The PDA's response to the Professional Standard Authority's:

"Consultation on our approach to Performance Review"

March 2021

Summary:

The Professional Standard Authority (PSA)is consulting its approach to reviewing the 10 healthcare regulators that it oversees.

At present, the PSA publishes a detailed annual Performance Review for each of the 10 regulators to measure their performance against 18 performance standards that regulators should meet. The reviews contain information which would otherwise not be publicly available and also includes a significant narrative to give meaningful context.

The Performance Reviews form part of the assurance process by which the PSA demonstrates to Parliament that it has fulfilled its statutory oversight duty of the 10 healthcare regulators.

The consultation seeks views around 5 key areas :

- **Scope of reviews: should all of the Standards of Good Regulation be assessed annually for all the regulators?**
- **Assessing risk: how can we best identify risks to public protection and public confidence through the performance review process?**
- **Decision-making: should we retain the current binary system - where regulators meet or do not meet a Standard - or adopt a different approach?**
- **Supporting improvement: how can we ensure that our performance reviews add the greatest value and enhance the work of the regulators in protecting the public?**
- **Thematic reviews: do you think thematic reviews would assist us in our scrutiny of the regulators and enhance our public protection role?**

The consultation runs until 04 March 2021.

About the Pharmacists' Defence Association:

With over 32,000 members, the PDA is the largest pharmacists' membership organisation and only independent trade union exclusively for pharmacists in the UK. Our practicing members are registered with either, or both, of the two pharmacy regulators within the PSA's scope; the General Pharmaceutical Council (GPhC) and Pharmaceutical Society of Northern Ireland (PSNI).

Our services to members include indemnity insurance cover and defence association benefits, alongside our trade union representation. We also have a significant number of pharmacy students and pre-registration trainees among our members. We therefore interact with the GPhC and PSNI across a significant proportion of their activity, including education, regulation and fitness to practice.

Introduction:

In light of the November 2020 Government paper which states that there will be a consultation in early 2021 on major reform of professional regulation we welcome the PSA taking anticipatory measures to enable it to continue to discharge its oversight functions effectively.

The major reforms may include a review of the number of regulators, changes to fitness to practise processes including potentially a far greater use of consensual disposal, better collaboration between regulators and a whole host of other measures including changes to the powers the PSA has to ensure good regulatory practice.

The oversight role of the PSA is critical in the assurance of healthcare regulation. Indeed the 2014 Law Commission review of healthcare regulation noted:

> ***"... We consider that such is the importance of the Authority's role in the new legal framework, that the Government must ensure that sufficient resources are available to fund the Authority's expanded role. " (1)***

This sufficiency of resource should not be restricted to only monetary considerations. The PSA operates with a budget of around £4m which is significantly less than 2% of the total income of all the 10 regulators it oversees. This is excellent value for money given the scope of work undertaken.

We believe that the sufficiency of resource should also encompass the PSA being given powers to ensure that its recommendations are implemented by the regulators. At present the PSA cannot direct regulators to follow its recommendations.

Similarly, the PSA has authority to challenge adjudications using the S29 process but would have no right to do so for any concerns closed by way of Consensual Disposal. The Government has already indicated that they expect Fitness to Practice (FtP) concerns to be managed by consensual disposal rather than by hearings and this is expected to be an area of major forthcoming reform. The power for consensual disposal must have a counter-balance measure that the disposal can be open to challenge by a mechanism akin to the S29 process.

The Covid-19 pandemic has led all regulators, like healthcare providers and society in general, to make major changes in how they operate. Some of these changes may become permanent.

The majority of the UK's pharmacists, c 58,000 practice in Great Britain and are therefore regulated by the GPhC; there are c. 3,000 pharmacists regulated by the PSNI. our experience is therefore proportionate and mainly with the General Pharmaceutical Council (GPhC). We can illustrate some of the points specifically in relation to the GPhC, but this may also be relevant to the PSNI and indeed may be universal across all the regulators.

In the case of the GPhC, virtual hearings and changes to the servicing of documents, the radical overhaul of the MPharm degree which will lead to all pharmacists having prescriber status at point of entry to the register, together with new proposals for managing concerns have introduced a significant quantum of operational and execution risk.

A good example of the consequence of how the PSA not having powers to direct can be seen when the GPhC did not make changes in response to the PSA concerns surrounding the GPhC proposals for new threshold standards. In 2017 the PSA voiced concerns about the changes to threshold standards proposed by the GPhC.

