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Monday, 10 September 2018

Dear David

Review of the Standards of Good Regulation

Thank you for the opportunity to respond to the second phase of the review of the Standards of Good Regulation and we remain keen to work closely with the Authority as it implements these new Standards from 2020.

We have set out our comments to the consultation questions below. Please note that we have structured our response around the key sections in the consultation document and addressed some questions together in order to avoid duplication.

Section 1: General

- 1. Do the new Standards appropriately reflect the areas the Authority should be considering across the regulators' functions?**
- 2. Is any of the wording of the general Standards unclear or inappropriate? Please suggest changes.**
- 3. Do you anticipate any particular difficulties for regulators in providing evidence to demonstrate performance against the general Standards?**
- 4. Are there particular points about the general Standards where you would welcome further clarity?**

We welcome the inclusion this new group of general Standards, which cover elements of the regulators' governance and behaviours that affect performance, together with activities which cross the range of the key functions. We are particularly pleased to note the inclusion of a specific Standard in relation to equality and diversity as we were supportive of this change in our original consultation response. We are also encouraged to note that a specific governance Standard has not been included as this was an issue of concern raised in our original response.

We are pleased that the Authority will be looking at how regulators are clear about their purpose; how they apply policies appropriately and share learning across all functions; and, how they report on and address concerns about performance. However, we are keen to understand the extent to which these new general Standards will be used to ensure appropriate and consistent action by the healthcare regulators to combat the important issues

identified through recent public reports such as the PSA Lessons Learned Review and the Report of the Gosport Independent Panel. For example, how regulators are seeking assurances that a culture exists where concerns can be raised and acted on appropriately, and how they are supporting and engaging with patients and families at different stages of the process.

We have no specific concerns about the evidential requirements for this new group of Standards.

Section 2: Standards and Guidance

Questions 5. Do the revised Standards governing standards and guidance appropriately reflect the outcomes of this area of the regulators' work?

6. Does the reference to 'patient and service user centred care and safety' remain appropriate? What other words would you suggest?

7. Do you have any views about the evidence requirements in respect of the Standards about standards and guidance?

We welcome the overall reduction of standards in this area from four to two, and we have no specific concerns about the outcomes described in this section.

The consultation raises a question about whether the wording of Standard 7 is cumbersome [*the regulator provides guidance to help registrant apply the Standards and ensures this guidance is up to date, addresses new and developing areas of practice, and prioritises patient and service user centred care and safety*] and whether this should be replaced with the statutory objective of ensuring patient safety, maintaining professional standards and maintaining public confidence. In our view, it is helpful to retain the focus on the interests of patients and service users. However, using our own *Standards for Pharmacy Professionals* as an example, this could be simplified to 'person centred care'. This would incorporate both the person receiving care and the patient's carers or representatives. We tested this wording through our consultation on our Standards in 2016 and, overall, this was welcomed and understood by both the public and professionals.

We note that the evidential requirements will be similar to those for the equivalent existing standards with the addition of more targeted information from third parties, for example, employers, academics and other regulators to ensure that the standards remain up to date. We would welcome further clarity from the Authority on how these targeted questions for employers and academics will be constructed and considered as part of the performance review. We suggest that this is an area that might be explored in more detail through the initial pilot phase of the new standards in 2019.

Area 3: Education and Training

8. Do the revised Standards in respect of education and training appropriately reflect the outcomes of this area of the regulators' work?

9. Are there other aspects in respect of education and training work which ought to be included?

10. Do you have any views about the evidence requirements in respect of the Standards about education and training?

We welcome the overall reduction of the number of Standards in this area from four to two and the continued focus on the two aspects of the education function: development and maintenance of standards for education

and training, and the quality assurance of the programmes and places that provide training to potential registrants. We have no specific concerns about the outcomes described in this section.

In terms of the evidence framework, we note the proposal to seek more targeted information from third parties, for example, employers, academics and other regulators also applies to this section. We agree that standards of initial education and training should reflect the changing needs of patients in today's healthcare environment and support the delivery of person centred care and professionalism. They should also provide assurance that professionals are receiving the right education and training to prepare them to provide safe and effective care from their first day on the job, and to take account of the changing environments in which professionals are working. However, as with section 2 above, we would welcome further clarity from the Authority on how these targeted questions for employers and academics will be constructed and taken into account as part of the performance review.

Area 4: Registration and continuing fitness to practise

11. Do the revised Standards about registration and continuing fitness to practise appropriately reflect the outcomes in this area of the regulators' work?

12. Are there other aspects in respect of registration and continuing fitness to practise which ought to be included?

13. Does Standard Thirteen provide an appropriate level of protection for the public while ensuring that regulators have the flexibility to develop arrangements which are suitable for their registrants and service users?

