

Response to *Regulating healthcare professionals, protecting the public*

Covering letter

We warmly welcome the Department of Health and Social Care's (DHSC) consultation as a major step towards fulfilling the UK government's longstanding commitment to reform of professional regulation.

Independent professional regulation exists to protect the public. But the regulatory and legislative structures that govern how this is done have struggled to keep pace with the changing needs of the healthcare systems within which the professions work, and with society's expectations of modern regulation.

Some of the legislation, as in the case of ours, has its origins in the 19th century. Although it has been updated at various times, the result is a regulatory infrastructure that is complex, overly prescriptive and slow to adapt to change. As individual professionals increasingly work together as part of the wider healthcare team, the differences and disconnections between the way different professions are regulated have become all too apparent. This lack of consistency and co-ordination has hampered regulators in their efforts to protect the public and support those we regulate to deliver great care.

We therefore keenly support the consultation's aims of:

- Improving public protection
- Supporting the development of a flexible workforce that better meets the challenges of delivering healthcare
- Improving the support given to regulated professionals in delivering high quality care
- Enabling regulators to address concerns about the performance and conduct of regulated professionals in a timely and proportionate manner
- Increasing the efficiency of the regulatory system.

The proposed changes will help to modernise and improve professional regulation. They'll provide a more flexible and proportionate framework for addressing persistent regulatory problems. And they'll deliver tangible benefits for patients, registrants, employers and providers, educators and trainers. Above all, reform will strengthen public protection.

Inevitably, given the breadth of the consultation, there are some proposals which need further explanation, to help us better understand what they're seeking to deliver, and the means through which they might do so. We've summarised these below. More detail on each are set out in our answers to the individual questions. We would welcome further discussions with DHSC on these.

Regulatory independence

Regulators will need operational autonomy and flexibility to deliver the reforms. But we agree that these must be coupled with proper accountability.

That accountability is evident in the proposals including:

- a requirement for transparency and proportionality in all that we do
- in the make-up of our Councils – unitary boards, as they will become
- a duty to report on our work to each of the devolved administrations and the UK Parliament.

You can find more information on our response to these in our answers to questions two, three, four and 11.

All of this we welcome. However, while previous proposals* have always emphasised that independence from government is a fundamental principle of regulation, this consultation is silent on the issue. Independence is key to the trust and confidence that the public and professions have in regulation. We believe that in a system of healthcare dominated by the UK's national health systems – four separate state funded providers – it's vital that regulators are able to operate independently of government and all other stakeholders. Instead we must work to balance the legitimate interests of different stakeholders in accordance with our statutory objectives as laid down by the UK Parliament.

We ask that, in its response to the outcome of this consultation, the Government gives an explicit commitment to maintaining the principle of regulatory independence when drafting the legislation underpinning the reforms.

Balancing consistency with public protection

* [Enabling Excellence paras 3.13 and 6.5]

One of the main aims of the reforms is to introduce consistency across regulation. While we support this intention, this cannot be to the detriment of public protection. We are concerned that some of the proposals may risk undermining this in several areas.

For example, we believe that consolidating the grounds for action in fitness to practise cases to just two categories - misconduct and lack of competence - may lead to unforeseen consequences. In particular, it risks undermining our ability to protect the public where a health condition or lack of knowledge of English poses a risk to a doctor's ability to practise safely, but where harm has not yet occurred.

Similarly, we're concerned that the proposals omit an existing provision in the Medical Act (1983) which gives the Registrar ultimate discretion to grant registration, only if they think 'fit so to direct'. Although used in less than 1% of relevant applications, this has provided an additional check to ensure all public protection considerations are taken into account before registration is granted.

For example, it was used in a case where a doctor, who had been out of medical practice for many years, met the basic criteria for registration by passing the Professional and Linguistic Assessment Board (PLAB) test, after multiple previous failures. In that instance, the Registrar's discretion not to grant registration was a necessary exercise of caution in the public interest. The same discretionary power can also be used in an applicant's favour. As the reforms seek to give regulators more operational flexibility and discretion, we'd be concerned if existing discretions were removed.

We also believe that registration criteria must include a requirement for regulators to be satisfied of any applicant's fitness to practise, before they're registered. Our answer to question 34 sets out our full views on the importance of retaining the 'fit so to direct' principle.

Furthermore, in a number of areas, there are specific issues that are unique to medical practice or our registration of it which may require a more tailored regulatory approach to ensure public protection (and may therefore require a different approach to that taken by other regulators). For example, the way that we approve postgraduate medical education and training is specific to us. Our response to question 18 sets out why this needs to be maintained in the new framework. We look forward to further discussions with the DHSC on this, and related issues, in due course.

Focusing on what works

We welcome the proposed new regulatory powers and duties set out in the DHSC's consultation. However, we caution against making any unnecessary changes where the status quo has already proven to be effective and working as intended.

For example, we have existing powers to deal with doctors who refuse to cooperate during a fitness to practise investigation. Between 2016 and 2020 we made 31 non-compliance orders. Without this power, we may not have been able to put in place

measures to protect the public, and patients could have been at risk. The current legal certainty provided by our non-compliance powers mustn't be jeopardised.

Governance and Operating 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.

As we set out in our [corporate strategy for 2021-25](#), we agree that close partnership working is essential for improving working environments and cultures, making them supportive, inclusive and fair for all healthcare professionals.

However, we believe that the duty could go further by promoting and facilitating engagement with non-health related bodies and organisations where this is required to meet our statutory objectives. For example, engaging with the police and independent public reviews and inquiries into care failings. In addition, while we welcome the expectation that we co-operate with others, this can only be effective if there is an equivalent duty on other agencies to co-operate with us.

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

We agree.

We appreciate that the proposals are designed to give regulators more flexibility over our own processes, and to make it easier for us to alter them in response to changes in the UK healthcare systems. We also recognise that increased autonomy and flexibility must be accompanied by greater transparency and accountability, to ensure that we use our new powers appropriately.

While [transparency is already one of our core organisational values](#), these reforms will create a new objective for regulators to be transparent when carrying out their role. This will strengthen existing requirements for transparency in all areas of our work.

We broadly support this proposal and the exceptions to when this objective can't be met – recognising that our legal obligations to individuals may require us to withhold information or conduct hearings in private. For example, where information relates to a registrant's health.

We also support the duty to consult on changes to rules and standards, where it's meaningful to do so. However, we believe that each regulator should be able to determine when it's meaningful to consult, and who should be consulted. Providing this discretion will

enable us to make small changes to our rules and standards in a more proportionate and efficient way. In turn this means that we won't burden our stakeholders by asking them to respond to changes that won't have a significant impact.

The new duties of accountability and transparency, along with the requirement for regulators to assess the impact of proposed changes, will ensure that regulators aren't failing to consult on meaningful changes. In addition, the Professional Standards Authority (PSA), as the body that oversees the work of all regulators, will no doubt wish to satisfy itself that regulators are fulfilling their new duties adequately.

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, providing the assessment is proportionate to the proposed change. Regulators should have the flexibility to determine how best to meet this duty in each case.

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 accept the conclusion of the 2018 consultation *Promoting professionalism, reforming regulation* that existing councils should be replaced by a new governance structure.

We are scoping and developing plans to transition to the new governance structure. We'll publicly consult on the Board's structure and composition, as this will be set out in our future rules. This will ensure our stakeholders, including our registrants, are able to share their views.

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 agree with this proposal.

