the information they need to carry out their role.

11. Do you agree or disagree that regulators should produce an annual report to the Parliament of each UK country in which it operates? Please give a reason for your answer.

This would depend on the amount of additional workload that this entails and to what purpose the annual report would be used by the Parliament of each country. What would they do with the data and why would they need it? If it is a large additional workload the cost of doing it may be passed on to registrants with no determined useful outcome. However, we recognise the importance of this report to identify potential trends and patterns etc. and the fact that a report of trends could be shared with other such as patient safety officers.

12. Do you agree or disagree that the Privy Council's default powers should apply to the GDC and GPhC? Please give a reason for your answer.

Yes, we agree. All regulators should be equal so either the powers should apply to all or to none. This will allow for more proportionate regulation.

13. Do you agree or disagree that all regulators should have the power to set:

- **standards for the outcomes of education and training which leads to registration or annotation of the register for individual learners;**
- **standards for providers who deliver courses or programmes of training which lead to registration;**
- **standards for specific courses or programmes of training which lead to registration;**
- **additional standards for providers who deliver post-registration courses of programmes of training which lead to annotation of the register; and**
- **additional standards for specific courses or programmes of training which lead to annotation of the register?**

Please give a reason for your answer.

Our views on this are significantly affected by what is likely to be annotated in future. The requirement for annotation should be proportionate and with a clear need. We feel that a register with many annotations would potentially be more confusing for the public.

We are mindful that the role of the regulator is to assure patient safety. The approval of courses focuses only on a minimum standard and does not differentiate best practice.

There are a range of approaches to recognising that outcomes had been achieved which could be adopted i.e., accreditation of training courses or providers vs setting an end point assessment vs both. Within pharmacy we have degree courses that have met the minimum standard but at the same time their graduates consistently have a very low pass rate for the registration assessment. This suggests that accreditation of courses in isolation is not achieving the desired outcome. We would like to see regulation address the current issues in the initial education and training standards.

In post registration practice, pharmacists may follow many different paths to support their development. The consultation does not define "training courses". We are mindful that pharmacists access many different sources of high-quality continuing professional development (CPD). We are concerned that the approval of training courses will drive people down one path, thereby limiting choice and flexibility. Instead, we strongly support a focus on an end point so that registrants can determine their own approach to meeting the standards such as, pick and choose short courses or modules to suit, or mix academic programmes with private provision or collate a portfolio of vocational experience. We are also concerned that if all training providers need to be accredited by a regulator, the costs of this are likely to affect the market of available provision.

We would also like to see a focus on clinical and educational supervision whereby there is a focus on learning environments and creating an infrastructure in which registrants learn while practicing.

We note that there is international experience in course accreditation. In the USA the Board of Pharmacy Specialties accredits a range of programmes that meet the requirements of the international accreditation service.

Much as we welcome a role for the GPhC in enhanced post registration regulation in the future, we are concerned about their capacity to extend into this area in the short term and would not want to see any dilution of focus on the current reform in the initial education and training period.

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.

Yes, we agree. The powers should be the same across all regulators. The process and criteria for approval need to be very clearly laid out so Education and Training providers know what they must do to gain approval.

15. Do you agree that all regulators should have the power to issue warnings and impose conditions? Please give a reason for your answer.

Yes, we agree. The powers should be the same across all regulators. We support the issuing of warnings, especially when there has been consistent longitudinally demonstrated poor performance. We appreciate that the withdrawal of approval is often multifactorial and challenging. We can therefore see a clear role for warnings to help gaps to be addressed.

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.

Yes, we agree. Education and training providers must have this right so that all information is considered

17. Do you agree that:

- **education and training providers should have the right to appeal approval decisions;**
- **that this appeal right should not apply when conditions are attached to an approval;**
- **that regulators should be required to set out the grounds for appeals and appeals processes in rules?**

Please provide a reason for your answer.

Yes, we agree. The right to appeal should exist and that appealing on conditions attached to approval is not necessary provided they can the appeal the refusal if conditions are not met. In terms of setting out grounds for appeal, we have some concerns in this area in terms of how robust the process for appeal will be. It would depend on what this means as we believe that any refusal should be allowed at least one appeal. If the regulator sets out specific grounds for appeal would this mean that some refusals would not allowed to be challenged? Any grounds for appeal should be developed in consultation.

18. Do you agree or disagree that regulators should retain all existing approval and standard setting powers? Please provide a reason for your answer.

