

PSA Consultation on the *Standards of Good Regulation*: GMC Response

Introduction

- 1 The General Medical Council (GMC) is an independent organisation that helps to protect patients and improve medical education and practice across the UK.

 - We decide which doctors are qualified to work here and we oversee UK medical education and training.
 - We set the standards that doctors need to follow, and make sure that they continue to meet these standards throughout their careers.
 - We take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.
- 2 Every patient should receive a high standard of care. Our role is to help achieve that by working closely with doctors, their employers and patients, to make sure that the trust patients have in their doctors is fully justified.
- 3 On the 2 December 2016 we responded to the Professional Standard's Authority's pre-consultation on the *Standards of Good Regulation*. Our response to the pre-consultation is available at Annex A.
- 4 On 12 June 2017 the PSA launched their formal public consultation on reviewing the *Standards for Good Regulation*, which regulators are assessed against on an annual basis. We understand that this is the first of two formal public consultations. In this document we set out our response to each of the questions in the consultation document.

- 5 We welcome the direction of travel for the development of the Standards as set out in your proposals, in particular the additional focus on education and training and equality and diversity measures. However we think there are some specific areas in the consultation where further clarity and exploration is needed, in particular:
- Education – making sure the Standards are broad enough to take account of the range of factors that affect regulators’ performance in education and training and our very specific role within it;
 - Duplication of assessment – clarification that where other bodies already exist to assess a regulators performance against a particular aspect of their statutory functions e.g. information governance, the PSA would not seek to duplicate assessment of that function without good reason;
 - Greater focus on outcomes, particularly in relation to Fitness to Practise – moving away from concentrating solely on volume and timeliness and taking clear account of underlying performance and adjusting your performance decisions based on assessing outliers, non-recurrent issues or simply things that are out of our control;
 - Continuing Fitness to Practise schemes – importance of greater understanding the GMC’s revalidation scheme and how it works specifically for doctors.
- 6 More generally the Standards as set out in your proposals lack recognition of our wider system responsibilities and the importance and impact of working with others across the healthcare sector. We have broader strategic ambitions to work more collaboratively with others to stop issues arising before they happen, through effective information, insight and intelligence sharing. Currently the Standards do not reflect consideration of how regulators are working with each other and others outside the professional regulatory sector, to further patient safety and public protection. They therefore don’t necessarily link easily with some of the work you are trying to drive through in *Right touch Regulation* and risk incentivising the wrong things. You get what you measure, and this is a real chance to reassess the performance review so that it is strategic, future-focussed and future-proofed in line with your own and our thinking on how regulation will change in the future.
- 7 We therefore feel that you have an important role in setting and offering the right incentives for the system you and we want to see and we invite you to think about this with us, in detail, so that we can understand and engage in this agenda together. We are also mindful that there may be some overlap with forthcoming plans for Department of Health consultations on the shape of regulation and would like ensure

there is no duplication or differential conclusions drawn between these two pieces of work.

- 8** We thank you for the chance to comment and look forward to working with you on this agenda in the coming months.

Consultation response

1a) Should the Standards cover the regulators' performance in respect of Standards and guidance?

- 9** Yes. We agree that providing Standards and guidance for safe and effective practice is a core role of regulators. Given that the purpose of the PSA's assessment of the Standards is to inform their reports to Parliament on the regulators' performance, we agree that the Standards should cover the regulator's performance in this respect.

1b) Which aspects of work related to the setting standards and guidance for registrants should the Standards focus on?

- 10** We think the current Standards reflect the main aspects of work related to setting standards and guidance for registrants. We agree that requirements for the regulator to publish and promote standards for professionalism, openness and transparency, and possibly other areas, could be useful additions. We recognise the importance of these areas which are embedded within our own guidance. However we would like to caution that any burden on the regulators in respect of new Standards should be proportionate, and there should be flexibility for individual regulators to determine what their own standards need to include. The overall palette of a regulator's guidance and standards will vary according to their individual registrant base and associated considerations for patient safety.

2a) Should the Standards cover the regulators' performance in respect of education and training as set out in these proposals?

- 11** We agree that setting and quality assuring education and training standards is a core role of the regulators, and that the Standards should continue to cover the regulators' performance in this respect. However we have some concerns that your proposals as currently set out are not broad enough to take account of the range of factors that affect regulators' performance in education and training.
- 12** Your consultation document says at paragraph 3.5 'Regulators should ensure that there is a proportionate process for the quality assurance of education programmes so that the public can be assured that education providers provide students, trainees and professionals with the skills and knowledge to practise safely and effectively' However, the current Standards state that the process for quality assuring education programmes should be 'focused on ensuring the education providers can develop students and trainees so that they meet the regulator's standards for registration'. We think it is important that the revised Standards do not focus on quality assurance

to the exclusion of other ways that regulators may be working with education providers to ensure that registrants are effectively trained.

