Response

Department of Health and Social Care (DHSC)
Regulating healthcare professionals, protecting the public

June 2021

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About the Company Chemists' Association (CCA)

Established in 1898, the CCA is the trade association for large pharmacy operators in England, Scotland and Wales. The CCA membership includes ASDA, Boots, LloydsPharmacy, Morrisons, Rowlands Pharmacy, Superdrug, Tesco, and Well, who between them own and operate around 6,000 pharmacies, which represents nearly half the market. CCA members deliver a broad range of healthcare and wellbeing services, from a variety of locations and settings, as well as dispensing almost 500 million NHS prescription items every year. The CCA represents the interests of its members and brings together their unique skills, knowledge, and scale for the benefit of community pharmacy, the NHS, patients and the public.

Executive summary

The Company Chemists' Association welcomes this consultation on the reform of regulators that oversee professionals working in health and social care. The Company Chemists' Association's response is from the perspective of our members, large pharmacy operatives in community pharmacy. The regulator that oversees the community pharmacy sector, the General Pharmaceutical Council (GPhC), is one of the newest regulators of the ten that the Professional Standards Authority (PSA) regulate. However, even though the Pharmacy Order was laid relatively recently in 2010, the profession has undergone unprecedented change which shows no sign of slowing. Overly prescriptive and bureaucratic legislation holds back the sector and individual professionals in their careers. Therefore, we believe that these proposals will have a real impact on frontline pharmacy professionals, and that it is important that all healthcare professionals are aware of the potential impact of these changes and are consulted on them.

We note that this consultation does not provide an expected timescale for legislative change however we understand that Section 60 orders are expected to be laid from early 2022. The General Medical Council (GMC) and the Nursing and Midwifery Council (NMC) have been timetabled first. Given that the consultations for the Section 60 orders will not all come out at once, we are concerned that the GMC and the NMC will set the direction of travel. This could provide an issue where regulators do not agree but decisions around change are dominated by the more prominent regulators.

There are a few areas of the regulatory reform proposals that specifically affect pharmacy. The first is the move to incorporate the GPhC (and the General Dental Council) so that it is accountable to the Privy Council. Secondly is the issue of premises regulation and how that will be handled if the output of the consultation is to merge functions across regulators. Lastly, the overarching aim of this consultation which is to streamline regulatory processes will bring about the introduction of case examiners and consensual disposal in fitness to practise cases.

Whilst we agree that moves toward enabling a progressive regulatory model is a positive step, we have concerns about whether the GPhC currently has the capacity to keep up with the pace of change. Unlike the GMC and NMC, the GPhC is yet to finalise the reformation of its fitness to practise strategy. The report from their consultation on this topic is due to be published shortly.

We question the extent to which patients have been involved in the regulatory reform proposals. The duty to collaborate appears to extend only across regulatory bodies and other health professional bodies. The risk is that the proposals could mean that processes become less transparent to these groups. This may particularly be a concern where professionals and regulators agree outcomes for fitness to practise cases.

Furthermore, while some of the proposals provide regulators with the desired autonomy and flexibility, there is also a need for the right level of safeguards. This includes maintaining PSA's position and ability to challenge outcomes and ensuring that there is consistency across regulators.

With a few of the proposals we are concerned that, if rolled out within a merged landscape, there could be a loss of pharmacy's professional voice. This is highlighted in the suggestion that professionals need not be represented on the Unitary Board. We do not support a regulatory model that does not have a pharmacy professional voice at each level of decision making. Such a move would also erode trust in the regulator among both the profession and the public.

On the other hand, there could have been more in the consultation to explain the benefits of merged functions across professionals. The Health and Care Professions Council (HCPC) is an organisation familiar with multi-professional regulation and may have insight to share which would have also been helpful to have in the consultation in case studies. Equally, modelling that explained how regulation would change and how regulators would work together collaboratively and effectively would have added value and we believe that measures for effective collaboration could fall through the gaps of this reform.