Whilst we would not want to remove powers from regulators there should be consistency across all regulators so these powers should potentially be made available to all regulators, especially in terms of recognition of curricula or education and training that leads to registration and/or annotation.

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.

Yes, we agree. This may be particularly helpful in times of national emergencies, such as the Covid-19 pandemic. The assessment to join the register should include an assessment of English language competency.

Consideration should also be given as to how the exams can potentially be delegated.

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.

No comment

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.

No, we do not agree. We feel that the focus of the regulator should be on the end point assessment to ensure there is a consistent standard i.e., irrespective of the route to achieve the learning outcomes. Within post registration training, registrants seek flexibility in their means to achieve the outcomes. This could be via modules from different training providers or experiential learning. We are in favor of the regulator quality assuring assessments, akin to the GMC, to ensure they are aligned to best educational practice. We believe that the regulator setting and assessing all of post registration practice would not have a clear patient benefit and would be very expensive.

We believe that a focus on ensuring a consistent outcome from high stakes assessments is preferable to accreditation of programmes. This supports a breadth of training providers to be innovative and flexible to workforce needs whilst maintaining a focus on outcomes.
We note that there is no intention to extend the abilities of regulators to approve curricula in the same way that the GMC does. We can see how the delegation of curriculum setting and managing assessments to professional leadership bodies/ royal colleges could be beneficial to ensure there is a level of detail nuanced to the profession and appropriate assessment

methodologies such as programmatic assessment as opposed to traditional examinations. A number of professional leadership bodies and Royal Colleges, including the RPS currently credential registrants to practice at different levels post registration. This focus on end point assessment has a clean divide between training provision and formal assessment of outcomes. We would like to see a stronger relationship between these bodies e.g., delegated authority from the respective regulator rather than different routes to recognition.

The current arrangement of having multiple regulators, each with their own standards, accrediting independent prescribing courses is burdensome and we query the value of that given that those completing the course require the same knowledge and skills. Some regulators have a focus on input such as numeracy assessment at entry vs outcomes, so there would be considerable work to do to align the approach across regulators. A singular agreed standards framework would support this. For example, both the NMC and HCPC have adopted the RPS Prescribing Competency Framework as the basis of their Prescribing Standards.

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.

No comment

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.

Yes, we agree. We support that each regulator should be able to set their own rules for revalidation. It is important that this sits alongside annotation as a means of ensuring that this is current in practice.

We recognise that the risks may vary across professions and the revalidation requirements should be sensitive to this. We believe that pharmacy has a good safety record at present but recognise that the risks may change as roles evolve.

Revalidation needs to reflect the breadth of practice in the profession as not everyone is in patient facing roles. We welcome a requirement for revalidation to reflect your level of practice, not just at the baseline entry point to the register.

We would also recommend that there are opportunities at all levels, undergraduate and post registration, for healthcare professionals to learn together. This breaks down boundaries between professions and helps them to understand each other's roles.

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.

Yes, we agree. However, again there should be analysis of the different approaches to determine what works best. Regulators must work together to ensure consistency of the rules they establish in terms of registration.

25. Do you agree or disagree that all regulators should be required to publish the following information about their registrants:

- **Name**
- **Profession**
- **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)**
- **Registration number or personal identification number (PIN)**
- **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 a regulator)**
- **Registration history**

Please provide a reason for your answer.

Yes, we agree. In terms of qualifications this should contain any annotations of advanced practice/additional qualifications/specialties, etc. Consideration also needs to be given as to whether an annotation is always a qualification and whether a qualification is always related to a credit bearing academic programme.

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.

Yes, we agree. It must be made clear what data they are asking for and why this is needed in order to carry out their statutory duties. If this information is not already held by the regulator than there should be a consultation on what additional specific information the regulator wants to collect and for what purpose and why this may be of benefit.

27. Should they be given a discretionary power allowing them to publish specific data about their registrants? Please give a reason for your answer.

Yes, we agree but only if it is made clear as to what the benefit of publishing the specific data will be and how publishing such data will improve public safety

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.

Yes, we agree. But it must be made clear which annotations will be made available on the register and why, in terms of public safety. Also, any charges that will be made to registrants to annotate the register should be made clear from the outset and not be disproportionate to other fees charged for registration. Regulation must be proportionate to the profession and area of practice that is being regulated.

29. Do you agree or disagree that all of the regulators should be given a permanent emergency registration power as set out above? Please give a reason for your answer.

Yes, we agree. It is useful to be able to mobilize the retired workforce in a timely manner in emergency circumstances.