- 13** We also think that it is important to distinguish between trainees' readiness for registration, and readiness for entering a career of continuous learning and development.
- 14** It is therefore important that a 'focus on the regulator having methods for assuring themselves that the learning outcomes required for registration are appropriately set and assessed', is not taken in a narrow sense.
- 15** In order to broaden out the Standards for education and training, we suggest some other key areas of focus that are not addressed in your proposals. These are reflective of our wide range of responsibilities in this sphere; the increasing importance and emphasis we and system partners are placing on educational outcomes and environments, and established research into educating professionals which goes further than merely preparing them for registration. This would include:
 - skills, knowledge, behaviour and outcomes – beyond what is required for registration
 - service and workforce needs which need to be considered in curriculum development along with patient safety and patient-centred care
 - the education or training experience – as well as acquiring competence
 - the importance of the training environment
 - 'approved' will be different for different regulators
 - Furthermore we would like to highlight the importance of clarity of definitions. For example 'programmes', is narrow, and will mean something different to each regulator. We think this should also allow for Continuing Professional Development (CPD) and development of "professionalism". In addition, the definition of 'approved' will be vary for different regulators.
- 16** We also recognise the challenges of creating Standards in relation to education and training which are consistent across each of the regulators; in particular this would risk simplifying statutory functions which are naturally quite complex.

2b) Which aspects of the work related to education and training should the Standards focus on?

17 As mentioned in our response to question 2a) we think the Standards should be broadened out to cover the following areas of the work related to education and training including:

- patient safety/public protection
- fairness and equality
- excellence
- educational approach
- training or learning environment
- quality improvement/assurance and monitoring
- effective and appropriate assessments (but not just exams or tests of knowledge and skills)
- embedding generic professional capabilities/human factors.

18 Education and training need to be part of the wider system to ensure patients receive safe, competent and effective care. There should be some emphasis on professional standards and patient needs but this should be balanced against the expectation that training will meet long term population needs and workforce requirements (for example capabilities needed for the future workforce such as teamwork).

19 We refer you to some of our recent standards and guidance documents which show how these elements can be brought together.

- [*Promoting excellence: standards for medical education and training*](#)
- [*Excellence by design: standards for postgraduate curricula*](#)
- [*Designing and maintaining postgraduate assessment programmes*](#)
- [*Generic professional capabilities framework*](#)

3a) Should the Standards cover the design and delivery of continuing fitness to practise schemes?

- 20** As the current PSA standard simply requires regulators to have a scheme of CPD/revalidation, it seems appropriate for the Standards to be expanded to include how the regulator has ensured that the design and delivery meets their scheme's aims. For example, why the regulator has designed the system in the way it has, and how the system will be monitored and reviewed.
- 21** However, any additional Standards should acknowledge that these schemes and processes are, in most cases, relatively new. They should recognise that they may operate as part of, and in conjunction with, other assurance mechanisms and clinical governance processes within the wider healthcare system. Given the varying levels of maturity of these systems, in comparison to more established registration and education processes, as well as the availability of data with which to evidence compliance, expectations should be set accordingly. For these reasons, the efficacy of CPD schemes may be something you look to assess initially through a maturity model as opposed to a binary pass or fail judgement.

3b) Which aspects of the design and delivery of continuing fitness to practise schemes should the Standards include?

- 22** We have set out below which aspects of the design and delivery of continuing fitness to practise schemes we think should be included in the Standards:
- Delivery: data on compliance with schemes' provisions and on appeals (including outcomes)
 - Whether guidance for continuing fitness to practise schemes clearly sets out the requirements of the scheme and is accessible
 - Fairness and consistency of decision-making as an area that could be examined as part of a new standard.
 - The monitoring and review of the CPD/revalidation schemes might specifically ask regulators to:
 - Consider whether, in its current state, the scheme remains the most reliable and proportionate method of adding to public protection
 - Demonstrate how they have taken account of stakeholders' views and experiences of the scheme, including the voice of patients and the public

- Demonstrate how they have stayed alive to the context in which the regulated profession practices and, where appropriate, have responded to the needs of the wider healthcare system.

23 The Standards should not however require the measurement of a scheme's impact on patient safety or other areas. While the GMC, and others, are investigating how, collectively, we might track the impact of revalidation, developing meaningful metrics in this area is challenging. This is in large part due to the difficulty of isolating the impact of a continuing fitness to practise scheme from the influence of other initiatives in the wider healthcare system that are also designed to support practitioners and improve patient care. To set Standards around impact of any scheme is likely to set the regulators up to fail. Also, given that the schemes operate very differently and have different requirements, it would be very difficult to draw any meaningful comparative data on impact of these schemes across the healthcare professions.

4a) Should the Standards cover the delivery of the registration function as set out in these proposals?