Despite the PSA having reservations **(2)** about these threshold standards the GPhC, following public consultation went ahead with them. Most telling was that in the review of the consultation the GPhC, as evidenced from its own post consultation

document, presented to its own Council a review of responses which had omitted to note the PSA concerns but instead stated:

> ***"The PSA confirmed that they had no concerns about this approach overall, but made it clear that they will continue to monitor the impact of the revised criteria going forward." (3)***

The ensuing problems once the revised threshold standards were implemented has meant that the GPhC FtP process has failed to achieve the standards expected of a competent regulator for each of the 2 years following their introduction. Even more telling is that fact that the GPhC has refuted and refused to accept the findings of the independent audit conducted by the PSA. This lack of PSA power enables a regulator to overrise PSA concerns and recommendations.

The Covid-19 pandemic has brought to the fore the need for regulatory agility and newer more efficient ways of working. The regulators, like their registrants, have had to adapt to different ways of working and in a manner which may involve long term adjustment of how healthcare is delivered.

For example, the use of virtual video technology to undertake patient consultations may become the norm for doctors and pharmacists. For regulators virtual video hearings during FtP has become the new normal. Both areas pose risk but in different ways and both need robust scrutiny to ensure that the process is not compromising patient safety.

We agree that the PSA may need different tools to exercise its oversight in a post-Covid world. However, given the scale and nature of changes that are occurring in healthcare practice we would contend that there is an even greater role and need for the PSA to continue with the annual performance review of all regulators.

We discuss these and other issues in depth in our formal answer to the 14 questions and our recommendations are in context of the 5 broad areas the consultation has sought views upon.

Some of the areas identified raise fundamental questions about our approach and we wish to explore these in the paper. We therefore seek views on the following five areas:

- Scope of reviews: should all of the Standards of Good Regulation be assessed annually for all the regulators?
- Assessing risk: how can we best identify risks to public protection and public confidence through the performance review process?
- Decision making: should we retain the current binary system or adopt a different approach?
- Supporting improvement: how can we ensure that our performance reviews add the greatest value and enhance the work of the regulators in protecting the public?
- Thematic reviews: do you think thematic reviews would assist us in our scrutiny of the regulators and enhance our public protection role?

Summary of Recommendations around the 5 broad areas:

1. We would recommend the current process be retained with the addition of thematic review outcomes applicable across all regulators. The 2 processes should not be seen as being mutually exclusive but should be seen as complementary.

2. An enhanced dataset collection may aid in identifying areas of emerging concern. It may also aid to identify the areas that may warrant a thematic review. The enhanced dataset may form part of a more extensive ongoing monitoring process as is carried out by the Legal Services Board (which has a similar oversight role to the PSA).

3. An enhanced stakeholder engagement process so that stakeholders such as trade union representatives, registrants including student cohorts and members of the public can draw attention to issues that they have encountered, and which may in reality be a wider systemic risk and may be a way to identify areas for future thematic reviews. We would also expect the PSA to be able to carry out oversight of consultation processes, analysis and the interpretation of responses, often the analysis can seem simplistic.

4. We would not be concerned by a move from a binary system to a more nuanced approach providing that it was properly defined. So, if the binary system evolved to a multiple part breakdown, such as a RAG status (Red-Amber-Green) then each part would have clear thresholds and be fully defined. For example, a “not met but improving” should only apply if the datasets were showing a consistent and demonstrable improvement and the “met” and “not met” had clear published threshold levels and the consequences of not attaining the defined threshold was clear. We believe the PSA should consult again once any proposed “RAG” status criteria and the express consequences of each being applied are clearly defined.

5. We have serious concerns about the twice a decade full review of the regulators and were this to go ahead there is a real risk that regulatory failure would not be identified in a timely manner.

6. The PSA should seek to bring into force its direction making power and also seek the power to ensure that regulators co-operate with any activities that enable the PSA to discharge its statutory duty. The Legal Services Board (which has a similar oversight role to the PSA) has an extensive range of powers for it to effectively discharge its oversight functions.

7. The Annual Performance Review is a process. The process and the skillsets to develop an eye, a sixth sense as it were, to spot something not quite being right would inexorably be lost were the annual process diminished. An annual process across all regulators may reveal an emerging theme that would otherwise only be seen as an isolated issue.

8. A greater engagement process throughout the year between the PSA and the regulators to reduce the necessity for more information at later stages of the annual cycle. This should include improvements in communication with stakeholders around what could be improved and analysis of decision making.

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

A number of regulators have the power to regulate premises and businesses. In addition, the CQC has inspection rights over many NHS premises (including GP surgeries). The Law commission review of Healthcare Regulation considered a number of issues surrounding business registration and business regulation.

Certainly, in context of the GPhC, we have seen a disproportionality in the treatment of individual registrants when compared to the treatment of premises and owners when it comes to fitness to practice. In the first 8 years of operation the GPhC issued 4,011 sanctions to individual registrants, but despite identifying major patient safety concerns in 667 pharmacy inspections issued zero sanctions to corporate owners. **(4)**

A significant number of pharmacy premises are mainly owned by large corporate entities with some owning in excess of 1500 premises. Some now operate off-site hub-spoke assembly of prescriptions and many also have their own websites with an in-house private prescriber and an ability to supply. These operational activities introduce a systemic process risk which has, to date, not been adequately dealt with by the GPhC.