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?

Yes, we agree.

31. Do you agree or disagree that the protection of title offences should be intent offences or 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)? Please give a reason for your answer.

For an individual's use of a protected title, such as pharmacist, these should be intent offences but for protected titles of premises, such as pharmacies, these should include non-intent offences.

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.

Yes, we agree. This ensures efficient and effective operation of the regulatory duties should the registrar be unavailable for whatever reason and it can promote continuity for professions.

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.

Yes, we agree. The process for application needs to be made clear to those wishing to apply to be on the register

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 have concerns over how the registrar would justify the refusal. Also, how can the applicant take remedial action to meet the criteria if the refusal was made purely on a discretionary basis? It should be part of the regulator's role to have a transparent system where the criteria are clear and the applicant knows what to do to demonstrate they have kept up to date and if the regulator doesn't agree they could provide support to help them meet the criteria. So, we agree that applicants should be turned down if they fail to meet the new criteria for registration but are not in agreement that registrars be given a discretion to turn down an application for registration.

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.

No comment

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.

Yes, we agree. If the registrant then takes the necessary action the suspension can be lifted without them having to reapply to be on the register which could be costly.

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.

No, we don't agree. We believe it is vital that the processes are consistent across the professions and it would be difficult to get consensus if the regulators would need to agree them between themselves. However, we understand that the processes are easier to amend if set out in regulation rather than legislation.

38. Do you think any additional appealable decisions should be included within legislation? Please give a reason for your answer.

We cannot think of any additional appealable decisions, but we would ask why these set out in legislation rather than regulation.

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.

We agree that these should be set out in rules. However, any rules, and future changes to rules, must be consulted on. In terms of the registrant failing to pay any fee in accordance with the rules, this process should include a warning and an opportunity for the payment to be made before a registrant is removed for this reason.

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.

We do not agree. From a workforce planning perspective, it would be helpful if regulators hold a definitive list of the workforce pipeline. However, we are aware that additional registers have the potential to be confusing to the public.

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.

Yes, we agree. Only those who are competent to practice should be on the register. Having people on there who are not registered to practice is confusing 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.

Yes, we agree. The processes, however, needs to be clearly defined so everyone can understand what is required. A competency in English language must be a requirement

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:

- **1: initial assessment**
- **2: case examiner stage**
- **3: fitness to practise panel stage?**

Please give a reason for your answer.

Yes, we agree as this should lead to a quicker resolution of cases. When registrants are investigated, whether formally or informally, there are adverse implications for their careers, reputation and wellbeing. We heard of instances where this has led to mental breakdown and even the attempted suicide of individuals under investigation. With the RPS workforce wellbeing survey showing a profession under strain, we welcome the impact that these enquires may have in investigating the right concerns only and in a timelier fashion.

However, clarity needs to be given around the following issues:

- In terms of initial assessment who will assess the cases – and will they have a background in the profession they are assessing as well as an understanding of the particular role of the professional they are assessing?
- All case examiners need to understand the profession and the circumstances in which the individual is practicing
- The make-up of the panel needs to be clarified and it should be easier to find the information about who is on these panels
- We assume that where there is no impairment to practice the case is dismissed with no sanctions.

44. Do you agree or disagree that:

- **All regulators should be provided with two grounds for action – lack of competence, and misconduct?**
- **Lack of competence and misconduct are the most appropriate terminology for these grounds for action?**
- **Any separate grounds for action relating to health and English language should be removed from the legislation, and concerns of this kind investigated under the ground of lack of competence?**
- **This proposal provides sufficient scope for regulators to investigate concerns about registrants and ensure public protection?**

Please give a reason for your answers.

We have concerns about the proposed removal of health from the grounds for action and would like to see regulators keep the powers they have now to handle health concerns about a professional if there is a risk to the public.

The current arrangements generally allow regulators to deal with health cases appropriately and with compassion. By contrast, the proposal would potentially lead to health cases being treated as incompetence, which could be difficult for registrants. Powers need to be retained within regulation without the need for investigation as it is not a crime to be ill so there needs to be flexibility in powers around when an investigation is needed.

In addition, the removal of English language from the grounds could raise inequalities issues.

If someone has health concerns a more supportive route should be available than the fitness to practice route, but in some cases suspension from the register on those grounds would be necessary so it is vital that option is retained.

