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Dear Teena

Review of the Standards of Good Regulation

We welcome the opportunity to respond to the review of the Standards of Good Regulation and remain keen to work closely with the Authority as it develops and implements any changes to the Standards. We have structured our response around the key sections in the consultation document and addressed some questions together in order to avoid duplication.

Section 3: What should the Standards cover?

Questions 1 - 7

We agree that the Standards should continue to cover the regulators' performance in the core areas set out in Section 3 of the consultation document. However, we believe that this review provides an opportunity for the Authority to make further, more wide-reaching improvements to the current Standards.

The consultation indicates that the Standards are intended to set the outcomes of good regulation, as well as how good regulation promotes and protects the public. However, in our view, the current Standards are not truly outcomes-focused. The Standards continue to focus heavily on process and less on the outcomes that the regulators are expected to achieve, or their effectiveness in protecting the public and promote confidence in the professions. We recommend that the Authority moves away from a prescriptive, process-heavy approach, towards one that is better suited to deliver effective regulation against the backdrop of significant and welcome modernisation.

The regulators that the Authority oversees are varied and they regulate different numbers of individuals and systems, with varying degrees of complexity. They also operate within different legislative and governance frameworks, with very different budgets and resources. By shifting the emphasis and focusing on outcomes, we believe that the Authority will enable regulators to exercise greater flexibility in how best to meet those outcomes, without lowering standards, and enable the Authority to get the best out of its relationship with the regulators.

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

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

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

Yes. We agree that it would be useful for the Authority to consider organisational governance as part of its review of performance against the Standards. However, the focus should be on outcomes as opposed to specific governance activities or processes, specifically whether there is effective oversight to enable the regulators to meet their statutory objectives. If this change is implemented, the Authority should be transparent about the criteria or methodology that will be used to assess performance against the Standard, and provide clarity on when a formal review of governance is likely to be triggered.

Changes to the Standards covering the core activities

Questions 8 – 16

Question 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?

In principle, we believe that regulators should be concerned with patient safety in training environments, including encouraging a culture of openness and transparency where patient safety can be enhanced. However, the Authority may need to consider how this standard is phrased to ensure that its outcomes are focused and recognises the varying systems and professional regulators across the sector.

It is important to highlight that there are many examples of good practice and innovation being observed during the education quality assurance processes. For example, we already capture feedback from students through our existing processes and we are seeking to gather more information to inform our regulatory function, including around level 3 pharmacy technicians. However, these activities are not being captured through the current Standards, which continue to focus on the process rather than the outcomes and impact.

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

We agree that the Standards should consider whether there are appropriate mechanisms in place to quality assure education programmes. However, we encourage any drafting of a new Standard to focus on outcomes in terms of the competency of new professionals rather than process.

Question 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?

Yes. We are in support of this proposal. However, it is important for the Authority to be sensitive to where each regulator is in its development cycle. Those regulators further down the line are likely to be able to provide evidence that relates to implementation, joining of intelligence to other regulatory functions and evaluation of impact and responsiveness to evaluation and intelligence. Others may be limited to providing evidence related to their development process, including the evidence they are collecting, their methods of

engagement and consultation, and the viability of the model to deliver its intended outcomes in a measurable way. For example, it would be challenging for us to demonstrate integrated intelligence and learning in practice because we are yet to implement our new revalidation processes. But, we can demonstrate how we intend the model to operate and we can later be held to account in following years of review. These differences would need to be recognised, and addressed fairly, within the performance review process.

Question 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?

No. We do not agree that an additional Standard is required to address the concerns highlighted in the consultation relating to under-prosecution of fitness to practise cases, or inadequate decision-making due to poorly drafted allegations. We believe that the existing processes are sufficient to enable these types of concerns to be identified and addressed, including the Section 29 referral process as well as the dissemination of learning from the decisions reviewed by the Authority. Further, the consultation is not clear about how this Standard would be assessed, or about the potential regulatory and operational impact of this change on the regulators.

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

Yes. Our existing fitness to practise processes include disposal options such as giving advice to the registrant (or any other person involved in the investigation); giving a warning to the registrant; or, agreeing undertakings with the registrant, if the registrant admits their fitness to practise is impaired.