We're already able to set our own fees without Privy Council approval. This has given us the ability to vary our fees as necessary. For example in 2018, [we reduced our annual retention fee](#) and introduced a fixed term discount for registrants in their first five years of practice.

As we set out in our response to the 2018 consultation *Promoting professionalism, reforming regulation*, we believe that regulators should be accountable for ensuring their fees are appropriate to how they deliver their statutory objectives; and that they deploy their resources efficiently and in a way that's consistent with their responsibilities.

However, any attempt to prescribe, in statute or elsewhere, precisely how regulators must allocate their resources would seriously undermine their independence and operational

effectiveness. It would risk stifling efficiency and innovation, and be at odds with the consultation's aim of giving regulators greater autonomy and flexibility in how they protect the public.

We welcome the flexibility to define an approach to fee setting more broadly beyond the Annual Retention Fee, including the fees that we already charge for other activities, for example, taking our PLAB test.

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. We also agree with the duty to consult on changes to the overall strategic framework within which fees are set; provided we're not also required to consult on individual fee changes made in accordance with the framework.

This mirrors our current approach where we are able to set fees against an agreed framework, without Privy Council approval.

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 agree with this proposal.

It will provide us with greater flexibility to decide which committees we require - and what their composition and constitution should be - without having to adhere to rigid and prescriptive requirements in primary legislation, which, over time, will become out of date.

Although the proposed changes mean that the Medical Practitioners Tribunal Service (MPTS) would no longer be established as a statutory committee, we recognise the ongoing importance of the MPTS's role. We therefore don't propose to change the current model, which provides operational separation between our role in investigating concerns, and the MPTS's role in managing hearings and independent tribunal decision making.

The MPTS would remain a separate committee underpinned by GMC rules setting out its composition and constitution, which would be publicly consulted on. We're also identifying options for the MPTS to continue to report to the UK Parliament, either separately or as part of our annual report process.

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.

This power will allow us to recover some of the costs from our activities outside of the UK. For example, quality assuring overseas medical education and training where it's administered by UK education and training providers. Some of the services that we provide are costly, and at present, we have no power to recoup costs from any of the services that we provide to third parties. Ultimately this means our registrants pay these, through their fees.

9. Do you agree or disagree that regulators should have the power to delegate the performance of a function to a third party including another regulator? Please give a reason for your answer.

We recognise this gives regulators and others across the healthcare systems the opportunity to work together more effectively. It enables organisations to pool expertise to streamline how functions are delivered, recognising that some may require a multi-disciplinary perspective and collaborative approach, in order to strengthen public protection.

While we agree with the proposal, there are likely to be tax implications for some regulators, which may challenge its application in practice.

We believe that the delegating party should retain ultimate responsibility for delivering that function; along with ensuring that a third party or other regulator was carrying out the function appropriately. In addition, before delegation to a third party, appropriate safeguards for equality, diversity and inclusion, human rights, information governance and other impacts, should be in place.

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.

Modern regulation relies on good quality data to inform and shape our own processes, and those of the wider health systems within which we operate. Where it's in the public interest, we already have powers to obtain and share information in our fitness to practise processes. It's important that these are retained.

However, because we have limited ability to collect and share data in other areas of our work, our regulatory effectiveness has been hampered on a number of occasions. It's important this is addressed. We therefore agree that regulators should be able to collect and share a wider range of data than is currently possible. This must comply with all relevant data protection legislation and be done in a way that reflects the legitimate concerns that stakeholders may have about how data is used.

We look forward to further discussions with DHSC about current and future challenges around data collection, and how these might be addressed through the proposed reforms.

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

We agree with this proposal.

Improved autonomy and flexibility for regulators must be accompanied by strengthened accountability. As we set out in our response to the 2018 consultation *Promoting professionalism, reforming regulation*, we believe that should include accountability to the UK Parliament, the Scottish Parliament, the Senedd and the Northern Ireland Assembly.

As health systems in the UK diverge, it will be important for the regulators to continue engaging directly with the four UK administrations and legislatures on issues affecting them. As a regulator with jurisdiction across all four countries we welcome and recognise the need for this. We have offices in Northern Ireland, Scotland, Wales and England and work closely with the governments in each country. We have also given written and oral evidence to committees in the devolved legislatures, and are happy to continue to do so.

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 with this proposal. Each of the healthcare regulators should have the same balance of flexibility and accountability under the new legislation.

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.

We agree that regulators should have the power to set these standards.

Assuring all aspects of education and training is a core function of regulation. It's important that all regulators have powers to set standards in order to ensure consistency in education and training across multi-professional teams.

This proposal would give us uniform powers across both undergraduate and postgraduate education and training. It also supports a more consistent regulatory approach across all levels of training. Having powers to approve specific courses and training programmes

means we'd be able to better target our approach to quality assurance. In doing so, we'd be able to further support medical students to be safe and ready to step into clinical practice.

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.

We agree that regulators should have this power. We believe it's essential for supporting students and trainees to work towards meeting the outcomes that are required of them. We do this through ensuring that they are being taught on courses and programmes that meet agreed standards and are relevant to the needs of patients, the public and the system.

Without the ability to approve, withdraw approval and re-approve we wouldn't be able to ensure that providers are meeting our standards and providing appropriate training for the future workforce.

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

We agree that regulators should have the power to issue warnings and impose conditions.

At present, when education providers fall short of the standards we set, we are limited in the action we can take.

For example, in undergraduate education, we can end recognition of a university entitled to hold qualifying examinations, which would mean that students are withdrawn from the programme. However, we don't currently have powers to impose lesser sanctions which, in some cases, would be more proportionate to concerns that need to be addressed. While it is important, in some cases, to be able to withdraw approval, this can ultimately have a detrimental effect on services to the public. That's why it would only be used as a last resort.

It would be helpful to have a wider variety of tools to help us take more proportionate, targeted and nuanced steps to improve education and training without having to fully remove approval. We currently have 36 postgraduate providers under enhanced monitoring. This means that they're not fully meeting our standards and we are monitoring them closely. A new set of sanctions would allow us to work more collaboratively with providers to drive improvements, and take targeted action to ensure they can achieve our standards over a reasonable timeframe. They'd also mean we could take action in relation to either the course/programme or the provider itself, depending on the nature of the concerns.

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.

We agree that education and training providers should have the right to submit observations that will be taken into account during the decision-making process. We already do this through our existing processes.

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

We don't object to a right of appeal against approval decisions, providing the appeal process is determined by regulators through rules, as they see fit. This will provide transparency and assure a fair process for appellants and regulators alike.

Decisions made about education providers are different from those made in other areas of regulation. Our approval and quality assurance processes involve an ongoing dialogue with organisations to try and ensure that any concerns can be addressed efficiently, effectively and without disruption. This includes ensuring that providers have a chance to offer observations or provide new information to show they've addressed our concerns before any decision is made.

As approval decisions can be a continuous process, it's important that any appeal process sets out clearly defined grounds on which appeals can be made. For example, when the original decision was based on factual inaccuracies.

We agree that the right to appeal shouldn't apply when conditions are attached to an approval. This is because setting conditions will allow courses to continue to be approved while steps are taken to make them safe. We believe that a right of appeal in this instance could mean that the important steps set out in the conditions are not taken by the deadlines imposed, which in turn could risk patient safety. If the conditions are not applied because an appeal has been made, it might exacerbate the issues the conditions were designed to address, necessitating escalation in sanctions to require the removal of trainees.