24 The proposals ask whether the Standards should cover: the accuracy, accessibility and clarity of the register. We agree that this would be a sensible approach though consideration should be given to how regulators and the PSA would measure these. We have highlighted areas below where we think further clarity and detail is needed in relation to your proposals.

25 More emphasis on accuracy could be added into the existing Registration Standard 2 (The registration process, including the management of appeals, is fair, based on the regulators' standards, efficient, transparent, secure, and continuously improving). However it would be helpful to clearly define what is meant by 'accuracy'. Registration standard 1 already covers accuracy in respect that the register must be accurate in containing only the names of those who meet the standards. Additionally all healthcare regulators are already subject to statutory duties under the Data Protection Act which includes provision on accuracy of data and this could lead to challenges over which takes precedence especially if PSA disagree with our actions under the DPA.

26 Further clarity is needed on what additional requirements around accuracy are being asked; would it simply include keeping the register up to date with the individuals' registration status? For example, updating entries when individuals need to be removed (either because they have voluntarily relinquished their registration, had it removed by the regulator, or through death notification) or a change in the status of an individual's licence or qualifications. Or would this requirement include keeping

additional information such as scope of practise and personal information up to date? This would be difficult for regulators to deliver as we rely on registrants in the accuracy of this information.

- 27** Registration standard 3 already addresses accessibility, so it would be useful to clarify what additional 'accessibility' requirements would be assessed, particularly if it would be something other than ease of access to the register and the information contained within it.
- 28** Registration standard 4 could be expanded to highlight the importance of the information on the register being clear to employers and patients, including explaining both the meaning of the information and the implications of the information.

5a) Should the Authority continue to monitor regulators' activities to prevent illegal or unregistered practice and what level of priority should be given to this work?

- 29** We think this links to the regulators' processes to ensure registration standard 1 is met ('Only those who meet the regulator's requirements are registered'); if we have robust processes in place to ensure this standard is met we can help to mitigate the risk of illegal practice.
- 30** Being able to seek information and updates from other regulators about their own processes to prevent illegal or unregistered practice could also be of use in order to develop learning and share good practice between regulators.
- 31** We believe the level of priority given to monitoring this activity should be proportionate to the small number of cases of illegal practice/unregistered practice that are seen.
- 32** Though we would like to highlight the importance of acknowledging the current difficulties in being able to monitor regulator's activities in this area, particularly for the GMC as our existing legislation in relation to protected titles is archaic. It refers to 'medical practitioner' as opposed to 'doctor' which is not currently a protected title, thus the criminal activity is holding yourself out to be a Registered Medical Practitioner, not a doctor.

5b) If yes, do you agree that the Standard(s) should be limited to the areas we have identified above?

- 33** In your consultation you are proposing that the Standards focus on the following:

- Whether the regulator has appropriate methods for identifying those cases which pose a risk of harm to the public.
 - The proportionality of decision-making according to the regulators' assessment of risk.
 - How effectively the regulator liaises with other relevant authorities.
- 34** You acknowledge in the consultation document that it can be difficult to assess performance in this area and liaison with other bodies often means that the final decision lies outside regulator's control. In addition, measuring performance is complicated by the fact that the size of the problem is not known. We do not, and never could, know how much unregistered/illegal practice is actually taking place. Regulators can only know about the unregistered practice that is reported to them – and then take action accordingly.
- 35** Whether the regulator has appropriate methods for identifying those cases which pose a risk of harm to the public presumably means those cases which are reported to us. If not, and it means proactively seeking out and identifying cases, this would be significant challenge as we are reliant on cases being reported to us. It is not possible for regulators to know the actual occurrence of illegal practice.
- 36** Qualitative analysis of regulators' approach of how they deal with cases brought to their attention would be more appropriate than a quantitative analysis. The significant variation in the regulators' legislation and registrant base means that there is a wide variety of approaches to dealing with illegal practice. The variation in the different healthcare regulators' legislative powers in this area means that it is easier for some to gather evidence and meet the threshold for a prosecution than others. So a simple comparison of number of cases and the relative outcomes does not give a true picture of success.
- 37** An assessment of the methods each individual regulator has of investigating, in the context of the confines of their own legislation, and how they assess risk and use that to inform their decision on what action they will take, is probably a more meaningful assessment. Again the Authority must take into account, when assessing the outcomes of cases each regulator has dealt with, that the ability to conclude a case may fall outside the control of the regulator, and that for a regulator to take action themselves might be a disproportionate use of their resources – particularly where there is another external body (such as the Police) who are better placed to act (in terms of the investigative powers available to them) and the sanctions they can impose.

5c) In general, what aspects of work related to the prevention of illegal or unregistered practice should the Standards focus on?

38 The areas of the current standard, that cases are dealt with in a proportionate and risk-based manner are important, and should be maintained. Given the variations between, and challenges faced by, different regulators, further Standards may not be appropriate, and may not produce meaningful data for analysis.