The Optical and Dental professions are facing a similar diversity in ownership models (and especially large corporate ownership). GP surgeries are increasingly merging and many have in excess of 100,000 registered patients with the largest "super-practice" having in excess of 300,000 registered patients.

The regulation of corporate owners and corporately owned business premises is a significant challenge about how to manage systemic risk across all healthcare professions and one which regulatory reforms will need to address if healthcare regulation is to remain fit for purpose. Certainly, the Williams Review was cognisant of the potential harm to patients caused by systemic risk as highlighted in the Bawa-Garba case. Similarly, Sir Liam Donaldson in his seminal review "Good Doctors: Safer Patients" observed the magnitude of risk posed by unsafe systems was several magnitudes higher than the risk posed by any single practitioner.

Question 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?

We support the current oversight role of the PSA and the current approach it takes to performance reviews. We are especially impressed with the detailed narrative that accompanies the Annual Performance Reviews as they give context which is especially useful for non-registrants or members of the public.

We support the collection of quarterly data and the annual review process which requires further detail from the regulator or an audit of the area of concern ***only*** when the initial information highlights some source of concern.

This is a fair and proportionate process given the nature of the responsibility of oversight that the PSA has to exercise and which it has to report to Parliament on an annual basis.

Question 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?

The current process where all standards are initially reviewed without the need for further detail from the regulator is appropriate. The next step of requiring further information or an audit ***only*** where there is a concern or more information is required is wholly appropriate and proportionate.

Were this annual process be reduced in scope to "targeted" standards there is a real risk that emerging trends and issues may not be picked up in a timely manner.

There is nothing to stop the PSA asking for further information around targeted areas once the initial all-standards preliminary review was done. Indeed it does so already.

The opportunity to look at all the standards every year should not be lost.

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

We agree that ***were*** the PSA change it approach, the following could apply:

> **"If we were to take a more targeted approach, the following factors might suggest that we can have confidence in the performance of a regulator in respect of some or all of the Standards and indicate a lower level of review.**
>
> **• Evidence that the regulator is aware of and addressing emerging risks in respect of the profession**
> **• Evidence that the regulator is reviewing its own performance regularly and taking action against concerns**
> **• The regulator is meeting appropriate key performance indicators and adhering to its business plan**
> **• The regulator has not made any significant changes to processes or policies**
> **• The dataset supplied by the regulator does not suggest serious adverse variations in performance ****
> **• Information from stakeholders does not suggest serious concerns**
> **• The previous performance review did not identify concerns in respect of the relevant Standards."**

** There should be an enhanced dataset sent quarterly to the PSA which may help to identify any areas of potential concern.

We are unsure what is meant by the term "lower level of review" as this has not been defined. However, as an example, the Legal Service Board uses a term "internal annual assessment" which they define as:

> ***"We carry out an internal annual assessment against the evidence gathered to determine whether any regulatory action is required such as a performance assessment." (5)***

We agree that there should be an obligation for all regulators to pro-actively draw attention to any matters it has identified as being of concern.

Question 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?

Agility to respond to serious risk

If the PSA implemented a "targeted review" system in place of a "an all standards review" system we would recommend a maximum 2 year interval between these "all standards reviews".

We cannot support a proposal of twice per decade review interval as being an appropriate interval between the full "an all standards performance review".

Numerous public inquiries have demonstrated the need for regulators to respond in a timely manner to concerns. A GMC review of its databases following The Morecombe Bay Inquiry showed that this particular Trust had been mentioned on 5217 occasions in its systems during the period 2007-2013.

There is a real risk that enhanced datasets sent by regulators and other information would merely be collected and archived but not reviewed as thoroughly because the whole performance review process was structured to be a twice per decade process.

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

We support a more robust monitoring process. However, we cannot support that in lieu of an annual review for the reasons detailed previously.

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

The following quote from the Francis Inquiry is especially pertinent to this question.

> ***"In preparation for its application for FT status, the Trust had been scrutinised by the local Strategic Health Authority (SHA) and the Department of Health (DH). Monitor (the independent regulator of NHS foundation trusts) had subjected it to assessment. It appeared largely compliant with the then applicable standards regulated by the Healthcare Commission (HCC). It had been rated by the NHS Litigation Authority (NHSLA) for its risk management. Local scrutiny committees and public involvement groups detected no systemic failings. In the end, the truth was uncovered in part by attention being paid to the true implications of its mortality rates, but mainly because of the persistent complaints made by a very determined group of patients and those close to them. This group wanted to know why they and their loved ones had been failed so badly."***

The quote above is long but shows that despite "reviews" by a whole host of agencies, all with their own unique approach, the underlying systemic problems at the Trust were not identified.