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 all existing approval and standard setting powers. For example, our ability to approve postgraduate curricula.

We recognise that there are nuances around how postgraduate medical education and training is managed that are specific to the GMC. We're keen to explore these further with the DHSC as we'd like to ensure they're maintained in the new framework.

For example, our current statutory powers for approving trainers are limited to those in general practice. We support the creation of an explicit power to approve all trainers, not just General Practitioner (GP) trainers. This would make our powers to approve trainer roles consistent across all stages of education, and be in line with other regulators who have powers to approve individuals to provide training.

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.

We agree with this proposal.

A number of regulators already have the ability to set and administer exams or other assessments that lead to registration. While we agree that this should continue, we also believe that this should be an express power in all regulators' legislative frameworks.

For example, we already set and administer the PLAB test for overseas qualified doctors to demonstrate they have the necessary knowledge and skills to practise medicine in the UK.

We believe that creating an express power will further support our work to introduce the Medical Licensing Assessment (MLA), creating a common threshold for individuals seeking to practise medicine within the UK. An express power will also give us the flexibility we need to assure ourselves over time that, as models of education, training, healthcare and assessment change, doctors joining the register have the essential knowledge, skills and behaviours to treat patients in the UK.

We would welcome discussing how this power could be flexibly used to support the flow of good doctors into our health services.

We don't plan to introduce a similar assessment for postgraduate training. We believe that the powers we have to approve curricula enable us to ensure safe development of training courses and programmes that meet the needs of the four countries of the UK and our standards. But this power will help to future-proof the legislation and provide flexibility around any developments in postgraduate medical training over the coming decades. We therefore believe it should apply across both under and postgraduate education, to ensure consistency across our powers.

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.

We disagree with this proposal. We think that regulators should be able to set and administer an assessment embedded within a course or programme that leads to registration or annotation of the register. We believe that we have an existing implied power to do this. As such it should be expressly recognised in the new regulatory framework.

We understand that there's a desire to ensure providers of approved courses or training programmes remain independent, with autonomy over their qualification awarding powers. But we believe it's possible to balance this wider independence and autonomy while still allowing regulators to set an assessment as part of the education and training that leads to registration or annotation of the register.

This would introduce a core element for entry to, or annotation of, the register that's common and standardised, but would still allow for diversity. Furthermore, it would complement a power to set a standalone test outside of the course or programme of training.

For example, expressly recognising our implied power to embed a test within a medical degree would help ensure that all UK graduates can meet a common threshold for safe practice for entry to that particular profession, which could in turn lead to improved standards over time. It would offer a number of similar benefits to the power outlined at question 19 by:

- providing us with the flexibility and agility to respond swiftly to future patient, public and service need
- allowing us to act autonomously and independently to regulate the gateway needed to enter the medical profession
- providing the foundation for us to develop an evolved MLA, which assesses all the outcomes we expect of a new doctor, rather than the core areas for safe practice, as a way to more confidently and assuredly move the point of full registration.

In addition, it would provide other benefits, including:

- avoiding double jeopardy issues (whereby students would need to pass their degree and then take a registration assessment) and thus smooth the flow of doctors into practice,
- a standardised approach towards policies such as the number of attempts allowed for an exam,
- a focus on doctors' readiness for practice rather than graduation, for example forward looking into clinical practice rather than an exam for graduating

- an independently standard-set core exam within a medical degree for increased confidence and assurance for ourselves, patients, public and employers,
- reduced variation in approach, including in candidates' experience – enhancing fairness
- mitigating concerns about assessment burden and additional costs.

As with our answer to question 19, we don't have any plans to introduce any sort of similar assessment for postgraduate training. We believe that the powers we have to approve curricula enable us to ensure safe development (of training courses and programmes that meet the needs of the four countries of the UK and our standards). Providing this power will help to future-proof the legislation and provide flexibility around any developments in medical training over the coming decades, as well as ensuring consistency in our powers, so we believe it should apply across both under and postgraduate education.

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.

We agree with this proposal.

Greater flexibility in how we assess training enables a more efficient use of resources. It supports a more proportionate approach to quality assurance depending on the specific needs of different organisations. It would also allow action to be targeted where the evidenced risk arises, reducing the burden on training providers.

22. Do you agree or disagree that the GMC's duty to award CCTs should be replaced with a power to make rules setting out the procedure in relation to, and evidence required in support of, CCTs? Please give a reason for your answer.

We agree with this proposal.

We want to ensure regulators have the flexibility to respond to changing needs. This is best achieved by making the awarding of all certificates, not just Certificates of Completion of Training (CCTs), a power rather than a duty.

While we have no plans to change the current process for awarding CCTs on completion of postgraduate training within the UK, we welcome the flexibility to review our approach in future if the situation requires it, subject to consultation.

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.

We agree that regulators should be able to set out their continuing professional development (CPD) and revalidation requirements in rules and guidance.

Regulation of approved learning is important, but only covers part of the training and learning that happens within the health service. Supporting and ensuring high standards for life-long learning, and evidencing this through revalidation, is equally essential.

As the delivery of healthcare, and the environment in which it is provided continues to evolve, it's important that regulators have the flexibility to revise requirements for CPD and revalidation through rules and guidance.

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 are neutral on this proposal.

If we're required to hold a single register, as opposed to separate registers for Anaesthesia Associates (AAs), Physician Associates (PAs) and doctors, there may be some challenges for those who are dual registered.

We'll need to find a clear way to show that an individual is registered in more than one part, in a way that does not cause confusion for patients and employers. This will be particularly important where individuals have restrictions on their practice relating to one or more parts.

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 that all regulators should be required to publish this information about their registrants. This will standardise the information that employers and members of the public can find out about healthcare professionals who treat them.

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 that regulators should be given a power allowing them to collect, hold and process data when it's in pursuit of their statutory objectives.

We're able to require certain information as part of our fitness to practise processes, but we believe that similar powers are needed across our functions to support us to deliver our statutory objectives. Any such power must be consistent with all data protection legislation.

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

We agree that regulators should be given a discretionary power that allows for the publication of specific data about registrants, in line with the General Data Protection Regulation (GDPR).

The Medical Act (1983) already requires us to collect and publish certain information about our registrants. It also gives us discretion to publish additional information. Therefore, this proposal won't fundamentally change what we already do in this area.

However, if we decide to use this discretion to collect and publish additional information in the future, we'd set this out in statutory rules, which would be first subject to public consultation. For example, we may wish to use this power to indicate whether or not a PA has prescribing rights if the DHSC give PAs the ability to prescribe.

Any publication of data would comply with all relevant data protection legislation.

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 that regulators should have the ability to annotate their registers to provide further information about registrants. Annotations will enable us to do this in a clear and accessible way. For example, it will allow patients, employers and members of the public to see if registrants have restrictions on their registration, or whether they can undertake additional roles because they've demonstrated specific qualifications, skills, knowledge and experience.

However, we believe that the use of annotations shouldn't just be limited to public protection. They should also be used to support our wider statutory objectives. For example, it may be helpful to show who is an approved trainer. This type of annotation would be relevant to employers, even though it may not directly protect the public.

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

We agree that all regulators should be given a permanent emergency registration power.

We already have this power. Its inherent flexibility enabled us to respond quickly and decisively to the coronavirus (COVID-19) pandemic, supporting us to give temporary emergency registration to over 35,000 doctors in 2020.

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 that all regulators should have the same offences. This will provide greater consistency and help regulators to protect titles.