Lastly, we question how effective the proposals in this consultation will be in supporting a changing health and social care landscape. Professionals are advancing their practice and working across multi-disciplinary teams which blurs lines of accountability and outdates current governance frameworks. We also think that regulation fails to appropriately address the locum population. Pharmacy employers are unable to provide locums with education and training without falling foul of HMRC's definition of an employee and regulators do not have adequate mechanisms for dealing with locums whose behaviour raises low level concerns across their places of employment. Furthermore, health care is being offered online more frequently than ever before, and sometimes for unscrupulous reasons, which puts patients at risk and requires a specialist approach. Therefore, we believe that the DHSC and regulators have further work to do, in collaboration, to address these forward-facing issues that cut across the health and social care landscape.

Consultation questions

Section one: Governance and Operation Framework

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.**

   We agree in principle that regulators should have a duty to co-operate with
   - Other healthcare regulators
   - Systems regulations across the UK
   - Education and training facilities
   - Providers of health and social care services

   However, there is a lack of explanation of how these proposals ensure that regulators are open and transparent with patients and the public. The cited reports (Gosport Inquiry and Morecambe Bay) highlight the need to listen to patients, take concerns seriously, follow duty of candour, and explain to patients how mistakes will be put right. With shifts towards closing fitness to practise concerns quickly, the regulators must also hold a duty to reassure patients that appropriate outcomes have been reached.

Furthermore, there should also be a duty to co-operate with organisations representing professionals including the Royal Colleges, Unions, and other representative bodies. This is to ensure that the regulators' autonomy over deciding proportionality in the governance and operations framework does not go unchecked and is fair to health professionals. This is particularly important with regards to professionals from ethnic minority backgrounds who are already disproportionately represented in fitness to practise processes.

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

We agree with this for the reasons set out above in our response to question 1.

Additionally, government should consider whether there should be an obligation for regulators to publish their own reports on failings to ensure that these errors do not happen again. The consultation cites the PSA's Lesson Learned Review into the NMC's handling of fitness to practise cases at Furness General Hospital but there appears to be no duty for the regulator to publish its own report. In this case, handling was poor with regards to patient engagement. However, there have been other high-profile instances where professionals have been treated unfairly such as the case of Dr Bawa Garba. The handling of this case was criticised and there were concerns about decisions being biased in relation to the doctor's ethnicity. Therefore, we believe that more could be done around being transparent about cases to tackle disproportionality.

In terms of pharmacy, the GPhC has a number of PSA reviews outstanding in relation to how it handles fitness to practise cases. Regulators should be required to reflect on what has gone wrong and publish, and keep to, an action plan with timescales to put these concerns right.

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**

We agree with this proposal in principle. There must also be caveats for when changes are required in exceptional circumstances. For example, the move to online hearings and alternative arrangements around registration of health professionals because of the significant challenges brought about by COVID-19.

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.**

We disagree on the basis that specific professional input is essential to the Board; ideally this should involve professionals (registrants) as full non-executive members of the Board.
We have significant concerns about this proposal. The new arrangements will see Unitary Boards being comprised by non-executive members in the majority. There will also no longer be a requirement for lay and professional members to be appointed. We believe that the Board should have professionals (registrants) as full non-executive members. Without the input of people well-versed in pharmacy there is a risk that decisions are made by well-intentioned but

poorly informed individuals. At least one registrant is essential to ensure the Board understand pharmacy law and ethics and can apply this knowledge to 'everyday life in pharmacy'. Therefore, the appointment by 'merit' needs to be clearer.

In the instance that one regulator is formed across the health sector, there is a risk that the professional interests of pharmacists and pharmacy technicians will be lost. Therefore, work is required to understand how this can be guarded against. It is suggested that the HCPC, as a multi-professional regulator, may have learning to share with DHSC and other regulators in this regard.

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.**

   We disagree with this proposal. The GPhC already sets its fees without Privy Council approval and these fees have been steadily increasing. More accountability is required so that registrants can see how the regulator is taking steps to reduce its costs, such as building rent and other overheads. In addition, the GPhC should make registrants aware of how it is using savings from reduced physical inspections and online hearings during COVID-19.

