Regulating anaesthesia associates and physician associates – consultation response to Department of Health and Social Care

16 May 2023

Part 1: general

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

In relation to Article 2(2)(a) we consider that Health should be a ground for action with regards to impairment of fitness to practise. It is important that regulators can act in circumstances where harm or misconduct has not yet occurred, but where a registrant's health causes a significant risk to patients and the public. It is unclear as to whether the two grounds for action, as written, will appropriately allow for this approach. There is also an argument that retaining health as a ground for action allows regulators to deal with such issues in a more sensitive and appropriate way.

In relation to 2(1) Final Measure and Interim Measure, we would seek assurance that the definitions as written provide adequate description that an interim measure relates to a different test than a final measure. i.e., one will be based on a fitness to practise test and one will be on a risk assessment test. Is this appropriately grounded in the proposed Order?

Part 2: standards and approvals

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**

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?

The Pharmaceutical Society NI regulates both pharmacists and pharmacies and this section will need to ensure that pharmacy premises can be registered, when developed for us.

We note that Article 3(b) states that the Regulator may determine other standards in relation to associates. We think there should be a bolstered and standalone provision for the setting and maintaining of Standards of Conduct and Performance for healthcare professionals. This is one of the 4 core tenets of the Regulators' work, and we consider that a standalone provision is necessary to give the requisite authority. It will also be closely linked to the grounds for action in the provision relating to the inability to provide care to a sufficient standard.

Part 3: the register

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**

No future comment

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**

See response to next question.

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.

We consider restoration relates to those who are being restored to the register after being removed for FtP purposes. All others are re-joining the register as part of registration processes. Restoring, which requires a different test of suitability, related to fitness to practise history and maintaining public confidence, and re-joining, because you meet all the eligibility criteria, should be within separate provisions as they are telling the public different things related to public confidence in the profession and individual professionals.

We welcome the inclusion of making registration/restoration subject to conditions under Article 7, however, we are unsure of how this will link to a determination of an FtP panel which has considered an applicant's restoration after removal by Final Measure. The FtP panel should decide the Conditions related to a restoration. As in other areas of the proposed Order, we are uncertain as to who has the appropriate legal authority to make the decision. If a panel decides an individual is fit to be restored and the Regulator then decides to make that subject to Conditions, this may form the basis for an appeal.

As one of the purposes of the legislation is to ensure greater consistency across the regulators in terms of outcomes, we consider it appropriate to state on the face of the Order the length of time all registrants must be 'struck off' for before they can reapply, rather than place it in Rules and leave it to individual regulators to decide. It is possible that registrants from different regulators, involved in the same incident being struck off, but one being restored to their register years before the other.

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 see response to the previous question related to link between an FtP panel's decision to restore after a Final Measure and a Regulator imposing Conditions.

The language in Article 7 relating to Conditions is somewhat confusing. In general Conditions on a registrant's practice have been clearly defined as relating to Fitness to Practise. 'Conditions' under Article 7 appear to relate to defining a registrant's scope of practice, this is potentially confusing and may benefit from clarification.

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.

Please see response to previous questions.

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.

We have some concerns about the proportionality of 8(2)(b)(aa). This relates to not having health as a ground for action in Fitness to Practise. 8(2)(b)(aa), suggests that a registrant subject to FtP related to their health who has engaged with the regulator or an FtP panel up to a point, but then disengages and stops getting the required medical test, could be administratively removed from the Register. We have some concerns as to the proportionality of this power and how it should be used. Regulators have a duty of care to their registrants. Making health a separate ground for FtP action, and once health has been identified, a Registrant should only be removed after an appropriate and proportionate process of support to restore health is undertaken, whilst protecting the public.

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?

No

Emergency registration

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.

No further comment

Part 4: fitness to practise

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.

We have some reservations about Part 4 in general. There is a need to provide a legislative basis for the early stages of the Fitness to Practise investigations. This should ensure that such areas as carrying out a jurisdictional test, the power to carry out an investigation and apply some form of threshold before a case is referred to a Case Examiner (CE), has a legislative footing.

This is necessary to clearly delineate the scope of CEs' activities and their ability to fairly and proportionately carryout their role. For example, at this stage it is unclear as to whether a CE will oversee the investigation, the framing of allegations and then proposing of an agreed final measure. CEs should be considered as independent decision makers, based on the investigations, and framing of allegations carried out by others – this is not to suggest a CE cannot request further investigations or information prior to engaging with the issues. There is a risk that Regulators may also take markedly different approaches to early stages if it is not defined in legislation.