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.

We are supportive of the expansion of our powers in relation to protection of title, but we disagree that the protection of title offences should be intent offences. Proving intent has a very high threshold that's difficult to evidence. Since we started recording the outcome of illegal practice investigations in 2015, we've dealt with numerous cases where we've been unable to persuade police to take action against individuals because of concerns about the ability to demonstrate intent.

Most concerns referred to us involve individuals running private clinics offering cosmetic procedures, of which there is limited regulation. The current threshold of 'intent' means there must be proof that the individual calling themselves 'doctor' meant patients to believe they were registered with us. However, we know from experience that patients who've been harmed through such procedures are often vulnerable. There can be complex reasons why they're reluctant to come forward and report what's happened. This makes gathering evidence very difficult and can mean the police are reluctant to investigate concerns.

We feel that a threshold of 'recklessness' is more in the interests of public protection, particularly when considering the independent nature of clinical practice compared to other professions.

Adopting this test would require the individual under investigation to have behaved recklessly in such a way that a patient would reasonably have assumed them to be registered even though they were not. We believe that this change would result in more visible outcomes in such cases. We'd also welcome the opportunity to discuss with the DHSC a separate offence for individuals who've previously been erased from our register

for fitness to practise reasons but continue to engage in medical practice. These individuals pose a significant threat to patient safety. We'd welcome simplification of the legislation to make it easier to secure a prosecution.

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 that all regulators should have the same powers to appoint a deputy and/or assistant registrar. This will ensure greater consistency between the regulators.

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 that regulators should be able to set out their registration processes in rules and guidance, as appropriate. We support the proposed criteria to be included in the legislation but also want to see the term *fitness to practise* specifically included, rather than as an additional criterion that the regulator may set through rules should it wish to do so. We do not believe that this should be an optional requirement, nor the terminology changed.

Fitness to practise is a well understood construct across the medical profession, is linked to the reform of regulation since 2004 and has a significant weight of case law to support its use. The current requirement to complete a fitness to practise declaration is critically important. It enables us to refuse to register any applicant who meets the criteria but whose non-medical conduct, for example criminal history, would diminish public confidence or call into question professional standards. Our view is that this should be retained as a mandatory requirement given that public protection is a fundamental statutory objective for all regulators.

34. Should all registrars be given a discretion to turn down an applicant for registration or should applicants be only turned down because they have failed to meet the new criteria for registration? Please give a reason for your answer.

We believe that granting or refusing registration should be at the discretion of the regulator, having regard to our overarching duty to protect the public.

Currently, we have a process of final registrar discretion through 'fit so to direct' (FSTD). This has been running, without controversy, for many decades. And the PSA has routinely concluded that we have sufficient measures in place to assure the quality of our registration decisions and processes.

We understand, from paragraph 192 of the consultation document, that granting registration is intended to be discretionary rather than an entitlement. To fulfil this aim,

the FSTD provision needs to be retained in legislation. Otherwise regulators would be obliged to grant registration when an applicant fulfils the criteria listed in paragraph 192.

The FSTD provision allows the Registrar to consider issues of concern that sit outside the main registration criteria. We use it in a balanced and proportionate way in the interests of patient safety to ensure only doctors who are safe to practise are granted registration*. Between 2014 – 2019 less than 1% of applications we received were referred for a FSTD decision. 8% of these were appealed. Of those, the decision to deny registration was upheld in 90% of cases. Removing FSTD could lead to a perception that we are prioritising applicants over our statutory duty to protect, promote and maintain public safety.

35. Do you agree or disagree that the GMC’s provisions relating to the licence to practise should be removed from primary legislation and that any requirements to hold a licence to practise and the procedure for granting or refusing a licence to practise should instead be set out in rules and guidance? Please give a reason for your answer.

We agree with this proposal.

We propose to manage the licence to practise as an annotation. Any doctor on the register who already holds a licence will have it automatically converted into a licence annotation. Doctors will still be able to relinquish their licence if they don’t need it and restore it if they’re returning to clinical practice – with this indicated on the register as an annotation.

Setting this out in rules and guidance will allow us the flexibility to alter our approach over time if circumstances require it.

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.

This would be a proportionate way of managing issues that could be easily resolved by temporarily ‘pausing’ someone’s registration, until requested information has been provided, or a fee has been paid.

For example, if a registrant fails to provide evidence of appropriate and adequate insurance and indemnity cover, or if they haven’t paid their annual retention fee, our only option is ‘erasing’ them from the medical register. This means that an applicant would

* For example, in 2019, 118 applicants were referred for Registrar decision under the FSTD provision; 45 applicants were granted registration and 40 refused. The remaining applications were closed, withdrawn or not eligible at the time the decision was made.

have to re-start the application process, which can be time-consuming and resource intensive.

We would prefer the phrase 'administrative exclusion' to be used to distinguish this process from the ability to suspend under our fitness to practise processes.

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 that regulators should be able to set this out in rules.

We already have rules setting out our approach to all types of voluntary removal, including when a doctor applies to leave the register when they're under a fitness to practise investigation. We propose that our rules continue to require a fitness to practise decision maker to decide any application for removal from the register when there's a question about the applicant's fitness to practise. They'll also be able to deny the request if it's necessary to protect the public.

While we support the criteria listed in paragraph 208, we don't support the expansion of administrative removal for health or English language concerns where a registrant is no longer safe to practise. We believe that if there's a concern that suggests a registrant is not safe to practise, this should be considered through our fitness to practise processes and we welcome the DHSC's recent clarification that it won't take forward administrative removal for health or English language concerns which won't meet the fitness to practise threshold.

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

We believe that paragraph 214 of the consultation document captures all the necessary registration appealable decisions. However, we'd welcome further discussion with the DHSC to clarify which refusal decision the new registration appeal right against 'not granting a person voluntary removal from a regulator's register' attaches to.

39. Do you agree or disagree that regulators should set out their registration appeals procedures in rules or should these be set out in their governing legislation? Please give a reason for your answer.

We agree that regulators should set out their registration appeals procedures in rules. We already have a registration appeals process set out within our rules. This provides registrants with the option to appeal decisions that affect their registration and licence to practise.

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 agree that regulators should not have discretionary powers to establish student registers. It's vital that regulators are able to assure the standards of those eligible to enter and practise the profession. While regulators will want to be assured that prospective registrants receive appropriate education and training to enter professional practice, it's inappropriate and disproportionate to regulate individual students who've yet to qualify.

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 therefore agree that regulators should not have powers to establish non-practising registers. The purpose of regulation is to provide assurance about those who are practising their profession. It should not be the role of regulation to establish registers specifically for those who are non-practising.

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.

This means that we will be able to remove elements of international registration legislation that are overly prescriptive. For example, the criteria and requirements for overseas qualified doctors applying for specialist and GP registration. Removing these will allow us to develop a new annotations rules and standards framework for the specialist annotations that will replace the specialist and GP registers.

We've been advocating for this change for some time following reviews into our specialist and GP registration, and associated processes.

The new framework will reflect the same approach we have for full registration for international doctors. It will be consistently applied to all applicants regardless of where they obtained their specialist qualifications. An applicant will need to demonstrate they have the skills, experience, and knowledge to be capable of safe and effective practice as a GP or specialist.

