

Mark Stobbs, Director of Scrutiny and Quality
Professional Standards Authority

2 March 2021

Dear Mark

GPhC response to the consultation on the approach to Performance Review

Please see below the GPhC's response to the consultation on the performance review process.

We note from the consultation document that it remains the Authority's intention to implement any changes to the process in 2022. We would reiterate the comment made in our response to the earlier consultations – namely that the recent changes to the Standards of Good Regulation were only introduced in the 2019/20 cycle and are starting to become embedded so it will be important to ensure that further change does not cause confusion and can bring value to the process overall. The challenge of adapting to a changed review process will be made greater for the regulators by the ongoing nature of the pandemic, the work arising from it and the demands it places on all of us. We note that any changes proposed as a result of this review will be the subject of further engagement and we welcome that.

As always, we would welcome the opportunity to discuss our response further.

1. Are there other concerns about the current performance review process that we have not identified here?

Section 2 of the consultation document identifies a number of issues with the current process and we are pleased to note that several of them are acknowledged in paragraph 2.10, including the timeliness of the reports, a greater focus on outcomes and whether further work can be done to reduce the burden on regulators by moving towards a more risk-based approach.

Broadly speaking, we support the areas identified in section 2 and do not wish to add any more. However, we would need further information on how these areas might be implemented to respond more fully. Our comments regarding the current 'met/not met' approach are set out in more detail below.

Additionally, the pandemic has illustrated the need for all organisations to be able to operate in an agile and flexible way, including those with regulatory and oversight responsibilities. This review could therefore provide the Authority with a timely opportunity to think about the flexibility within the review process and whether the process can respond to significant events impacting the regulators and how they should affect its assessment of their performance

2. Do you have any comments on our role or the broad approach that we take to performance review as we have set out here?

No - we have no significant comments on the role of the Authority or the broad approach to performance review. We do have some comments about including good practice, which are included in the response to question 11 below.

3. Do you think we should continue to look at the regulators' performance against all of the Standards every year or could the scope of our reviews be more targeted?

In principle, we think that the scope of the reviews could be more targeted. The current approach is partially risk based but not fully, in that the Authority still assesses performance against each Standard every year. We agree that there would be benefits to a more targeted approach, including allowing the Authority to focus its resources on areas where particular risk factors exist or Standards have previously not been met.

We would support reducing the review of areas where no concerns have been identified or significant changes made – we accept that significant change brings risk and that areas which have seen such change (such as new standards or forms of assessment) should be subject to review even if they have been meeting the Standards. However, we would also want assurance from the Authority that even where there is a reduced or targeted review of certain Standards, we will still receive a clear performance assessment outcome for those areas to indicate that Standards are still being met. This is because it is vital that the Authority is presenting a fair and balanced view about overall performance, including for external stakeholders.

The risks identified in paragraph 3.7 of the Authority becoming less familiar with certain areas of the regulators' work or missing emerging concerns about performance can be mitigated by the regular monitoring which the Authority undertakes with its reading of papers and other published materials, attendance at Council meetings to hear discussions and so on. Any remaining risk could be mitigated through more frequent engagement with the regulators outside the performance review process.

4. If we were to change our approach, are these the right factors for us to consider in determining the scope of the reviews? Is there anything else we should be considering?

We agree with the factors suggested as allowing the Authority to have confidence in the performance of a regulator against relevant standards and with the idea that the factors could in many cases be evidenced by material already available. We also support the principle that regulators should be given the opportunity to draw any particular points to the Authority's attention.

In relation to the factors which might indicate that a closer review was required, we would support the factors identified in principle. However, we would prefer to see them caveated slightly to take account of external circumstances and ongoing work. For example, the suggested factor 'Evidence that the regulator was not meeting appropriate key performance indicators or other targets (such as work set out in its business plan)' could more helpfully read 'Evidence that the regulator was not meeting appropriate key performance indicators or other targets (such as work set out in its business plan) without good reason'. The current pandemic has shown that all organisations can have their businesses disrupted with very good reason but without prior warning and in our view it would be preferable for the indicators to acknowledge this clearly.

We would suggest a similar change to ‘Concerns identified in previous performance reviews’ which we think might be better expressed as ‘Concerns identified in previous performance reviews and which are not being addressed through an action plan’ (or similar wording). Real change can take time to embed and, given that there is only a short gap between a regulator receiving one performance review report and being able to plan for any improvements needed and the process of the next review beginning it would be helpful - particularly to those trying to identify, develop and implement changes – if the criteria recognised that such change will not always be brought about quickly. We understand that the Authority would need to be confident that an improvement plan was in place and was being both implemented and monitored.

5. If we implemented a system as described above, do you agree that there should be a presumption that the Authority should actively review all of the Standards at regular intervals? What do you think an appropriate timeframe would be?

If the proposed targeted and risk-based approach works properly in the way described, and includes the appropriate safeguards as discussed above, then it would seem unnecessary to build in a regular review of all Standards. However, we accept that it may be helpful to schedule in a full review as a safety mechanism, at least until the new model becomes more established. In that case, the Authority’s suggestion that five years could be an appropriate maximum time to lapse between full reviews. As mentioned above, we would still expect to see some review and assessment of the ‘lower risk’ areas year on year, to maintain a balanced picture of our overall performance.

6. Do you agree that we should introduce monitoring processes as described above? Do you have any comments on these suggestions?