45. Do you agree or disagree that:

- **all measures (warnings, conditions, suspension orders and removal orders) should be made available to both Case Examiners and Fitness to Practise panels; and**
- **automatic removal orders should be made available to a regulator following conviction for a listed offence?**

Please give a reason for your answers.

Yes, we agree. But processes must be in place to deal with cases where an offence is repeated, or another offence carried out while a warning/suspension is already in place. And the investigations should take place in a timely manner.

46. Do you agree or disagree with the proposed powers for reviewing measures? Please give a reason for your answer.

Yes, we agree. If the registrant meets the measures set out before the expiry date, then it should be reviewed early and potentially the measures removed.

We have received positive feedback from our members about the GPhC knowledge hub supporting their practice during the pandemic. We support the aim of developing this hub to share case studies, insight, and shared learning in other areas such as Fitness to Practice and Inclusion and diversity. Sharing these examples and emerging concerns are likely encourage others to learn, improve, promote a culture of openness, and ultimately prevent future concerns.

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.

Yes, we agree. We welcome a more person-centered approach which, when applied, will offer greater support for everyone involved in fitness to practice cases. It is important that the notification process is monitored and audited to ensure that it benefits the person(s) who raised the concern.

Research commissioned by the PSA to explore with patients and the public their perspectives on future fitness to practice procedures found an expectation from some that there would be an online case management system which complainants would have access to. This tracking system would allow complainants to log on and see the progression of their case in real time. We understand that this is being looked at by the GPhC as 'Making key regulatory datasets available to the pharmacy sector 24/7 through a self-serve data portal' and is part of the GPhC strategic plan 2020-25. Participants also wanted telephone calls at key junctures in the process. We believe that these processes would be valuable for everyone involved in the fitness to practice case.

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.

Yes, we agree. Processes should be clearly set out and transparent so all know what is expected and where actions will be taken. Timeframes should also be made available. There should also be some guidance for regulators to ensure lay members are part of committee structures.

The timeliness of processing fitness to practise cases is a concern amongst our membership and these proposals have the potential to improve timeliness. Median timeframes are increasing in all three of the key stages of the fitness to practice process with median time from referral to a final Fitness to Practise Committee decision being 98.3 weeks in 2020. When registrants are investigated, whether formally or informally, there are adverse implications for their careers, reputation and wellbeing. We heard of instances where this has led to mental breakdown and even the attempted suicide of individuals under investigation. With the RPS workforce wellbeing survey showing a profession under strain, we welcome the impact that these enquires may have in investigating the right concerns only and in a timelier fashion.

It should be clear to registrants, employers, patients and service users when a concern needs to be referred to the regulator. It would be useful to have clear guidance on the extent to which (if at all) regulators wish to receive 'soft intelligence' which may of itself be minor, but if several others are seeing concerning patters and trends, could indicate a bigger problem that needs addressing.

We welcome the development of the Knowledge Hub by the GPhC to provide additional support for employers about referrals and actions taken to avoid the need for referral. This will be especially useful in the context of what constitutes professional vs unprofessional behaviour. Such issues often underpin employer referrals (and may not have an immediately obvious direct correlation to patient safety) and so the GPhC may opt not to progress. In such cases, a warning or advice intervention may help prevent a bigger issue further down the line. We welcome the development of a web-based tool to share learning and trends in concerns, and how these can be successfully resolved.

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.

Yes, we agree. The Cumberledge report has suggested this restriction should be removed and there should be no time limit due to the length of time it took to realise the dangers of mesh implants and side effects meaning that professionals who regularly dismissed patients concerns can no longer be held to account. Five years is an arbitrary time limit which does not benefit public protection. We are unsure, however, how likely is it that concerns would come to light after this period of time and how effective the investigation would be if you are relying on statements from individuals

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.

We agree that regulators should be provided with a separate power. Regulators should be able to address non-compliance to ensure confidence in their processes and the risk that only those who comply will be penalised.

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.

Yes, we agree with the approach to onward referral and the imposition of interim measures if necessary. With regards to the rules, these need to be clear and concise and there needs to be clarity under what circumstances grounds can be amended, we would suggest that this would have to be in exceptional circumstances.

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 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.

Yes, we agree. If a registrant was convicted of such an offense, we wouldn't want them to be practising as pharmacists.

53. Do you agree or disagree with our proposals that case examiners should:

- **have the full suite of measures available to them, including removal from the register?**
- **make final decisions on impairment if they have sufficient written evidence and the registrant has had the opportunity to make representations?**
- **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?**
- **be able to impose a decision if a registrant does not respond to an accepted outcomes proposal within 28 days?**

Please give a reason for your answers.

