ROYAL PHARMACEUTICAL SOCIETY

Regulating anaesthesia associates and physician associates

Royal Pharmaceutical Society response

1. **Do you have any comments relating to 'part 1: general' of the consultation?**

   We agree with the timetable proposed under this section to enable sufficient time for GMC to regulate both AAs and PAs and to allow for a transition period.

   Whilst we agree there should be consistency across all regulators in the reasons as to why a fitness to practice case may be initiated, we do have concerns over the references used to imply impaired fitness to practice. We do not agree that the impairments should be limited to the inability to provide care to a sufficient standard or misconduct.

   We have concerns about the removal of adverse 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 an inability to provide care to a sufficient standard, 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 lack of knowledge 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.

2. **Do you agree or disagree that the powers outlined in 'part 2: standards and approvals' are sufficient to enable the GMC to fulfil its role safely and effectively in relation to the education and training of AAs and PAs?**

   Note: This question does not relate to the GMC's powers for setting the standards for registration contained in Part 3.

   - **Agree**
   - **Disagree**
   - **Neither agree nor disagree**
   - **I don't know**

   Please explain your answer.

   No comment

3. **Do you have any additional comments on 'part 2: standards and approvals' in relation to the drafting approach as it would apply to all regulated healthcare professionals?**

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". 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.

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.

Article 3 will provide employers and others with assurance that, in the future, all regulated healthcare professionals entering the workforce have met the standards necessary for safe and effective practice. And that they will be held accountable for maintaining their professional standards throughout their careers.

4. **Do you agree or disagree that the draft order provides the GMC with the necessary powers to determine the standards and procedural requirements for registration?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

Please explain your answer.

A single legislative framework for registration will support consistency and fairness for both UK and international graduates. It will also allow regulators the operational flexibility to develop streamlined processes tailored to the circumstances of different groups. However, 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. It needs to be ensured that annotation is proportionate for the profession and also linked to public protection. This, in turn, should support the flow of regulated professionals into the workforce to deliver patient care.

5. **Do you agree or disagree that the draft order provides the GMC with proportionate powers for restoring AAs and PAs to the register where they have previously been removed due to a final measure?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

6. **Do you agree or disagree that the draft order provides the GMC with proportionate powers for restoring AAs and PAs to the register where the regulator identifies in rules that it is necessary for the applicant to satisfy the regulator that their fitness to practise is not impaired?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No additional comments

7. **Do you agree or disagree that the powers in the draft order relating to the content of the register and its publication will enable the GMC to effectively maintain a register of AAs and PAs who meet the standards required to practise in the UK?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

8. **Do you agree or disagree that the draft order provides the GMC with the necessary and proportionate powers to reflect different categories of registration and any conditions that apply to the registration of people in those categories?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

9. **Do you agree or disagree that the draft order provides the GMC with proportionate and necessary powers in relation to the removal of AA and PA entries from the register which will enable it to operate a safe and fair system of regulation that protects the public?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

No comment

10. **Do you have any additional comments on 'part 3: the register' in relation to the drafting approach as it would apply to all regulated healthcare professionals?**

    We believe that the removal and readmittance processes to the register for administrative reasons should be set out in primary legislation. 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.

    Proposed new powers to administratively remove from the register individuals who have been convicted of the most serious criminal offences, for example, murder and rape, will also strengthen the regulator's ability to act swiftly and decisively to protect the public and maintain confidence in the regulated professions. We would question whether individuals convicted of such serious offences should not be eligible to seek restoration to the register at any time.

    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.

11. **Do you agree or disagree that the draft order provides the necessary powers to enable the GMC to implement an efficient and safe system of temporary registration for AAs and PAs during a period of emergency as declared by the Secretary of State?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    These powers need to be consistent across all regulators as it is useful to be able to mobilise the retired workforce in a timely manner in emergency circumstances.

12. **Do you agree or disagree that the powers in the draft order enable the GMC to implement a 3-stage fitness to practise process for AAs and PAs proportionately and sufficiently?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

13. **Do you agree or disagree that the powers in the draft order enable case examiners to carry out their roles appropriately and that the powers help to ensure the safe and effective regulation of AAs and PAs?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

14. **Do you agree or disagree that the powers in the draft order enable panels to carry out their roles appropriately and that the powers help to ensure the safe and effective regulation of AAs and PAs?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

15. **Do you agree or disagree that the powers in the draft order on reviewing interim measures are proportionate and sufficient for the safe and effective regulation of AAs and PAs?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

16. **Do you have any additional comments on 'part 4: fitness to practise' in relation to the drafting approach as it would apply to all regulated healthcare professionals?**

    Whilst we agree with the proposed 3 stage fitness to practice assessment, we would like to see further clarity 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 fitness to practice panel needs to be clarified and it should be easy 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.
    - There should also be some guidance for regulators to ensure lay members are part of committee structures

    We support the Government's intention to give regulators greater discretion in the initial assessment stage to determine what and how they should investigate. In terms of making the decision as to whether or not to investigate, 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. 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.

    We agree that regulators should be able to apply suspensions to the register and that 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.

In terms of imposing sanctions and reviewing measures we believe that 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.