6a) Should the Standards cover fitness to practise?

39 We agree that the Standards should cover fitness to practise.

6b) Which aspects of the activities related to fitness to practise should the Standards focus on?

40 We do believe that the Standards should focus on aspects such as volumes of cases, timeliness of fitness to practise processes and outcomes, but the Standards should not solely focus on these aspects. Fewer Standards in relation to fitness to practise would be welcome, with more focus on education and assurance. The Standards need to take account of outliers and seek to normalise performance, in order to provide the PSA with an accurate picture of actual and controllable performance of a regulator.

41 Currently the Standards are too quantitative and need to include more qualitative measures for example whether regulators have a culture of learning, improvement and assurance. The PSA should be striving to encourage regulators to drive improvements and learn from best practice of others, which does not lend itself to the 'met/not met' measurement for assessing regulators against the Standards.

42 We also think there is a need for the PSA to move to a more risk based and proportionate approach to reviewing FtP outcomes, for example instead of the current approach to reviewing all final determinations through the PSA's s.29 powers. Again there is scope for greater added value and helping identify performance improvements by adopting such an approach, and ultimately better protecting the public.

7a) Should the Standards cover the governance activities of the regulators?

43 The GMC believes that good governance is fundamental to effective regulation. Good governance ensures we have in place clear, robust and accountable decision-making structures and processes that enable us to fulfil our statutory functions and, in so doing, to act to protect the safety of patients. It also ensures that we are well-led, that we engage effectively with our registrants, stakeholders and the public, and that

we strive for continuous improvement through evaluation and review. The GMC therefore welcomes the PSA's emphasis on the importance of good governance among professional regulators, and we agree that it is crucial to the effectiveness of regulators and to public confidence in them.

- 44** The consultation asks whether the governance activities of regulators should be included in the PSA's *Standards of Good Regulation*. The GMC believes that all regulators should be able to demonstrate in an open and transparent way the effectiveness of their governance arrangements and considers that the PSA could have an important role to play in setting out the characteristics of good governance in healthcare professional regulation.
- 45** We are not persuaded, however, that this is best served through incorporating governance into the *Standards*, which are rightly focused on the outcomes of our regulatory activity. Instead, we suggest that a more effective means of the PSA understanding the robustness of governance arrangements would be through defining a clear set of principles which could apply to all healthcare professional regulators on a 'comply or explain' basis, reflecting the approach set out in the [UK Corporate Governance Code](#) and the [Charity Governance Code](#).
- 46** In our view, a principles-based approach, drawing on existing codes of governance, has a number of advantages. First, the principles are well established and represent best practice. Second, they are stretching and provide the basis for encouraging future improvement as well as current compliance. Third, they provide flexibility for regulators to tailor their governance arrangements to their specific circumstances. And fourth, they are consistent across sectors, which is particularly relevant for those regulators – like the GMC – who already apply these principles as registered charities. Likewise, the 'comply or explain' provisions enable professional regulators of very different shapes and sizes to apply the principles of good governance in a proportionate, flexible and tailored way.
- 47** While some tailoring of the principles of existing codes to the specific context within which healthcare professional regulators work would be necessary, these codes capture the four core elements of a potential standard proposed in the consultation document as well as other elements that are essential to good governance. The Charity Governance Code, for example, sets out seven principles in relation to: organisational purpose; leadership; integrity; decision-making, risk and control; board effectiveness; diversity; and openness and accountability. The GMC would be very happy to work closely with the PSA in developing a set of good governance principles for healthcare professional regulators.

- 48** It is also important that regulators learn from one another, from both successes and failures. We noted a number of learning points following your investigation in 2014 into the General Dental Council's handling of a whistleblower's disclosure about the Investigating Committee, which included reflecting on the separation of roles between administrative and decision making functions, the managerial oversight and leadership of regulatory functions, feedback processes, response and action plans to deal with concerns raised about internal processes and how we capture these issues in the risk register. More frequent reporting on the effectiveness of regulator's governance arrangements as part of the annual performance review process could provide valuable learning opportunities for all regulators.
- 49** We are always looking to continuously improve our governance arrangements and are currently undertaking a review of our governance model and developing ways to streamline our governance processes.

7b) Which aspects of the activities related to governance should the Standards focus on?