We agree that these proposals could speed up the process. However, the case examiners will need to understand the practice of pharmacy in the area of practice that the registrant works in to be able to fully assess the case and the context.

Under these proposals, accepted outcomes would be made by agreement between the regulator and the registrant without a public hearing, although decisions would be published. In terms of making an appeal against the accepted outcome, this would rely on patients requesting a review of an accepted outcome. This puts the burden of public protection on the shoulders of the people that regulation is meant to serve. Handing responsibility for these review decisions over to the regulators themselves would remove the last remaining layer of independence from the process, which may not be in the best interests of public protection.

In addition, there are also potentially some diversity issues if decisions are being made by one person. The Independent review of gross negligence manslaughter and culpable homicide recommendation that all relevant healthcare sector organisations should have published measures and aspirations for diverse workforce representation in key roles and at all levels involved in decision making would not be followed in these circumstances. A review by one person does not fall in line with these principles.

54. Do you agree or disagree with our proposed powers for Interim Measures, set out above? Please give a reason for your answer.

Yes, we agree in principle. In practice timescales would need to be specified. An interim measure would be put in place prior to a hearing or finding if it was felt the person posed an immediate risk, in which case the interim measures panel would need to meet with some urgency if the measures were not accepted. How likely would this be able to happen in practice?

55. Do you agree or disagree that regulators should be able to determine in rules the details of how the Fitness to Practise panel stage operates? Please give a reason for your answer.

Yes, we agree. This must be consistent across professions. Also, if the regulator can compel witnesses, then in an ideal world they should provide support for them to do so, as being part of the process may have an impact on them.

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.

Yes, we agree. If the initial decision can be hidden from an alternative case examiner, then they could undertake the appeal assessment Alternatively they could be referred to a body independent of the regulator to give the registrants confidence in the process.

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.

No comment

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.

Yes, we agree. There should be some consistency across professions around time frames and processes.

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.

Yes, we agree. The registrant may have further evidence that supports their restoration to the register.

60. 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.

No comment

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.

Yes, we agree. It is not expected that these cases would warrant a trip to court to challenge them as the most serious offences should already have been referred to Fitness to Practice panels. It is also important that there is a check on the work of case examiners to maintain public confidence in the processes. However, people could learn from the less euripus cases were a professional had made changes/accepted liability resulting in lesser sanctions, so learning needs to be shared.

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. Do you agree or disagree with this proposed mechanism? Please provide any reasons for your answer.

We question whether the Authority's proposal for section 29 powers to appeal accepted outcomes would run in parallel with or instead of the registrar review mechanism?
In addition, in relation to the role of the Authority's performance reviews in identifying issues with the regulators we are concerned that potential changes to the performance review process (which were recently consulted on) happening alongside the proposed reforms could lead to diminished oversight of the regulators and emerging issues being missed; for example, if performance reviews occurred less than annually. In this scenario, a registrant might accept an outcome because they do not know about problems behind the scenes.

63. Do you have any further comments on our proposed model for fitness to practice?

Under these proposals, the final say about whether an outcome should be changed because it is unsafe would sit with the regulator, rather than with the courts as it does now. This new model would make the regulator not only investigator, prosecutor, and judge, but also appeal court. This concentration of powers could mean that mistakes are not spotted or challenged. This approach to fitness to practise would seem to put the regulators' flexibility ahead of what is needed for public protection.

We would like to see the PSA be able to apply the public protection safety net they currently have to all final fitness to practise decisions, and not just those that are made by panels.

Some independent checks and balances need to be maintained to ensure that the way regulation works is safe and consistent across professions where it needs to be.

64. Do you agree or disagree with the proposed approach to the regulation of PAs and AAs? Please give a reason for your answer.

No comment

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.

No comment

66. Do you agree or disagree with the transitional arrangements for PAs and AAs set out above? Please give a reason for your answer

No comment

67. Do you agree or disagree that PAs and AAs should be required to demonstrate that they remain fit to practice to maintain their registration? Please give a reason for your answer.

No comment

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 benefits you consider to be relevant and any evidence to support your views.

No comment

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.

No comment

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?

- **Yes – positively**
- **Yes - negatively**
- No
- Don’t know

Please provide further information to support your answer.

There is a potential for these proposals to positively and negatively impact on people with protected characteristics.

We have concerns about the potential consequences of the proposed removal of health and the English language from the grounds to raise concern.