The basis upon which a CE is making decisions could be further clarified in the draft Order. Current full FtP decisions are based on three stages: agreed or established facts of the case; agreed or established impairment of Fitness to Practise; and Sanction. As the powers are set out in Article 9(2)(a) for CEs it remains somewhat unclear as to whether they will establish the facts of a case. This brings into question the basis upon which any appeal revision would take place. The legislation should clearly state that the registrant should agree to the facts of the case, that their FtP is impaired and the CE's findings in that respect, and the final measure.

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.

Please see response to previous question, without an initial stage being legislated for the remit and responsibilities of CEs remains unclear. We retain concerns related to the ability of a CE to impose a Final Measure when a registrant does not engage with the process, this is linked to the need to ensure appropriate establishment of the facts of the case. In the interests of transparency, proportionality and fairness, cases where a registrant is non-compliant, should be referred to an FtP panel for consideration.

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.

We retain concerns that an FtP panel will not have the power to give a 'Warning' after a finding of impairment. We recognise that not all regulators currently have this power, but the Pharmaceutical Society NI does and consider it beneficial and proportionate. Not having the power to give a 'Warning' with impairment may impact cases where a panel considers that a Registrant has shown appropriate insight and remediation in relation to their misconduct, but their misconduct was of a nature that a finding of impairment is necessary to ensure public confidence in the profession. If the only options available to a panel are suspension or striking off, (conditions are usually not workable in these types of cases) then the panel may be more minded to make a finding of no -impairment. We do not consider this to be in the wider public interest nor in the interests of regulated professions and we have seen no clear articulation/rationale as to why a Warning with impairment has not been included.

Please also see response to questions relating to Part 5 on Revisions and Appeals.

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 further comment

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?

There is no mention of Public Protection within Part 4 of the proposed Order, and this reflects the limited clarity within Part 4 and Part 5 as to what the objectives are in relation to Impairment, Interim Measures and Final Measures and reviewing/revising them. Part 4 and Part 5 together are not clear enough in relation to the purpose, and related powers of CEs and Panels.

Part 5: revisions and appeals

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.

Part 5 is hard to follow and seems overly complex- FtP appeals and appeals/revisions against education accreditation and registration decisions should be separated out.

There appears to be no automatic review power for when a CE or Panel imposes Conditions or Suspension. This is different to revising, based on an error, as outlined, or a material change of circumstances in 11(2), but is closely linked to the public protection role, to ensure that a registrant either remains impaired and requires further sanction or is now fit to practise.

The ground to revise and appeal decisions relating to CEs makes no reference to a decision being inadequate to protect the public, the revision/appeal provisions being related to administrative error only.

The process for appealing restoration decisions appears overly complex. What is the rationale for the inclusion of the County Court?

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 further comment

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?

Please See response to previous questions.

Part 6: miscellaneous

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**

No further comment

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?

The style of drafting, i.e., having the rights to make representations in FtP proceedings outlined in a separate Part of the draft Order under Miscellaneous, does not lend itself to an intuitive understanding of the proposed law and rights associated with FtP procedures and powers.

Schedule 1: the regulator

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**

No Further comment

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?

The Pharmaceutical Society NI is a devolved regulator, which is overseen by the Northern Ireland Assembly. The Privy Council plays no role in this regard. We also have a different relationship with the Department of Health in Northern Ireland, under the Pharmacy (Northern Ireland) Order 1976, by comparison to other Regulators' current relationship with DHSC. Careful consideration will have to be given as to how these reforms will work in the devolved setting within which we operate.

Schedule 2: listed offences

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

No

Schedule 3: evidence gathering, notifications, publications and data

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 further comment

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?

No

Schedule 4: rules

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**

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**

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**

We have some concerns that Paragraph 7(2) as written may limit the ability of regulators to hold appropriate reserves and therefore function appropriately. The provision does not reflect unpredictability of income and expenditure, such as the number and complexity of FtP cases and variation in the number of registrants.

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.

See response in relation to fee setting Rules.

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?

No

Schedule 5: consequential amendments

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

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

Whilst we acknowledge that legislation is often complex, the draft Order is extremely hard to follow and lacks basic readability, which is important for the public and regulators alike, as they attempt to understand the intentions of Government and how the regulation of healthcare professions works and will work in the future.

Public protection, the core purpose of regulation, is not adequately imbedded throughout the legislation, in light of this there is a concern that too many provisions are open to interpretation, as to why certain powers have been provided.

The draft Order appears to conflate some important and foundational powers, such as registration and restoration, reviews, revisions and appeals.

The initial stage of Fitness to Practise needs to be set out in the Order and this has implications for the rule making powers.

There is no specific provision for Continuing Professional Development/revalidation which we consider needs a separate legal footing, over and above registration requirements.

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?

No