We are open to the idea that formal monitoring process could mitigate risks associated with a reduction in the scope of reviews subject to the concerns set out below. According to the consultation, this would involve an assessment of key points to understand risks and performance. However, we would want to see that as a proportionate exercise so that the work required of the regulators was not simply shifted to another part of the review process. Also, we would want to know more about what would be expected from the regulators here and how they would be expected to contribute to the process, and importantly what proactive work the Authority would be doing to lead this monitoring process. For example, much of the relevant information will be readily available to the Authority through attendance at Council meetings and published papers etc. It is important that a formal monitoring process does not become overly burdensome or disproportionate.

We are also open to the idea that there could be benefits to a formal monitoring process where the Authority needs to look closely at a regulator’s performance in a particular area. However, we would reiterate the point made above that real change can take time to design and embed successfully and for that reason we think that it would be important for the timescale to be agreed with the regulator, allowing positive change to be realised with a focus on the benefits for patient protection rather than on meeting a particular deadline.

7. Have we identified the right areas of our approach that we need to develop in this area? Is there anything else that we should be considering?

Identifying risk and regulatory failings is fundamental. However, we are not clear on the benefit of all of the options suggested as there is currently not much detail in the proposals. It would be

important to be clear about what would be required under any new requirements in the evidence base and the benefits that they would provide.

We set out our views on thematic reviews at the answer to question 12, below.

8. How could we best engage with stakeholders, to ensure that we are aware of risks to public protection? Is there any other evidence that we should be seeking to inform our performance reviews?

We have no specific comments to add here. As stated in the consultation, the revised Standards of Good Regulation have specific requirements on how the regulators identify and manage risks to the public. And, through the review process, we provide detailed information about how we engage with our stakeholders. We do not have any further comments on how the Authority should engage with stakeholders.

9. Should we retain a binary system or adopt a more nuanced approach?

We note that the Authority has decided to re-visit this question in the light of its experience of assessing performance against the implementation of the new Standards. We remain of the view that met/not met is a clear approach, supported by a narrative which recognises where improvements are taking place or concerns have been identified. The narrative should also recognise where regulators are likely to sustain or improve performance. We provided this feedback in previous consultations when this question was posed. We have not seen any new information or evidence to suggest why this position should change.

10. If we were to adopt a different approach, what alternative approach would you prefer and why?

As set out above, we have not seen any new information or evidence to support a change in approach.

11. Would these changes support the regulators to learn from our work and that of other regulators, in order to better protect the public?

We agree that the Authority should not issue instructions to regulators if it has performance concerns as the regulators themselves are best placed to identify how best to improve. However, we do not think that the same logic applies to the sharing of good practice and continue to be of the view that the Authority could play a stronger role in identifying and sharing good practice and that this is a good way for the Authority to have a positive impact, supporting the regulators to learn from its work.

While we acknowledge the point made in paragraph 3.3 that what may be identified as good practice for one regulator may not necessarily be good practice for another, we remain of the opinion that the performance review process could do more to highlight and share good practice. Where legislation or systems mean that identical processes could not be adopted, there could still be learning for other regulators in approaches or outcomes.

We would support the reports being more explicit in identifying strong performance or good practice by a particular regulator. We would also support further activities such as engagement through seminars and other activities.

We would not wish to see the Authority making formal recommendations about how an individual regulator should improve its processes, as we support the point made in paragraph 3.29 that the regulators themselves are best placed to do this.

Providing high level recommendations to the sector around risks which apply across it or to several of the regulators might be useful. However, if recommendations are not to be regulator-specific (and we do not think that they should be), then the recommendations may be so high-level as to be of little practical use. If this were to happen, there would need to be clear parameters around how far the Authority expected to see any recommendations implemented by each of the regulators and whether – and if so, how – the implementation would be assessed in a future performance review.

We remain of the view, as we have said previously, that the Authority could play a stronger role in sharing and disseminating examples of good practice and that good practice can be identified through the performance review process and published material; and does not necessarily require an additional thematic review in all cases.

12. Do you think thematic reviews would assist us in our scrutiny of the regulators and enhance our public protection role?

We set out our views on thematic reviews in our response to the Authority's previous question on the subject, submitted on 30 January 2020. While we remain supportive of the principle behind them (i.e. identifying and sharing good practice and challenges across the regulators and establishing guidance on future expectations), we also remain concerned about the challenge to the regulators of resourcing such reviews.

Thematic reviews would need to be manageable, particularly when being carried out alongside individual performance reviews. The regulators would need time to consider whether they were in a position to take part in any given review and could manage the work involved alongside their existing workloads and commitments.

As we have noted previously, we would expect that much of the material on which a thematic review would be based could be sourced through the existing review process and/or published materials which could be collated, analysed and shared without significant further input from the regulators.

If the purpose of a thematic review is truly about sharing good practice and adding value, it should not be framed or conducted in the format and style of a traditional, transactional audit or focus on matters of compliance. They should be holistic, learning-focused and forward-looking, providing useful insights on the approaches across the sector and drawing out best practice, innovation and emerging initiatives. They should include clear examples or case studies, which could be used or adapted by other regulators going forward.

13. Please set out any impacts that the proposals set out in this paper would be likely to have on your organisation or considerations that we should take into account when assessing the impact of the proposals.

The main implication would obviously be in staff resource to carry out whatever work was required, provide data etc. It is difficult to quantify the impact of the proposals until they are

finalised and even then they could vary from year to year. We would welcome further engagement on these proposals, including how they might be implemented in practice.

14. **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 characteristics defined under the Equality Act 2010?**

No.

Best wishes

Duncan Rudkin

Chief Executive and Registrar

E: duncan.rudkin@pharmacyregulation.org