- 50** We believe that the breadth of the principles set out in existing codes are important to ensuring good governance, but in terms of healthcare professional regulation we think the following are particularly important in light of the particular governance structures in the sector:
- That there is a schedule of authority in place that sets out clearly how the powers assigned to Council are delegated within the organisation, and that this is reviewed at regular intervals (at least once in every Council term of four years);
 - That each regulator has in place clear policies governing the management of conflicts of interest covering Council members and senior executives and that a register of interests is maintained, reviewed regularly (at least annually) and is publicly available;
 - That regulators have in place clear arrangements for assessing current and future risk and providing assurance on this;
 - That regulators review regularly their governance structures (at least once every Council term of four years) and that Councils reflect on their own effectiveness on an annual basis;
- 51** In particular the existence of an effective risk management framework provides the opportunity for challenge and could be an area that the Standards focus on. We believe it is important to have a framework for managing risk effectively, particularly at a time when regulators are growing/developing their legislative bounds in different

ways for different purposes. Transparent reporting arrangements within governance processes are also essential to ensure regular scrutiny and oversight.

- 52** The GMC believes that the most effective way of reporting on good governance is through the annual report. Again, this would mirror the approach set out in the *UK Corporate Governance Code* and *Charity Governance Code*. The GMC already sets out in the annual report which we lay before Parliament details of: the current membership of Council; the governance structures; details of Council committees and boards, including role, membership and chairing arrangements, and member attendance at Council and committees; Council appointments and reappointments; details of the publication of Council papers; and activities undertaken in relation to reviews of Council effectiveness and annual appraisals of members. It also contains a report of the Audit and Risk Committee and the independent auditors' report to Council. We believe that a proportionate way for professional regulators to report on good governance would be to include a statement in the annual report setting out how the regulator has sought to comply with the principles of good governance during that year, and setting out the reasons for any departures from those principles. Assurance on this could be provided through both internal audit and the report of the regulator's independent external auditors. The PSA could use these statements in annual reports to determine where further consideration of the robustness of a particular regulator's governance arrangements may be necessary.

7c) Do you have other comments on our approach to governance?

- 53** In terms of more general reflections on the PSA's approach to governance, we would encourage the PSA to engage with all professional regulators in developing a set of principles to ensure that these work for all organisations recognising their different sizes and legislative frameworks. We would ask that the PSA ensures that any reporting requirements and expectations are clear and proportionate, and that there is clarity as to the information required to demonstrate good governance and how that will be assessed.

8) Should we introduce a new Standard that requires regulators to have mechanisms that enable them to gather information from students and tutors about compliance with minimum standards of safety?

- 54** We would cautiously welcome this, and agree in principle with such a standard. We gather information from students and tutors about safety and other issues as part of our regional reviews, which provides valuable information we might otherwise not get from management teams, or from organisations' self-assessments. Over the last few years we have made it easier for doctors and doctors in training to raise concerns with us. In 2012 we established a confidential helpline and we have developed and

expanded our National Training Survey (NTS) to ensure it is a reliable source for identifying concerns within education environments, including concerns about patient safety. Both of these methods different – for example the NTS is a point-in-time collection of data – which illustrates that it would be important for any such Standard to make clear what is meant by ‘gathering information’ and how this may differ from standard patient safety escalation procedures.

- 55** We also think it is important that ‘information gathering’ would not be restricted to information from students and tutors – there should also be an expectation to engage with doctors in training, trainers, and those who employ them. Additionally it is not always easy, possible or effective to gather this information from students – they are not yet regulated by the regulator so there’s no incentive for them to complete a survey; and they are not always the best source for this type of information.
- 56** Caution would be needed around confidentiality, anonymity, and expectations but we think there is value in focussing on the training and learning environment, and meeting the regulator’s expectations for the design and implementation of training standards. These factors have an implicit impact on patient safety but would not necessarily be captured through standard patient safety escalation processes.
- 57** Furthermore, it is important that any Standard in this area would make clear what the regulators’ responsibilities are in regards to acting on such information. For example, data can be used to help identify risk in cohorts of registrants or training environments as well as individual patient safety incidents. This is a complex area with varying levels of maturity across the regulators. The PSA should also consider that methods for collecting feedback would likely vary significantly across the regulators due in part to the size of their respective student and tutor stakeholder groups.

9) Should we adjust the wording of the Standards to focus on regulators’ work in ensuring the robustness of learning assessments?

- 58** We do not agree with this proposal as it stands. Learning assessments are only one part of the wider expectations and mechanisms for making sure education and training are effective. Focusing on learning assessments would be at the exclusion of other important factors which contribute to effective training in the longer term, such as:
- professionalism
 - the training environment
 - student fitness to practise

- assessment for learning (as opposed to assessment for registration).

59 All assessments test candidates against a sample of potential outcomes, there will inevitably be some false positives/negatives and some essential outcomes are difficult or impossible to assess in summative assessment – all of which argues for a more holistic review of professional education by professional regulators.

60 There should be more focus on the evaluation of how all aspects of the training fit together to demonstrate the learner has met regulatory expectations/registration. This involves a defined strategy for assessments that evaluates learners against standards/outcomes. It must take account of wider expectations such as:

- peer/colleague feedback
- workplace-based assessments
- review by supervisors.