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.**

   We agree with this proposal and note that the pharmacy regulator is currently consulting in this regard.

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.**

   We disagree with this principle. There may be benefits of greater autonomy for regulators with this proposal. However, it appears incongruent with the overarching principle of aligning regulator activities across the different healthcare professions. Furthermore, it appears to contravene the key principles of corporate governance, which require the establishment and maintenance of core committees, such as for audit and remuneration. It is accepted that different professional regulators will probably need flexibility to determine which committees meet their individual requirements; however, certain committees – e.g. education and fitness to practise should be fundamental to each one.

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.**

   We agree with this proposal. It should not be incumbent upon registrants to cover costs not directly associated with regulating their profession.

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 agree in principle that delegation for the example outlined, accrediting the same course on prescribing, is logical. However, we believe that a third party is not suitable for core functions such as fitness to practise. We hold concerns already that the outsourcing of fitness to practise cases to external private legal teams has a detrimental impact on the registrant because there is a lack of knowledge and experience in pharmacy and regulatory proceedings. Therefore, we would want to see this function enhanced and kept in-house.

There may be scope for work across the regulators which has not been accounted for in the consultation. For example, ongoing issues with online prescribing from doctors and pharmacists set up in the UK and overseas may need a multi-regulator task force and new forms of regulation, and potentially legislation, to support this.

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.**

We agree with this proposal in principle. Sharing registrants' details must be done proportionally with these bodies and the first line must be to get informed consent from registrants about how their details will be stored and used.

Proportionality is key and there would need to be set guidance for the regulator and transparency around the disclosure process.

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

We agree with this principle as it is essential for accountability. However, we would caveat this response by adding that producing this report should not involve unnecessary additional costs which are passed on to registrants.

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.**

We agree that the Privy Council's powers should apply to the GDC and GPhC. It is essential that all regulators are held accountable to the same standard and this anomaly must be addressed. Furthermore, the Privy Council's default powers are a mechanism to ensure public protection. It has the power to direct regulators where they have failed to carry out their statutory functions. As noted in an earlier answer, the GPhC has yet to address certain aspects of its PSA review on fitness to practise. Therefore, this additional accountability is likely to benefit both patients and professionals.

Section two: Education and Training

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.

    Whilst there are numerous high-quality programmes of training and education, which are not assured by the regulator, we are aware that access to professional development is varied, and standards can be inconsistent.

    We support the development of a holistic programme of continued professional development for pharmacy registrants. To ensure consistent rollout and standards, we believe that oversight of such a program should sit with the regulator. As a body representing employers, we welcome opportunities to work closely with NHSE/I and the regulator to support the development of this.

    Whilst we support the principle of allowing the regulator to have powers to set additional standards which may lead to annotation, in practice a careful approach will need to be adopted. At present only independent prescribing is annotated on the pharmacist register. We are mindful that the addition of numerous annotations may be confusing for patients and employers alike. We do not recommend any further annotations to the pharmacist register.

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.**

    Whilst we are not able to comment on the needs of sectors which fall outside of our immediate expertise (pharmacy), in our experience an approach which involves the regulator in the accreditation of education providers (i.e. approval or withdrawal of approval), as in the case for pharmacy, is effective.

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

    Warnings and conditions are a useful mechanism to support the identification and addressing of gaps. The GPhC is already able to issue such warnings and we recommend this power is retained.

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, education and training providers should have the opportunity to submit relevant evidence. We recommend a clear process to set out how the regulator responds and provides feedback to additional evidence or observations which are submitted.

17. **Do you agree that:**
    a. **education and training providers should have the right to appeal approval decisions;**
    b. **that this appeal right should not apply when conditions are attached to an approval;**
    c. **that regulators should be required to set out the grounds for appeals and appeals processes in rules?**

    Please provide a reason for your answer.