We are also committed to exploring the future design of our fitness to practise processes, including alternative ways of disposing cases and options for remediation.

If a new Standard is introduced to scrutinise how effectively the regulators are implementing alternative mechanisms in a way that protects the public, the Authority must recognise must recognise the different statutory frameworks, so a 'one size fits all' approach may not be appropriate. The key question would seem to be whether the mechanisms used by the regulators are sufficient to protect the public and uphold trust in the profession, and whether they are used appropriately and effectively. Again, this would need to be recognised, and addressed fairly, within the performance review process.

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

Yes. We are committed to equality, diversity and inclusion (EDI) in everything that we do as a regulator, employer and provider of services, and we have published EDI objectives aligned with our business planning objectives.

We agree with the Authority that there is great value in understanding equality data relating to our registrant body, including pharmacy students. This is vital to making sure that we are able to carry out vigorous equality impact assessments and ensure that our policies, guidance and processes do not impact adversely of any of our registrants.

We also believe that it is important that health professions regulators are encouraged to understand the diversity of their registrant population and do all that we can to promote equality, diversity, inclusion and fairness in all areas of regulation. Having developed our experiences in this area we now intend to enhance our ability to gather data on the protected characteristics of registrants and particularly students to understand any barriers to success in our assessment examination. This does, and will continue to present challenges as we are aware that for instance, there is some reluctance amongst registrants to provide us with personal information. The introduction of a new Standard will provide us with further mandate to proceed.

Question 14) Do you agree with our proposals to rationalise the Standards [relating to Guidance and Standards] in the areas we have suggested?

Yes. We agree that there is duplication in this area and that the overall number of Standards could be reduced substantially.

Question 15) Are there any other areas where you think the Standards [relating to Guidance and Standards] could be rationalised or simplified?

See our response to questions 1 to 7 above.

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

No. We do not consider that a specific Standard on information governance is necessary, given the role of the Information Commissioner's Office as regulator for data protection legislation and the Authority's commitment to right-touch regulation. However, information governance will continue to be at the heart of our activities and embedded in our processes.

**Section 4: How the Standards are presented: two options
Questions 17- 24**

We have considered the two options for expressing the Standards as outlined in the consultation: retain existing framework where standards are grouped by regulatory function, or introduce a new framework based on principles of 'Right-touch regulation', with the additional concepts of fairness and efficiency.

In principle, we have no objection to a new approach where the Standards are aligned to the overarching principles, which inform the regulators' approach to all of their functions. However, it is difficult to envisage how this will work in practice. There are also a number of disadvantages with this approach, notably the additional burden and uncertainty, as well as difficulties in drawing comparisons with previous performance reviews.

As to the potential advantages outlined in the consultation (less process-driven, enabling a focus on behaviours, recognising the differences between regulators, reducing duplication), we believe that these could still be achieved by retaining the existing framework and streamlining the current Standards.

An alternative option may be to include some broader, principle-based standards, alongside reduced core Standards covering regulatory functions. This would enable the Authority to hold regulators to the same

core principles, while recognising some of the distinct differences, such as our own unique involvement in systems and professionals regulation. It would also help to recognise the current joined-up and collaborative approach to regulation, and enable the regulators to provide evidence of best practice in the areas that cut across multiple functions.

Section 5: Measurement

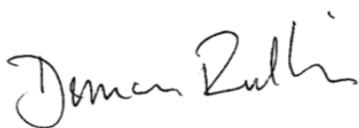
Questions 25-26

The current review process involves an assessment of performance and compliance with the Standards. There is, however, no indication as to what methodology, criteria or frameworks are used as the basis of these assessments. If the Authority continues to describe performance against the Standards as being 'met' or 'not met', there must be transparency and consistency in how these assessments are applied.

We do not support a purely narrative approach to assessment as this could dilute the accountability of the regulators. However, some 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.

Overall, we want to see a more transparent, proportionate review process, consistent with the Authority's 'right-touch' principles. It would be helpful to see a more detailed assessment of the potential impact of these proposals on the different regulators. However, our approach to engaging with the performance review remains positive and constructive, and we would welcome the opportunity to discuss our comments and concerns further.

Yours sincerely,



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