14. Do you have any views about the evidence requirements in respect of the Standards about registration and continuing fitness to practise?

We welcome the reduced number of registration Standards from six to four, and we have no specific concerns about the outcomes described in this section.

We are pleased to note that Standard 13 [*the regulator has proportionate requirements to satisfy itself that registrants continue to be fit to practise*] takes account of our original suggestion that this should be sufficiently flexible to allow different approaches to continuing fitness to practise and to recognise that regulators may be at different stages in their development cycle. However, it would be helpful for the Authority to share any learning or other comparative information to indicate how this Standard will be assessed and to clarify how proportionality is viewed in the different contexts and approaches to continuing fitness to practise or revalidation.

The consultation also asks whether Standard 13 should include an explicit link to public protection and patient safety. We do not consider this extra descriptor is necessary, as public protection and patient safety runs through all of the Standards.

The consultation recognises that some regulators also have roles in respect of businesses. Although this is not explicitly mentioned in the new Standards, the consultation highlights that the Authority expects that Standards 10 and 13 will cover the regulators' work in respect of businesses and that they do not expect to expand the existing evidence base in respect of these Standards.

The Standards do not currently cover our work in regulating registered pharmacies. However, we have said previously that we are keen to discuss and explore with the Authority whether this continues to be the right approach. We welcome the proposals set out in this consultation and would like to work with the Authority to consider how it might extend its oversight role to cover our work with registered pharmacies.

Area 5: Fitness to practise

15. Do the revised Standards appropriately reflect the outcomes of the fitness to practise area of the regulators' work?

16. Are there other aspects of fitness to practise work which ought to be included?

17. Are the Standards appropriately flexible to enable regulators to adapt their fitness to practise processes where necessary?

18. Do you have any views about the evidence requirements in respect of the Standards about fitness to practise?

We welcome the reduced number of Standards in this area from ten to five, and we have no specific concerns about the outcomes described in this section.

We note that Standard 16 [*the regulator ensures that all decisions are made in accordance with its processes, are proportionate, consistent and fair, take account of the statutory objectives, the regulator's standards and the relevant case law and prioritise patient and service user safety*] is intended to cover all decisions, including those to progress complaints, those made by committees as well as those of panels.

We note that the new Standards do not make specific reference to consensual mechanisms for disposal of fitness to practise cases and options for remediation, which was put forward in the original consultation document. We would welcome clarity on how strategic changes to the fitness practise process such as the introduction of mechanisms for consensual disposal or remediation might be captured through the new Standards and performance review process in the future.

We are pleased to see that Standard 18 [*all parties to a complaint are kept updated on the progress of their case and supported to participate effectively in the process*] has been retained. As part of the assessment of this Standard, we would expect the Authority to consider how regulators are engaging with patients and their families, to ensure they are informed of the process and progress, and that regulators are analysing and taking their evidence seriously. This is even more significant in light of the recent public reports including the Report of the Gosport Independent Panel and the PSA Lessons Learned Review. It is important that the Standards are used to assess how regulators are ensuring that the right culture exists within the organisation to ensure that victims and their families are listened to and treated with compassion at all stages of an investigation.

We have no specific concerns about the evidential requirements for the fitness to practise standards and note that these will remain as they are now.

Implementation and impact

19. Do you have any concerns about our proposal to implement the new Standards in the performance reviews beginning in 2020?

20. Would you support a pilot process in 2019? If you are a regulator, would you be willing to take part in the pilot?

We have no specific concerns about the proposals to implement the approach from January 2020 onwards, and we would be happy to take part in testing one or two of the new areas in the 2019 pilot phase.

Overall, we welcome the new approach, particularly the flexibility given to the regulators in demonstrating out they meet the Standards and the removal of areas of duplication. We note the Authority's decision to retain the 'met/not met' approach and the rationale for this. However, as highlighted in our original response, there must be transparency and consistency in how assessments are made. We consider that additional narrative could be added to the existing reports, to recognise and identify good practice that supports the regulators as they work to drive improvement and promote professionalism in their sectors. The inclusion of additional narrative could also recognise where regulators are likely to sustain or improve performance, and provide richer, more valuable feedback.

Further, providing a set of bespoke and constructive comments, supported by comparative findings, would be very helpful. We would like to see a commitment to including in the narrative of their reports sufficient material to enable the regulators to know where the issues are and what is expected of them going forward.

Finally, our approach to engaging with the performance review remains positive and constructive, and we would welcome the opportunity to discuss our comments further, including proposals for the 2019 pilot scheme.

Yours sincerely,

A handwritten signature in black ink, reading "Duncan Rudkin", enclosed in a thin black rectangular border.

Duncan Rudkin
Chief Executive and Registrar