61 The Standards should consider the robustness of regulators' processes to ensure learning outcomes are being met and that the training/learning environment is appropriate. We are not persuaded that other (non-professional) regulators and quality assurance mechanisms properly cover other aspects of medical education, but we are keen to share information and avoid duplication wherever possible given our substantial involvement in this area of work.

10) Should the Standard covering continuing fitness to practise be expanded to cover the efficacy of the scheme and the regulators' processes for using learning from the scheme to inform other functions?

62 Although we see the value in encouraging learning across regulators, as mentioned in our response to question 3b above, given the immaturity of some of the schemes, the focus should for now remain on effective development and maintenance of schemes as it would be difficult to draw any meaningful comparative data on the efficacy of these schemes across the healthcare professions.

11) Should we introduce a Standard that covers the portion of the fitness to practise process between the IC/case examiner decision and the final panel?

63 It would be useful for further clarity to be provided on what this would mean in practise and what the PSA would hope to achieve by introducing this Standard before we could form a view as to whether it should be introduced.

12) Should we introduce a Standard covering the operation of consensual mechanisms for disposal and the appropriateness of their outcomes?

- 64** We could potentially see the value in the PSA introducing a standard which covers consensual disposal mechanisms and the GMC has been capturing consensual disposal outcomes for a number of years. Though we would be concerned about measuring this in absolute numbers. We also think that considering the appropriateness of consensual disposal outcomes would require the PSA to access formal Case Examiner decisions and undertake extensive qualitative analysis which would be time consuming and potentially disproportionate.

13) Should we introduce Standards covering equality, diversity and fairness?

- 65** We agree that the PSA should introduce Standards covering equality and diversity as well as a standard around fairness and would welcome this addition to the Standards, given that these principles are intrinsic to confidence in our work as a regulator, and to meeting our statutory obligations under the Equality Act 2010. We think that there is a broader range of performance indicators than the two identified in the consultation document, e.g. compliance and fair decision-making. We have attached to this consultation response a draft framework that we have developed that provides more detail about the types of indicators and evidence that might provide greater assurance in this context. Some of these can be embedded by being made more explicit within the existing Standards.

- 66** It may also be helpful to clarify the scope of the two indicators identified in the consultation document at 3.41:

- *Understanding the diversity of registrant population and the environment generally* - We are assuming that 'environment' would include the workforce of healthcare professionals as well as population of patients and the public/service users.
- *Ensure that processes do not provide inappropriate barriers or otherwise disadvantage people with protected characteristics* - It is inevitable that some of our regulatory processes and activities will disadvantage some groups of people who share protected characteristics. The existence of differential impacts and outcomes is not always an indicator of the fairness of those processes or of not having done due diligence on equality and diversity. The equality duty requires us to be proactive in
 - identifying potential disadvantage for some groups
 - to take steps to understand what might be causing that disadvantage,
 - to minimise or reduce any gaps, or to mitigate the advantage

- be able to justify the activity despite the disadvantage, e.g. on the grounds of patient safety.

67 We feel any developments in this area need to take careful consideration of the law as quoted above so that we can both comply with it and the expectations of the The Authority in this regard.

14) Do you agree with our proposals to rationalise the Standards in the areas we have suggested?

68 We agree with your proposals to rationalise the Standards in the areas you have suggested to some extent, particularly where this would avoid duplication of requirements, for example in relation to engaging with stakeholders and taking account of feedback as part of the development and revision process for standards and guidance. Though, it is important that the Standards can still be applied flexibly to all regulators.

69 We understand the importance of effective communication with stakeholders and the need to ensure that key information is accessible and publicly available to stakeholders, however it is important that the right information is available to the right audience, making sure that communications are targeted and useful. Thus rationalising the Standards in relation to making information accessible should not just focus on the extent of information available but whether that information is appropriate for key audiences. We have recently focussed on transforming our digital communications in particular, with the aim of creating an easier, personalised experience for priority audiences and transforming our digital content to ensure it is simple and easy to find. As part of our consultation on developing the medical register which ran from July to October 2016, we also explored with stakeholders whether information currently provided on the register was useful for their individual needs as opposed to only seeking feedback on what information should be added to the medical register, this allowed us to understand better the needs of our audience in relation to how they access information about medical professionals.

15) Are there any other areas where you think the Standards could be rationalised or simplified?

70 We agree with your proposals to rationalise the Standards in the areas you have set out though would like to emphasise that simplification of Standards particularly in relation to education and training may not necessarily be the best approach in order to capture the range of factors that affect a regulators' performance. We could envisage a hybrid approach, where regulators are assessed against a set of rationalised and streamlined Standards in relation to their core functions, alongside a discussion about how regulators have demonstrated they have delivered their

statutory functions in accordance with a number of principles for example transparency and effective governance.