    Education and training providers already have the right to appeal decisions as set out in section 39n of the Pharmacy Order, 2010. We support this provision.

    At present pharmacy education and training providers have the right to appeal conditions. We have concerns that the total removal of this provision may be too restrictive. If introduced, we recommend this proposal only applies to certain conditions and consultation should be undertaken to establish these conditions.

    We agree that regulators should be required to clearly set out the appeals process.

    We have concerns that if grounds for appeal are set out too definitively, they may exclude appropriate appeals if they have not been included in a pre-identified list. We recommend a flexible approach is taken to ensure a fair appeals process.

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

    We agree that regulators should retain existing approval and standard setting. Removing existing powers would be destabilising.

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.**

    As noted in the consultation, the GPhC has the power to set and administer exams or other assessments for applications to join the register or to have annotations on the register. We support this provision and believe it should remain in place.

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.**

    At present accredited higher education institutes set and administer exams and assessments which lead to registration. In our view, higher education institutes are experts in the administration and delivery of pharmacy education, and they should retain this power. In any

circumstances where they do not meet necessary standards there is an established process, as already discussed, for removing or withdrawing accreditation.

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.**

    The pandemic has already provided opportunities to take a more flexible approach to the assessment of education and training providers, courses, and training - specifically it has required and relied on a more technological approach.

    We agree that this approach can provide both regulators and providers or learners a more efficient and effective way to reach the same goals. Naturally, the speed at which processes have been developed has meant processes may not always have been as smooth as they could have. We encourage regulators to identify learnings to understand how processes could be improved.

    We believe there are opportunities to build on changes which have come into force and consideration should be given as to how learnings can be applied in other situations e.g. clinical assessments.

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 that each regulator should be able to set their own rules for revalidation.

Section 3: Registration

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.**

    We agree with this proposal in principle.

    However, the implementation may not work this way for practical reasons. For instance, the Nursing and Midwifery Council (NMC) has separate registers for nurses who have university qualifications and historic cohorts who do not. During the pandemic regulators also enacted temporary and provisional registers to ensure that newly qualified and retired professionals could support the health system. The important factor is that it is easy for members of the public to check the details of a registrant and that the information is accessed at a single point online without the need to access separate databases.

We have no concerns about a single register for all professions if it reduced cost and bureaucracy.

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.

    We agree with this proposal. It is important that there is consistency across regulators.

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.**

    We agree with this proposal in principle. The collection and processing of data must be aligned with the regulators' statutory objectives and proportionality is applied. As a requirement under the Data Protection Act 2018, professionals should be asked for consent and be informed about how their data will be used and stored.

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, in principle. (Please see response to question 26.)

    The consultation notes additional discretionary powers that the regulator would hold to request and publish other information. The more information published, the greater the cost to maintain to ensure accuracy. In addition, consideration must be given to public use of registers – the more information published the more challenging it will be to interpret accurately.

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.**

    We agree with this in principle. Annotations are also used to record additional skills that go above the minimum requirement for registration. Therefore, they could be used more widely to record advanced practice status and qualifications. In pharmacy, annotations could be used to record Independent Prescriber (IP) qualifications. In addition to public protection and demonstrating restrictions to practise, annotations also facilitate informed choice for the patient.

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

    We agree with this proposal.

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?**

    We agree with this proposal.

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.**

    We agree with this proposal with the caveat that there must be some standardisation around the required competence of the individuals(s) nominated.

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.**

    We agree with this proposal. There is a disparity among regulators about the evidence which overseas professionals (e.g. doctors) need to produce compared to those trained in EU countries. Although some of this divergence may be addressed through Brexit, there are cases where qualified professionals from overseas countries have been unable to get onto the register because their home country has been hostile in relation to providing their certificates and documentation. In cases such as these, where the regulator is dealing with refugees and can satisfy requirements around competence through other means, they should not be hamstrung by legislation.

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.**

    In principle, we believe registrars should have the discretion to take account of exceptional circumstances when making decisions about an applicant's registration. However, generally, there should be a clear policy on the circumstances in which registration would be turned down, which is available to all potential registrants in advance.