This change will mean that we can streamline the existing Certificate of Eligibility for Specialist Registration (CESR) / Certificate of Eligibility for General Practice Registration (CEGPR) process and develop new pathways for applicants to apply for a specialist annotation. We'll also be able to merge the specialist and GP registers into a single specialist annotation where general practice will be included on the list of specialties.

Fitness to practise

43. Do you agree with our proposal that regulators should be given powers to operate a three-step fitness to practise process, covering: initial assessment; case examiner stage; fitness to practise panel stage?

We agree that regulators should be given powers to operate a three-step fitness to practise process. It is a proportionate and effective model that's focused on retaining public protection, while supporting a less adversarial and more flexible model for dealing with fitness to practise concerns.

We believe it provides a clear and consistent process for those who raise concerns and for registrants to understand – for example:

- 1** The initial assessment stage will enable regulators to quickly determine which complaints they need to act on to protect the public, and which can be better dealt with locally or by others. We'll be able to focus our resources on those that require our intervention, taking swift action where necessary for the benefit of those who've raised concerns, and for registrants.
- 2** The case examiner stage will enable regulators to decide the necessary outcome to protect the public, and provide registrants with the opportunity to accept this, through the process of accepted outcomes. This will enable us to take swifter action to protect the public, while minimising the impact of our processes for those who've raised concerns, registrants, and others involved in the case such as experts and witnesses.
- 3** The fitness to practise panel stage will occur when registrants don't accept the measure we determine is necessary to protect the public, or where the case examiner is unable to make a decision on the written evidence alone.

This model allows us to respond more quickly and proportionately to concerns, adapting our approach to that which will best protect the public.

44. Do you agree that all regulators should be provided with two grounds for action – lack of competence, and misconduct?

We disagree with this proposal.

While we agree that grounds for action should be consistent across regulators, we don't believe that these should be reduced to only two grounds for action – lack of competence and misconduct. We question the rationale for such a significant change, without strong evidence that the current grounds for action, known as heads of impairment, are ineffective at enabling regulators to protect the public. We think consistency across regulators and clarity for the public could be achieved by providing regulators with aligned grounds for action that aren't limited to the two proposed.

We consider that removing separate grounds for action for both health and English language is a significant risk. We also think there are risks from the proposals for all types of cases.

The Law Commission extensively considered and publicly consulted on the best approach to grounds for action in its report in 2014* which we feel should continue to hold significant weight in this area. This concluded that adverse health as a separate ground should remain[†] and identified as a 'desirable reform' the creation of English language as a separate ground for action[‡] (para 7.17), The reason for this was so that regulators have powers to investigate language concerns '*before instances of deficient performance occur*'. English language, as a separate ground, was introduced for the GMC in 2014. Since then, we've successfully relied on this provision to protect the public.

The role for regulators in cases relating to convictions/cautions or determinations by other bodies is not to re-punish a registrant, but to have regard to the fact of a conviction/caution or determination when deciding on impaired fitness to practise. Currently, regulators can treat the existence of a conviction/caution or determination as sufficient evidence that the offence was committed or the facts behind the determination proved. If convictions/cautions and determinations are included under the misconduct ground for action, there could be more onus on regulators to go behind these to reprove the facts.

To meet the threshold for misconduct, regulators will need to demonstrate that the facts found proved, amount to a serious departure from the standards expected, before the question of impairment is considered.

This is particularly important for cases that relate to foreign convictions or determinations by other bodies that could be very difficult, if not impossible, for regulators in the UK to gather information on.

The proposal could raise the threshold for a finding of impairment and action in convictions/cautions or determinations cases. In turn this could impact on a regulator's ability to protect the public and the public's confidence in healthcare regulators. It could also make the process more adversarial, increase the length and complexity of investigations and hearings (if required).

Overall, we don't feel a clear rationale, including tangible benefits that outweigh the associated risks, has been provided for this proposal. We're concerned it could unintentionally redefine the meaning and scope of fitness to practise, which could significantly impact public protection.

* Regulation of Health Care Professionals; Regulation of Social Care Professionals in England
<https://www.lawcom.gov.uk/project/regulation-of-health-and-social-care-professionals/>

[†] Para 7.18-7.19

[‡] Para 7.17

- **Do you agree that lack of competence and misconduct are the most appropriate terminology for these grounds for action?**

We don't agree with the underlying principle that two grounds for action is the preferable approach.

If this is ultimately the approach adopted, we would urge the DHSC to clearly set out the parameters of the revised grounds so that regulators, registrants and the public have certainty as to what types of concerns would be included under each ground.

Case law around the current heads of impairment is extensive and well settled, particularly for misconduct and deficient professional performance. The proposals aren't detailed enough for us to understand how existing case law relates to the two grounds for action, and what concerns would be included under each ground for action. Therefore, it isn't possible to determine whether the proposed terminology is appropriate.

- **Do you agree that 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?**

We disagree with the proposal and don't support the removal of separate grounds for adverse health and English language from the legislation.

To protect the public, regulators must be able to take action to address a risk to the public before harm or specific clinical incidents have occurred. This is particularly relevant for cases related to a registrant's adverse health or lack of knowledge of English language, where we know that concerns can give rise to risks which could be managed before any harm occurs. We'd be concerned if we were only able to take action in these cases where we had evidence of harm having occurred either through a performance/competence or misconduct concern.

For example, currently, to investigate concerns about a registrant's knowledge of English language, they're required to take a language assessment and achieve a specific standard. Not achieving that standard, is primary evidence of fitness to practise impairment under the current English language head of impairment. However, the consultation proposal means a regulator must show that the registrant's English language difficulties mean they're impaired due to lack of competence.

We believe this approach could limit regulators ability to investigate concerns to only those where competence/performance issues have already occurred because of the registrant's language/health. This could be mitigated, to an extent, by adopting a broad definition of 'lack of competence' so that it clearly includes cases where a registrant's unrestricted practice poses a real risk of harm. However, even with this step, we still think that the proposal is likely to generate significant challenge and may make the process more, rather than less, adversarial.

Similarly, the approach could make it more difficult to obtain the evidence necessary to demonstrate impaired fitness to practise. In the case of English language, given that the language assessment doesn't assess an individual's language skills in a professional capacity, the regulator could be open to challenge that this evidence alone isn't sufficient to demonstrate impairment by reason of lack of competence. This would therefore require the collection of additional evidence to demonstrate that English language concerns are affecting the individual's competence and/or performance. This generates inefficiency and additional burden for all those involved in the fitness to practise system, and would reduce our ability to take swift action to address concerns which present a risk to the public.

We appreciate that there are finely balanced arguments about the parameters of regulatory action in respect of an ongoing health condition, especially where there are considerations relating to protected characteristics under the Equality Act. We believe that our current approach strikes an appropriate balance in this respect. Action is only taken where a health condition poses a risk to a doctor's ability to practise safely, and in recent years we've carried out significant work to ensure that cases involving health concerns are dealt with in a sensitive and proportionate way. Labelling an unwell registrant as having a lack of competence, would be a step backwards in our approach to sensitive handling of concerns about health matters.

Finally, the removal of separate grounds for adverse health and English Language would also remove the current statutory protection in place that means we cannot remove a registrant from the register where they are found to be impaired solely for adverse health or English language concerns.

- **This proposal provides sufficient scope for regulators to investigate concerns about registrants and ensure public protection?**

We disagree with this proposal as we believe it risks reducing regulators' ability to investigate concerns about registrants and protect the public.