- 71** Assessing 'fairness' appears in the consultation twice, first as a proposed standard and then as a proposed principle. To avoid duplication we think a sensible approach would be to assess 'fairness' as a principle rather than a Standard, judging whether a regulator has delivered its statutory functions 'fairly' would take the form of a subjective assessment, which is why it would be difficult to measure as a Standard.

16) Do you think our Standards should specifically include consideration of the information governance arrangements of the regulators?

- 72** We do not think the Standards should specifically include consideration of the information governance arrangements of the regulators. Whilst we do accept that information governance requirements are important for the regulators, we consider this to be sole focus of the Information Commissioner, who has statutory responsibility in respect of the Data Protection Act 1998, Freedom of Information Act 2000 and other associated laws.

- 73** When the General Data Protection Regulation comes in to force on 25 May 2018, organisations will be under an enhanced requirement of accountability in respect of data protection which will continue to be overseen by the Information Commissioner. We consider that there is already sufficient oversight of information governance requirements by the Information Commissioner and that there is potential for duplication if the PSA also seek to review information governance.

17) Do you agree with our assessment of the advantages and disadvantages of the current approach? Are there any considerations we should take into account?

- 74** We agree that the Standards need to be refreshed to reflect recent changes and developments in the healthcare and regulatory sector and feel that the current approach to the Standards is too focused on the processes and functions of regulators. We would like to see an approach to the Standards whereby other key behaviours are assessed, for example developing Standards which assess how regulators are attempting to reduce regulatory burden for the healthcare system, or how regulators are enhancing engagement with patients and the public and embedding a customer focussed approach to communications and regulatory interventions. The performance review could also explore how regulators are attempting to move towards more proactive regulation and drive more upstream interventions and support good practice.

75 Again we would like to emphasise the importance of using performance reviews to highlight and share good practice between regulators in order to help drive improvements across the healthcare regulation sector.

18) Do you agree with our assessment of the advantages and disadvantages of the principles-based approach? Are there any considerations we should take into account?

76 We agree with the advantages of the principles based approach as set out in the consultation document particularly in relation to taking account of differences amongst regulators and the shift away from process driven Standards. However we think the principles based approach could go further in measuring behaviours of regulators as mentioned in the previous question.

77 Assessing whether a regulator had 'met/not met' the principles would be entirely subjective and could be resource intensive as it would require looking at a range of information, not just information that was publicly available. Measuring a principles-based approach would be particularly challenging as not all the Standards fit neatly into the right-touch regulation principles. An easier approach would be to measure regulators against the principles using a maturity scale, assess how mature a regulator is in relation to being transparent, rather than judging whether a regulator is or is not transparent for example. A hybrid approach where some Standards exist which are pass and fail and others are dealt with on a principle / maturity level approach would be significant step in the right direction and help the PSA position itself as a system improvement agent as well as performance overseer – this would be in tune with other system/sector regulators in the healthcare space and beyond and would be a welcome addition to the PSA toolkit.

78 We also agree that a disadvantage to moving to a principles based approach would make it difficult to compare performance reports of regulators for previous years, yet moving to this approach would overtime enable greater sharing of practice and learning across each of the regulators.

19) Do you think that the Authority should use the principles in Right- touch regulation as the underlying concepts for its assessment of regulators' performance?

79 The Standards should not be considered in isolation from the vision for regulation set out in Right-touch regulation. Performance management and assessment needs to measure the behaviours and outcomes we want to encourage as opposed to those which are easiest to audit. We agree that the principles in Right-touch regulation are a good starting point for forming a principles-based approach to the performance review process and would welcome additional principles in relation to fairness and

efficiency (see comments above and below). However we have identified potential difficulties with “measuring” performance against some of the principles.

- 80** We understand the importance of encouraging consistency amongst each of the regulators but this should be balanced against the need for regulators to adapt and innovate in a flexible way which is specific to the needs of their registrants and the limitations of their underlying legislation. We support the promotion of harmonisation but the individual characteristics of the different professions and the circumstances in which they practice must also be recognised.
- 81** Measuring regulators performance against whether they are being targeted and agile seems sensible and emphasises the importance of driving more upstream regulation, focussing on identification of key risks and harms. Though, the ability for regulators to be agile can sometimes be challenging due to the restraints of our legislative frameworks. Agility could be measured by looking at how innovative regulators are being to evolve and develop their regulatory functions within their existing legal frameworks.

20) Should the Authority add the principles of Fairness and Efficiency?

- 82** We agree that there may be value in isolating ‘fairness’ as a principle to prompt greater scrutiny and awareness of the significance of this concept. There are also opportunities to integrate this principle in assessing performance against the existing principles of consistency and transparency (see response to Q13 and the attached draft framework).

21) Are there other principles that should be added or different ways of expressing the concepts which might suit our performance review better?