Many regulators do not have the 'registered' and 'registered with a licence to practise' distinction that the GMC does. We would question whether this makes sense to the public searching the register and therefore it maintains the patient safety function which it intends to. Our position is that all professionals have a duty to recognise and act within the limits of their competence. Pharmacists acting in a professional leadership capacity (e.g. superintendents and pharmacy managers) revalidate yearly with the GPhC, providing evidence of how they are maintaining their skills and competence within their area of work. These pharmacists can recognise that they may not be fit to practice in a pharmacy setting, dispensing medicines and consulting patients. Therefore, they would not work in this environment unless they had the appropriate retraining.

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.**

    We agree with this proposal.

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.**

    We agree with this proposal in principle. There must be an ability for others to scrutinise the decisions of regulators and there must be an appropriate level of transparency to patients. For example, if a regulator were to allow voluntary removal of a professional who did not want to go through a fitness to practise investigation, then this may not be compatible with the function of the regulator in the eyes of the public.

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

    We have no comments about which additional decisions should be added. However, we suggest that the approach must be consistent across all regulators.

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.**

    No comment.

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 disagree with this proposal. The GMC's 'provisional' register is a register of post-graduates who have not yet qualified in a specialty. It was noted earlier in this consultation that a framework similar to the GMC's should be applied across all regulators. In addition, regulators used student registers during the pandemic to mobilise a workforce who had not yet evidenced their registration requirements.

Furthermore, as the role of healthcare professionals continues to evolve, new professional behaviours need to be embedded (e.g. appropriate consultations both verbal and physical). We have concerns that some students may not be competent in regard to knowledge, skills or professionalism to meet the needs of patients in new practice. Having student registers could be a way of addressing concerns at an earlier stage, if necessary.

It may be that the 'provisional register' model is explored on a more permanent basis in pharmacy.

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.

We agree with this proposal. The earlier proposal for adopting the GMC model (where professionals can be registered with or without a license to practise) would override the need for a non-practicing register.

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.

We agree with this proposal. (Please see answer given to question 33.)

Section 4: Fitness to practise

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.**

We agree with this proposal in principle. The GMC has been taking this approach for several years, having found ways to adapt its current rules to allow for an initial assessment (or provisional enquiries). The approach to the initial assessments has been staggered with pilots to provide extra checks and balances to ensure that decisions are robust and to test which

cases are appropriate for an initial assessment. Therefore, there is a risk that simply applying the GMC approach to other regulators and expecting them 'to get on with it' is setting them up for failure. Clearly, a three-step fitness to practise process needs to be accompanied with robust principles and guidance.

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 disagree with these proposals. We believe that more appropriate terminology would be capability and conduct.

We do not feel that it is appropriate to class health concerns as 'lack of competence.' We strongly believe that cases involving health concerns should be addressed as a subset of capability. We appreciate that competence can be defined as appropriate skills, behaviours, knowledge, and judgement and therefore some health issues may indicate an inability to perform 'competently.' However, treating health cases in this way may have the effect of stigmatising registrants and bringing their professionalism into question for circumstances outside of their control.

Furthermore, the term conduct or misconduct is too broad. In practice, issues range from the (straightforward) gross misconduct issues to those more contentious issues relating to behaviour, where it is often difficult to establish what happened and to provide sufficient evidence for the GPhC to progress an investigation. Greater clarity is needed from the regulator about thresholds for conduct issues and what would initiate an investigation.

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.

We agree with these proposals as they are imperative for the safety of the public. However, we would urge that consideration is given to regulators' publication and disclosure policies.

Measures such as warnings which can be given as an admonishment for a serious one-off event, can often carry a symbolic value as a 'black mark' on a professional's record. This can lead to employment difficulties.

Sometimes concerns can sit close to the line between 'warning' and 'no further action.' In these instances, we would like to see case examiners provide a letter of advice to registrants so that they can reflect on the issues identified and remediate.