It's vital we're able to act where there's evidence that a registrant poses a risk to patients, before harm occurs or competence issues emerge. We're not satisfied that the proposal provides sufficient scope for regulators to investigate concerns and ensure public protection. Without a separate legal basis for regulatory action, a broad definition of 'lack of competence' may provide more scope for investigation, particularly for health and English language concerns. However, any reform must explicitly protect regulators' ability to take proactive, proportionate action before harm occurs where there's a real risk to the public. We've provided more detail on this risk in our answers above.

We don't think sufficient evidence has been provided to demonstrate that any benefits of a model based on two grounds for action outweigh the risk of creating legal and evidential barriers to regulators investigating, and acting promptly, to protect the public.

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 reasons for your answers.

We agree that all measures should be made available to both case examiners and fitness to practise panels. We note that the proposals include a defined timeframe of two years for publishing warnings. While we don't disagree with the timeframe, it would be helpful for the DHSC to clarify the rationale for including this in primary legislation.

We agree that automatic removal orders should be available if a registrant has a conviction for a listed offence. This has been our long-standing policy aspiration since 2014 when it was recommended in the Law Commission's report *Regulation of Health Care Professionals, Regulation of Social Care Professionals in England*. This would better support public protection and public confidence where registrants have a criminal conviction for the most serious offences. It would also reduce the impact on patients and witnesses who may otherwise be expected to attend a public hearing.

We discuss this proposal further in our response to question 52.

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

We support a simplified approach to reviewing measures. We agree that registrants should be able to request an early review of a measure, and for this process to be set out within a regulator's rules.

We'd expect the powers available to case examiners and fitness to practise panels would be to revoke, amend, extend, amend and extend, or substitute a new measure. But we'd welcome further clarification from the DHSC on this point.

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 the proposed notification provisions. It's important that both registrants and complainants are kept up to date on the progress of a fitness to practise investigation at key decision points. However, there may be times where the information we're able to provide is limited, such as where health concerns can't be shared. We also believe the proposal will enable us to share appropriate information about a fitness to practise investigation with the registrant's Responsible Officer and employer(s).

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 have discretion to decide whether and how to investigate a concern. The proposal gives regulators appropriate and proportionate powers to be able to target our activities, allowing us to reach swift and effective outcomes to protect the public. This also enables us to build on our successful provisional enquiries model, where we carry out a limited investigation of a complaint to determine whether a full investigation is needed.

We currently have to undertake prescriptive investigation steps for every allegation that a registrant's fitness to practise is impaired, even where it's clear that no regulatory action will be required. Providing us with discretion to investigate would minimise the unnecessary burden on registrants, those who raise concerns and others involved. It will also provide greater clarity about when we may and may not need to investigate concerns.

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 agree with the proposed removal. The five-year rule, as set out in our current legislative framework, has been an ongoing source of frustration for many complainants. This rule was highlighted by the Paterson Inquiry and the Independent Medicines and Medical Devices Safety Review in 2020 as a potential barrier to public protection. We believe that cases should be investigated on the merits of evidence and the risk to public protection, not an arbitrary time-limit, and support removal of the rule as part of the wider changes being proposed.

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

We strongly support separate powers to address non-compliance. Cooperating with formal inquiries and complaints procedures, and engaging with your regulator, are core principles of professional standards and regulation*.

Our non-compliance powers were introduced in 2015. They enable us to take action when a doctor refuses to cooperate with an assessment or comply with a request to provide information and that refusal prevents us from carrying out the investigation needed to determine if their fitness to practise is impaired. As this gap presents a significant patient safety risk, it's vital that our powers in this area are maintained. They are a proportionate and effective mechanism to protect the public. Between July 2016 and December 2020, 31

* Good Medical Practice paragraph 73

of 37 non-compliance cases heard by the MPTS concluded with a finding of non-compliance, and either conditions or suspensions were put in place to address a risk to public protection.

In an adverse inference model, a panel has the power to draw an adverse inference where a registrant hasn't complied with a direction or request for information. But this forms only one part of the overall evidence that a panel uses to make their decision on the case and a finding of impairment. There's a real risk that the regulator may be impeded from obtaining sufficient evidence to meet the test for a panel referral on the grounds of impairment. In cases where a panel referral can be made, there's a risk that the panel may not feel able to draw an adverse inference from the registrant's failure to comply, or they may not feel able to attribute enough weight to the adverse inference to make a finding of impairment to protect the public.

This leaves the regulator unable to protect the public as a result of the registrant obstructing the investigation process by not complying with the core principles of professional regulation.

Under an adverse inference model, we may not have been able to protect the public in the 31 cases highlighted above. It's also important to note that we faced challenges in successfully prosecuting these types of cases before we obtained our non-compliance powers in 2015.

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 registrants should be offered an opportunity to provide written submissions ahead of the decision to refer a case to a case examiner. We also agree that registrants should have an opportunity to provide written submissions at any point during an initial assessment. And, we support the power for regulators to seek written submissions from the person who raised the concern, where appropriate.

We are supportive of the need for regulators to make rules in this area, including the proposals for what the rules need to include.

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.

As we outline in our answer to question 45, we agree that regulators should be given a new power to automatically remove a registrant from the register if they've been convicted of a listed offence.

We agree that the powers should take the same form as those in the Social Work England framework. We also agree that the list of offences should not include convictions for gross negligence manslaughter (GNM).

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?**

We agree that case examiners should have the full suite of measures available to them, including removal from the register. Regulation exists to protect the public. Where a registrant is willing to accept a measure proposed by the case examiner, public protection is achieved in a less adversarial way. Resolving cases through accepted outcomes enables swift and effective action to protect the public. It also brings a quicker final resolution for the person who raised the concern, and the registrant.

Where there's a dispute between a registrant and the case examiner, or where a case examiner isn't able to make a decision on the basis of written submissions, a fitness to practise panel will make a determination on the case and impose measures.

- **make final decisions on impairment if they have sufficient written evidence and the registrant has had the opportunity to make representations?**

We agree with this proposal.

The ability for case examiners to make a finding of impairment is essential to them being able to propose a final measure. It will support the process for registrants to accept final measures that restrict their ability to practise meaning that cases can be resolved in a swifter, less adversarial way.

To decide on impairment, case examiners must have sufficient written evidence. The registrant must also have an opportunity to make representations.

To ensure this is a clear and fair process, case examiners will make decisions based on the same assessment of impairment that fitness to practise panels use. This consistency will give registrants and the public confidence that case examiner decisions are as robust as those made by fitness to practise panels, and that the public is equally protected through both processes.

- **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?**

We strongly support proposals for case examiners to conclude cases through accepted outcomes. It is important to note that the accepted outcome process is not a negotiation

between regulator and registrant, and the case examiner will propose the measure necessary to protect the public. We agree that within the process for offering registrants accepted outcomes it is right for a registrant to agree to both the case put to them (including a finding of impairment) and the proposed measure to ensure a robust process that the public can have confidence in.

- **be able to impose a decision if a registrant does not respond to an accepted outcomes proposal within 28 days? Please give a reason for your answers.**

We agree with this proposal. Where a registrant isn't engaging with the fitness to practise process by not responding to a case examiner's accepted outcome proposal, this shouldn't impede a regulator's ability to put measures in place to protect the public.

When applying this proposal, the regulator should make all reasonable efforts to notify the registrant of the case examiner's decision. The information they provide must enable the registrant to understand the consequences of not responding.

This process would only apply where the registrant has previously been informed of decisions at key stages of the fitness to practise investigation, before they're notified of the case examiner's accepted outcome proposal.