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

17. **Do you agree or disagree that the powers in the draft order provide the GMC with proportionate and sufficient powers in relation to the revision of decisions concerning the regulation of AAs and PAs?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

18. **Do you agree or disagree that the powers in the draft order provide individuals with proportionate and sufficient appeal rights in respect of decisions made by the GMC and its independent panels relating to the regulation of AAs and PAs?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

19. **Do you have any additional comments on 'part 5: revision and appeals' in relation to the drafting approach as it would apply to all regulated healthcare professionals?**

    A registrant should have a right of appeal against a decision by a case examiner, Fitness to Practise panel or Interim Measures panel. 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.

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.

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.

20. **Do you agree or disagree that the offences set out in the draft order are sufficient to ensure public protection and to maintain public confidence in the integrity of the AA and PA professions?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

21. **Do you have any additional comments on 'part 6: miscellaneous' in relation to the drafting approach as it would apply to any regulated healthcare professionals?**

    We believe 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. 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.

    Education and Training providers should have the right to appeal and that appealing on conditions attached to approval is not necessary provided they can 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 be allowed to be challenged? Any grounds for appeal should be developed in consultation.

    In terms of protection of title, 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.

22. **Do you agree or disagree with the proposed powers and duties included in schedule 1 the regulator in relation to AAs and PAs?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

23. **Do you have any additional comments on schedule 1, the regulator, in relation to the drafting approach as it would apply to all regulated healthcare professionals?**

There is likely to be an increased autonomy for regulators. This needs to be balanced by greater accountability. For example, in the duty to consult publicly on significant changes a regulator may wish to make and the duty to be proportionate, transparent and consistent in the way they work.

We do have some concerns around the delegation of functions. 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.

24. Do you have any comments on schedule 2, listed offences?

We would agree with the list proposed

25. Do you agree or disagree that the powers in the draft order enabling the GMC to gather, hold, process, disclose and assure information in relation to the regulation of AAs and PAs are necessary and proportionate for meeting its overarching objective of protecting the public?

- **Agree**
- **Disagree**
- **Neither agree nor disagree**
- **I don't know**

Please explain your answer.

No comment

26. Do you have any additional comments on schedule 3, evidence gathering, notifications, publication and data, in relation to the drafting approach as it would apply to any regulated healthcare professionals?

The new provisions regarding cooperation, acquisition and disclosure of data should allow regulators to work more closely with partners across the regulatory system to promote patient safety. 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 safe and used appropriately. Sharing of information is important for ensuring the safety officers etc have the information they need to carry out their role.

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.

In terms of holding and publishing data on a registrant's qualification, 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.

27. **Do you agree or disagree that the draft order provides the GMC with sufficient and proportionate rule making powers to enable it to effectively maintain a register of AAs and PAs who are safe to practise?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

28. **Do you agree or disagree that the draft order provides the GMC with proportionate and sufficient rule making powers to address non-compliance of AAs and PAs?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

29. **Do you agree or disagree with the provisions set out in the draft order for the setting and charging of fees in relation to the regulation of AAs and PAs?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

30. **Do you agree or disagree that the rule making powers set out in the draft order will enable the GMC to deliver the safe and effective regulation of AAs and PAs?**
    - **Agree**
    - **Disagree**
    - **Neither agree nor disagree**
    - **I don't know**

    Please explain your answer.

    No comment

31. **Do you have any additional comments on schedule 4, rules in relation to the drafting approach, as it would apply to all regulated healthcare professionals?**

    Regulators should be required to assess the impact of proposed changes to their rules, processes, and systems before they are introduced. 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.

Regulators should be able to set out their registration processes in rules and guidance. The process for application needs to be made clear to those wishing to apply to be on the register.

Regulators should be able to determine in rules the details of how the Fitness to Practise panel stage operates. 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.

Regulators should be able to set out in Rules their own restoration to the register processes in relation to fitness to practise cases. There should be some consistency across professions around time frames and processes.

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.

Regulators should be able to set their own fees in rules. 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.

32. In relation to schedule 5, consequential amendments, do you have any comments on how the draft order delivers the policy intention in relation to AAs and PAs?

No comment

33. Would you like to provide any further comments on the draft order?

If AAs and Pas are to be given prescribing rights inn the future, following consultation, given prescribing rights then we would expect their competency to be to the same level as other prescribers. To that end, we would advocate for them to use the prescribing competency framework, which is what all the other professions use.

34. Do you think there are any further impacts (including on protected characteristics covered by the public sector equality duty as set out in the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998) from the legislation as currently drafted?

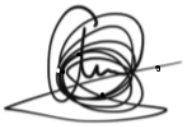
There is a potential for these proposals to positively and negatively impact on people with protected characteristics.

We have concerns about the potential consequences of the proposed removal of health and the English language from the grounds for action in fitness to practise cases.

Thorrun Govind

Chair, English Pharmacy Board

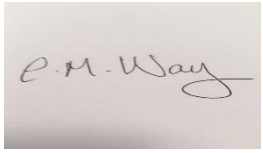
Royal Pharmaceutical Society



Andrew Carruthers

Chair, Scottish Pharmacy Board

Royal Pharmaceutical Society



Cheryl Way

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