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

We would suggest that further thought is required on this proposal, such as whether the views of the registrant's employer would be sought.

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.

We agree with this proposal and suggest that the person(s) who raised concerns should be updated at regular intervals (e.g. 6 weekly) even if this is just to advise that there has been no progress. It is unacceptable to have cases last for 18 months and for these person(s) to receive a letter to say the case has been closed.

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.

We agree that regulators should weigh up evidence and decide whether, on the balance of probabilities, the professional's fitness to practise is impaired at as early a stage as possible. However, rather than 'discretion', regulators require a robust consistent armory of tools including thresholds guidance, performance targets for completion of initial enquiries and case examiners (the GPhC does not currently have case examiners). Furthermore, as mentioned earlier in this consultation response, the GMC has had time to test and embed initial enquiries and therefore there must be principles and guidance to support all regulators in adopting this approach.

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.

We believe that this should be removed in order to protect public confidence. This is especially applicable with cases where there can be no remediation if proved. Cases which regulators have waived the five-year rule to investigate include performance and misconduct where the actions are so egregious that it is in the public interest to investigate. An example of this is the case of Dr Ian Paterson who performed over 1,000 unnecessary and harmful cleavage sparing mastectomies on women.

50. Do you think that regulators should be provided with a separate power to address noncompliance, or should non-compliance be managed using existing powers such as "adverse inferences"?
Please give a reason for your answer.

We do not agree that adverse inferences should be used to address non-compliance as this enables the regulator to make assumptions. This approach fails to recognise the punitive and fear-inducing reputation that the regulators hold with professionals. This reputation can be reinforced by the language the regulator uses and in the approach it takes. Therefore, a professional may not get in contact to attend a health assessment because the communication from the regulator has been prescriptive, punitive and anxiety inducing. However, it does not follow that the professional's fitness to practise is impaired. Such logic runs the risk of unfairness to those who ought to be protected under equality, diversity, and inclusion measures.

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.

We agree that this should be the process, where appropriate.

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.

We agree with this proposal.

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 do not agree with all these proposals. Removal from the register should be decided at a panel where the registrant can make submissions. This decision can also be challenged by the PSA.

There may be difficulties with imposing a decision in circumstances where the professional does not respond in 28 days. They may be in their home country, in hospital, or seeking legal advice. Therefore, in some circumstances it may not be appropriate to impose a decision.

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

We agree in principle with the proposals. We also think that the case handler should be able to request that the case examiner or panel review the interim order sooner if new information comes to light that challenges the rationale for the order or suggests that stricter conditions are required.

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.

We agree with this proposal. Additionally, we believe that the rules should be consistent across regulators.

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.

We agree with this proposal. A right of appeal is important for fair and robust proposals.

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.

We agree with this proposal. Regulators should work together to make this process consistent for all health professionals.

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.

No comment.

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.

We do not agree with this proposal. This the same as the regulator 'marking its own homework' and, in practical terms, the Registrar is the employer of the case examiner, often working side by side. An independent review mechanism is required.

Additionally, the impact on locums needs to be considered. Will they be eligible for accepted outcomes? There is a question of safety if accepted outcomes are agreed and not monitored within stable employment arrangements and a question of fairness if this cohort does not have this case disposal method available to them.

Under the model for regulation proposed in the consultation, cases may be closed at initial case stage if they do not meet the thresholds for investigation and have been reviewed by a case examiner. However, in these circumstances, there may be learnings that need to be communicated to the professional to prevent reoccurrence or a pattern of low-level undesirable behavior. A letter of advice may be helpful and again, it may be more difficult to communicate this advice to locums.

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

We disagree with this proposal for the reasons given above in answer to question 62.

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

No comment.

Regulation of new roles

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 practise 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.

Equality, diversity and inclusion

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. Our responses to the consultation questions outline the need for robust and consistent outcomes, transparency and measures that include all professionals, including locums. Furthermore, we are strongly against health cases being dealt with as a 'lack of competence.'