- 83** As mentioned in our response to the PSA’s pre-consultation on the *Standards of Good Regulation* in 2016, we believe to effectively assess the performance of the regulators there needs to be a robust framework with clear outcomes, and indicators for how success will be measured against these outcomes. There are some principles that we think are fundamental to such a framework:
- Outcomes-focused;
 - Aimed towards driving good practice;
 - Customer focussed
 - Proactive/upstream regulation

- Based on assurance of regulators' performance, and crucially how they are monitoring and seeking assurance of their own performance as opposed to the current approach, which is based in audit;
- Targeted at areas over which the regulator has the most influence, and adjusted for factors over which they have less or no control. Where relevant aim to standardise definitions and measurements to aid comparison.

22) Have you any initial comments on the draft wording used in the example (Annex B)?

84 The draft wording in Annex B seems to be consistent with the existing Standards and language used in Right-touch regulation. We do not have any further comments.

23) Do you have any observations about difficulties that may arise for regulators or the Authority in gathering information and evidence to operate the performance review under a principles based approach?

85 The information currently listed at Annex B which would be used as evidence for a performance review under a principle based approach, is not too dissimilar from the information that we currently provide to the PSA for the existing performance review process. We do not anticipate any difficulties in gathering the information you have proposed at Annex B.

86 We would however like to highlight some concerns around expanding scope of the Standards as set out in the consultation document, with continued focus on inputs and processes. This approach could lead to significantly increased resource requirements and regulatory burden for both the PSA and professional regulators which would appear to be in contrast with the principles of right touch regulation, and the governments well documented position that fees on regulated healthcare professionals should not increase in the current challenging climate. We would hope that the same expectation applies to the fees on professional regulators as they are intrinsically linked.

24) Do you think the Authority should adopt the first or second option?

87 We are supportive of a principles-based approach to the annual performance review and can see the value in assessing performance against particular behaviours rather than focussing solely on process and functions. Yet we believe there should be more emphasis on learning from good practice of other regulators, sharing experience and learning from others which can help drive future improvements. We think that more guidance on good practice should be embedded within the Standards themselves, for example through a set of good practice indicators.

25) Do you think that the Authority should continue with its 'met/not met approach'? If not, what other approach would you prefer?

- 88** We understand that describing regulators performance against the Standards as 'met/not met' provides clarity for stakeholders as to how well a regulator is performing. However we believe a more nuanced approach in describing performance would be of more value to both regulators and stakeholders, we can see the benefits of grading performance as set out in your proposals which would provide a more accurate picture of a regulator's performance, particularly if the PSA plan on moving to a principles-based approach. We would welcome a hybrid approach to performance reviews, where regulators are assessed against a set of rationalised and streamlined Standards alongside a discussion about how regulators have demonstrated they have delivered their statutory functions in accordance with the principles.
- 89** Narratives within performance reviews also need to focus more on improvement and the ability to share learning with others. It should be the responsibility of regulators to drive improvement with the PSA being responsible for capturing insight and sharing learning amongst the regulators.
- 90** As mentioned in our response to the PSA's pre-consultation on the *Standards of Good Regulation* in 2016, measures need the flexibility to take account of constantly evolving regulatory interventions so that you, and we, can see improvements and their effect. Managing unintended consequences from the measures you set is vital and being ready to change them when they occur – for example an increase in data security incident reporting is probably the sign of a healthy reporting culture and not an issue with data security and likewise when we close older cases our median figure will increase. Both of these examples show the inherent danger in too static a definition of measurement which could dis-incentivise ethical and innovative behaviour.

26) Are there other ways of reporting on performance that the Authority should consider?

- 91** As mentioned in our pre-consultation response on the Standards (2 December 2016), there will always be challenges in measuring performance. However, we do not think that the current framework and supporting dataset allows for meaningful comparison across regulators. You may want to consider whether a more flexible model is needed, which would allow for measurement of a core set of Standards with additional specific measures for each regulator based on an assessment of the current challenges it faces and what its scope of regulation is. For example, the GMC's role in post-graduate medical education is a significant and material difference in our operating model compared to other professional regulators. We also made reference in our pre-consultation response to the *Australasian Environmental Law*

Enforcement and Regulators network - Better Regulation Cluster as a useful example of a graduated maturity model which could be applied to PSA performance assessments. This model captures the spirit of driving improvements across regulators whilst being able to recognise the individuality of regulators.

27) Are there any aspects of these proposals that you feel could result in differential treatment of, or impact on, groups or individuals based on the following characteristics as defined under the Equality Act 2010:

Age

- *Gender reassignment*
- *Ethnicity*
- *Disability*
- *Pregnancy and maternity*
- *Race*
- *Religion or belief*
- *Sex*
- *Sexual orientation*
- *Other (please specify)*

If yes to any of the above, please explain why and what could be done to change this.

No.