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 with the proposed powers in principle but would welcome further clarification on some areas. There are benefits in a model for interim measures that's consistent across all health and care professional regulators. We also support the extension of our current powers - for interim measures and reviews of interim measures - to case examiners using the accepted outcome process.

We aren't opposed to a new registrant right of appeal against an interim measure imposed by an interim measure panel, or fitness to practise panel, (to the High Court in England and Wales, the Court of Session in Scotland or the High Court in Northern Ireland) providing the measure stays in effect during the appeal period, and until the determination of any appeal. This ensures that public protection is maintained throughout the entire appeal process.

We'd welcome greater clarity from the DHSC on the suggestion that regulators shouldn't be required to wait for written submissions before an interim measure comes into effect. We're unsure of the benefits of this proposal, and we're not sure how this power would be used in practice, especially as we understand that an interim measure proposed by a case examiner will only come into force if agreed by the registrant. We think it would be more effective to provide regulators with the power to set, on a case by case basis as necessary, a period that it considers reasonable for a registrant to provide written submissions. This would enable cases to be heard swiftly where it's necessary to protect

the public. It would also provide registrants with an opportunity for written submissions to be considered.

We're unclear whether the consultation proposes a duty or a power for regulators to be responsible for notifying the person who raised a concern about interim measures decisions. Paragraphs 286 and 289 indicate it would be a duty, because a regulator would be required to notify the person who raised a concern about interim measure decisions. In contrast, paragraph 333 indicates it would be a power because it suggests the regulator 'may' inform the person who raised the concern. We don't object to either approach, however it would be helpful for the DHSC to clarify the proposal.

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 that regulators should determine, in rules, the details of how the fitness to practise panel stage operates. This would provide the flexibility and autonomy that the reforms aim to deliver. It means we'd be able to adapt and improve our processes, subject to public consultation, over time. This would enable us to reflect societal change, to address emerging gaps in public protection, or to introduce improvements to support those who've raised concerns, registrants or others involved in the fitness to practise process.

We agree with the proposal, in paragraph 345, to require regulators to hold fitness to practise hearings which are accessible. We believe this should include virtual hearings. However, we think it would be appropriate for regulators to be provided with enforcement powers if information from public hearings, held virtually or otherwise, was used inappropriately. We note that these powers are available to courts and tribunals.

Several powers related to the running of fitness to practise hearings aren't covered by the consultation document but are currently provided for in our primary legislation. These include:

- case management powers
- powers for preliminary hearings
- enforcement powers, including powers to award costs, make adverse inferences, and exclude evidence.

It would be helpful for the DHSC to confirm that the new legislative framework will provide regulators with these powers, or enable regulators to make rules covering these areas, to ensure that we can continue to modernise adjudication processes.

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'd welcome clarification on some areas. We recognise that registrant rights of appeal are proposed for decisions where:

- an outcome is imposed on a registrant - including non-responding decisions by a case examiner
- interim measure decisions are made by an interim measure or fitness to practise panel
- decisions are made by fitness to practise panels where they've found a registrant's fitness to practise to be impaired, and a measure has been imposed.

We're less clear about the rationale for giving registrants a right of appeal where they've already agreed an outcome with the case examiner through the accepted outcome process. We think this could undermine a regulator's acceptance of a proposed measure, which risks reducing the public's confidence in the accepted outcomes model, thereby undermining the DHSC's objective for introducing the accepted outcome process.

In addition, we'd welcome greater clarity on how a registrant's right to appeal an accepted outcome interacts with a right for them to also request a review of a case examiner decision, under the Registrar Review proposals. We'd be concerned if there were two different routes available for a registrant to challenge the same decision, as this could be confusing to the public and registrants as well as being legally and operationally complex to manage.

The proposals don't include a timeframe within which a registrant could lodge an appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland. We assume it would be 28 days, which is the current timeframe for registrants, and that it would be included in the primary legislative framework. However, it would be helpful for the DHSC to clarify this.

The proposals don't include information about the grounds on which a registrant can appeal an automatic removal, following a criminal conviction for a listed offence. We note that the Social Work England regulations limit appeals against automatic removal on the grounds where a determination was based on an error of fact or of law*. We'd support a model with the same limited grounds for appeal, given the administrative nature of the determination being appealed.

* Social Workers Regulations 2018, regulation 27(1)

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.

We don't object to this being 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. We recognise this is consistent with our current framework for most appeals.

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 that regulators should have flexibility to set rules, subject to public consultation, to enable us to adapt and improve our process over time.

While the consultation doesn't refer to powers for restoration decisions, we assume case examiners and fitness to practise panels would have powers to approve or reject applications for restoration; and for the regulator to request further information and gather evidence where this is required.

The proposals don't reference our current power to indefinitely suspend a registrant's ability to make further restoration applications. It would be helpful for the DHSC to clarify its position on this.

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.

We don't object to this proposal. However, we don't think a two-stage appeal model is needed. Our preference is for a direct right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland.

An additional internal appeal stage isn't proportionate, or consistent with the registrant appeal model for the rest of fitness to practise decisions. We don't believe the two-stage model has clear benefits, and as such it would cause unnecessary confusion for registrants and the public. The consultation also doesn't mention the grounds or timeframe within which a registrant could lodge an appeal against a decision not to permit restoration to the register. We'd expect that both areas would be included in the primary legislation.

In our answer to question 58, we noted that the proposals don't mention our existing power to indefinitely suspend a registrant's ability to make further restoration applications where that registrant has made a second unsuccessful restoration application. If this ability is retained, we'd also expect a registrant's current right of appeal against that decision to be provided for in primary legislation. It would be helpful for the DHSC to confirm its position on this.

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.

We don't object to the proposal for rights of appeal to be to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland and recognise that this is consistent with our current framework for most appeals.

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 agree that the Registrar Review power provides sufficient oversight of decisions made by case examiners, including accepted outcome decisions.

It provides a proportionate mechanism for regulators to be able to review decisions. This will enable us to put things right, where necessary, through a process that's swifter and less adversarial than an appeal route.

It also provides effective oversight of decisions made by case examiners, although it's only one of several components that will provide oversight of case examiner decisions. Decisions by case examiners will be published, as panel decisions are. Regulators already have well established internal quality audit processes. In addition, they'll commission independent third-party audits, and be subject to both audit and annual performance review by the PSA.

We've used a similar Registrar Review power in our current procedures for many years. The approach is simple, easy to access and is well used by patients.

We agree that the current framework can be extended to cover the broader range of accepted outcome decisions made by case examiners. We also note the recent publication of the PSA's Review of Social work England's process for 'accepted outcomes' in fitness to practise cases. While this identified learning points to further improve the accepted outcomes process, the audit concluded that the process saved time and reached appropriate outcomes (while noting that certain types of cases - where facts were disputed - should be referred for adjudication).

Swift, conclusive, fitness to practise decisions are important to public protection but mistakes can happen. When this occurs, it's important they're put right quickly and effectively. We're concerned that the proposals don't include a timeframe for requesting a review of decisions under the Registrar Review power. We think it is essential that reasonable and proportionate timeframes are set. It would be helpful for the DHSC to clarify its policy intention, as the timeframe for requesting a Registrar Review could significantly impact how far the power meets the principles we have set out above.

We're also concerned about the interaction between this proposal, and the proposal for a registrant right of appeal against an accepted outcome measure that they've previously agreed with a case examiner. As we highlighted in our answer to question 56, we don't think there should be two different routes for a registrant to challenge the same decision. This could be confusing to the public and registrants, as well as being legally and operationally complex to manage. The proposals should specify a single route for a registrant to challenge an accepted outcome.

We note that interim measure decisions by case examiners are included within the scope of registrar review provisions. We question whether this is necessary given that registrants are able to request an early review of an interim measure.

62. Under our proposals, the PSA will not have a right to refer decisions made by case examiners (including accepted outcome decisions) to court, but they will have the right to request a registrar review as detailed above. Do you agree or disagree with this proposed mechanism? Please provide any reasons for your answer.

As we set out our response to question 61, we support the introduction of accepted outcomes noting that the proposals are designed to establish a less adversarial fitness to practise process and a proportionate mechanism for effective public protection.

We agree that anyone, including the PSA, should have the right to request a Registrar Review if they are concerned about the outcome of the investigation.

Effective internal review procedures are good practice and routine in a range of public bodies, reducing recourse to the Courts, and promoting confidence in administrative and other public body decision making. They also provide direct access for patients and the public unlike appeals to the Courts in which individuals play no part. We have used a registrar review process since 2004, where patients are able to request a review of cases closed during the initial assessment (Triage) and for cases that are closed, with no action, following investigation. The process works well and since 2013 (we do not have data for before this point) we have received 4,136 requests for review leading to 305 decisions being reopened.

Over the past ten years, we have introduced a series of measures to further support complainants throughout our procedures. This includes the introduction of our Patient Liaison Service in 2015 to provide an opportunity to explain our investigation process and subsequent decision, as well as any questions the complainant may have. We have used these meetings to gather learning about how our procedures meet the needs of patients and the public and to drive improvement, for example, a joint campaign with Mencap to improve the understanding of doctors about treating patients who lack mental capacity and a range of improvements to how we respond to complaints about their care. This service will also be able to meet with patients to explain in detail any accepted outcome decisions and the right to request a Registrar Review of that decision. And we will also consider expanding the PLS to accommodate this if required.

We believe that the Registrar Review, together with our wider quality assurance processes referred to in our answer to question 61, provides the right framework for scrutiny and challenge of decisions made by case examiners, and we do not believe that there is a case for a specific PSA right of appeal which would replicate the lengthy and bureaucratic Court processes that the reforms are seeking to reduce. Providing a right of appeal, as well as the right to request a review, could increase the time it takes for patients to get a resolution to their complaint. It may also increase the frequency of more adversarial panel hearings if registrants are less willing to agree an accepted outcome due to the risk of a prolonged appeal.

We agree that it is essential that the accepted outcomes approach holds the confidence of all stakeholders as a robust and fair system, and that we review and learn from experience in its use. We would expect the existing arrangements for audit and performance review undertaken by the PSA to provide an opportunity to review our use of accepted outcomes and to identify any further learning points for our decision making in this regard (and we note the PSA's recent audit of accepted outcome decisions taken by Social Work England as an example of this approach).

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

No.

MAPs

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

We agree with the proposed approach to the regulation of Physician Associates (PAs) and Anaesthesia Associates (AAs).

As we noted in our response to the DHSC's consultation in 2017, *The regulation of Medical Associate Professionals in the UK*, regulation plays an important role in letting patients and employers know that healthcare professionals are safe to practise; and that they can be held to account if serious concerns are raised about their conduct or performance.

While voluntary registers, administered by the Faculty of Physician Associates and Royal College of Anaesthetists, have helped to professionalise PA and AA roles and promote patient protection, by definition they can't reach those who choose not to be regulated. They also can't enable definitive action to be taken when concerns are raised.

Statutory regulation means that we can build on their work and help drive up standards in these roles. It will also provide assurance to patients, employers and other regulated professionals who place their trust in PAs and AAs.

The framework outlined in the consultation document is consistent with the regulation of other healthcare professionals. And we agree that PAs and AAs should be regulated in the same way as other groups of registrants.

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.

We agree that we should be given a power to approve high level curricula, and set and administer exams, for PAs and AAs.

There are 35 institutions across the UK running courses leading to the award of a PA qualification, and a single institution providing courses leading to an AA qualification. We expect that these numbers will increase following the introduction of statutory regulation. It's essential that each course covers the same curriculum to ensure that individuals are gaining the knowledge and skills required for safe and effective practice.

As practice evolves for AAs and PAs, their knowledge, and skills, will need to keep pace. It's therefore essential that we retain the flexibility to review and reapprove high level curricula for PAs and AAs as required.

As we said in our answer to question 19, we support the proposal for an express power to set and administer exams that either lead to registration or an annotation. For PAs and AAs, this power will enable us to continue the UK wide exams for PAs currently administered by the Royal College of Physicians. It will also support the development of an equivalent assessment for AAs. Ensuring that all PAs and AAs meet a defined threshold before registration will help us uphold the standards we expect of every individual entering our register, whether they have qualified in the UK or overseas.

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

We agree with the proposed transitional arrangements. We've worked closely with DHSC, the FPA and the RCoA to plan the timely transfer of the voluntary registers held by both organisations to our register.

The proposed transitional arrangements are in line with the approach taken by other UK regulators when bringing new professions into regulation. They balance the rights of established practitioners with the need to protect patients and the integrity of the register.

To ensure that patients and employers can have confidence that individuals listed on the register are fit to practise, it's essential that any concerns are identified as part of the transitional process. We're seeking to do this by requiring PAs and AAs to make a fitness to practise declaration when they apply to join the register.

We're working with the FPA and the RCoA to establish what information they may be able to share to help the registration process run as smoothly and proportionately as possible.

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.

We agree that PAs and AAs, like other regulated professionals, should be required to demonstrate that they remain fit to practise to maintain their registration.

Revalidation is an important process for doctors in demonstrating their continued competence and it's right that the same principles apply to PAs and AAs. This is essential for patient and public confidence in the professions who are caring for them, and for the confidence of the professionals with whom PAs and AAs work.

In due course, we'll engage stakeholders to help design an effective and proportionate approach to continued competence for PAs and AAs.

Assessments

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.

We agree with the high-level benefits identified in the tables on pages 95 and 96 of the consultation document. Once we have further clarity on how the proposals will be translated into the new legislation, and we've scoped how these might be translated into our new rules, policies and processes, we'll be better placed to comment on the benefits and costs of the reforms in more detail.

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.

We agree with the high-level costs identified in the table on page 96 of the consultation document. Once we have further clarity on how the proposals will be translated into the new legislation, and we've scoped how these might be translated into our new rules, policies and processes, we'll be better placed to comment on the benefits and costs of the reforms in more detail.

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

Please provide further information to support your answer.

We have a diverse registrant base. We'll use the reforms to address the existing drivers of inequality for our registrants.

We believe that the proposals will help build a more flexible model of regulation that's better able to achieve equality of opportunity for our registrants; and for patients and members of the public to access regulation.

We expect to see benefits throughout all areas of regulation. For example:

- fitness to practise reforms will lead to less adversarial processes and reduce stress on all participants
- registration reforms will provide for an equality of opportunity for UK and overseas professionals, including speciality and associate specialist doctors who are disproportionately from an ethnic minority background and overseas qualified.
- education and training reforms will allow us to provide greater support for students of all backgrounds.

As we develop our plans for implementing these and other changes, impact assessments will help ensure proper understanding of the implications of different approaches for those with protected characteristics.