In context of this PSA consultation, there is a real risk that a diminished Annual Performance Process may become overly reliant on a tick box of dataset analysis and a measurement of "outputs" rather than process and inputs.

As the quote above shows, even hard data about mortality rates did not cause sufficient concern and it was only the action of patient stakeholders that revealed the scale of the issue missed.

It may well be that even an Annual Performance Review misses something in one year, but we think the likelihood of repeatedly missing an emerging issue year after year is highly improbable especially if the PSA engages more with stakeholders during the performance review process.

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

There should be an obligation for regulators to demonstrate that they have meaningfully engaged with stakeholders, including the representatives of registrants such as Unions. They should also publish in full the details of the stakeholders they have engaged with and how often, and submit this to the PSA as part of the datasets.

Regulators should also provide data to the PSA about Freedom of Information requests they have fulfilled. This may be a pointer towards an area of concern and all recent requests from the preceding 5 year period should be on the regulator's website. There is no need to hide previous requests and in fact it may identify underlying issues.

Finally, all regulators should have a complaints page and the datasets around this should be part of the quarterly datasets sent to the PSA. How corporate complaints are managed is a key performance indicator.

Question 9: Should we retain the binary system or adopt a more nuanced approach?

We appreciate that regulators may prefer a nuanced approach as changing a regulatory process may not be instant. However, there has to be a balance between nuance and loss of clarity. We would not be concerned with a non-binary system provided that the thresholds for each rating assessment was clearly defined and easily understood.

The Francis Inquiry was clear on the link between proper performance management and strategic oversight and metrics on quality and outcomes. In all cases a top metric of "met" and a bottom metric of "not met" should be retained for clarity to even the most casual reader.

The PSA needs to engage more with stakeholders and part of the process will involve stakeholders looking at past reviews. If the ratings become incomprehensible or structured to appease regulators then this has a potential consequence of undermining confidence in the whole regulatory process.

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

Please see our response above.

Question 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 understand that the PSA facilitates numerous engagement events and conferences with the regulators to share academic research and best practice examples. However, as we have seen repeatedly across all healthcare organisations it is the quality of leadership and its willingness to engage which ultimately drives the organisation and its focus.

We would also urge that the PSA invites key stakeholders such as insurance indemnity providers, trade unions and professional bodies to such events as they are in positions to provide unique insights into the workings of the regulators and the working lives and experiences of registrants.

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

Thematic reviews may assist in ensuring that best practice, when identified, is carried across all regulators. It may also assist in identifying where a regulator is falling short of the best practice adopted by other regulators.

In pharmacy there is the added factor of two bodies simultaneously regulating the same sector, sometimes including different branches of the exact same corporation, in different parts of the UK. There is clearly a case for any learning from one of these regulators to be shared and best practice adopted by both after a PSA review.

However, without the power to direct the PSA may not be able to meaningfully ensure that regulators adopt accepted best practice or follow its advice.

Question 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 Pharmacists' Defence Association has in excess of 32,000 pharmacist and pharmacy student members. We engage with the GPhC and PSNI formally and informally but this still does not give us the level of insight or information that the Annual Performance Review does.

For example, the revelation in the PSA 2018-2019 Annual Performance Review that the PSA had significant concern about the fairness and transparency of the GPhC FtP process would never have been identified without the PSA performance review.

The GPhC had shown little insight into the matter and without this PSA audit and assessment, registrants (and especially BAME registrants) may have been impacted is subsequent years even when their fitness to practice was not impaired.

The PDA relies on the PSA reviews to provide it with information which it would never be able to access even with a Freedom of Information Request.

It is this loss of information flow and the knock on consequence of being blind-sided in discussions when one party (the regulator) has all the data and information and the other(the PDA or any other stakeholder) does not.

Poor and unfair regulation of registrants ultimately is detrimental to the public as registrants will practice defensively and will be less likely take part in innovative practice and development. A seemingly diligent regulator seen to be taking action which subsequently turns out to be unfair does not protect the public.

Question 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 following characteristics as defined under the Equality Act 2010:

- Age ☑
- Disability ☑
- Gender reassignment ☑
- Mariage and civil partnership ☑
- 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 ☑

A reduction in oversight has the potential to impact all persons with protected characteristics when they interact with regulators. To reduce potential negative impacts, all regulators should reflect the registrant population and the wider community.

Certainly, one of the key areas we would expect to see a number of thematic reviews to be focused on would be around this topic area so an increase in focus for the PSA on thematic reviews may positively impact all those with protected characteristics.

For example, a thematic review around the disproportionality of BAME FtP referrals across all the healthcare regulators is of major concern. How each regulator deals with this disproportionality is important to monitor and share best practice on. For example, some regulators have no facility to record the ethnicity of the complainant and there is ample evidence to suggest that there is a societal issue around this.

Similarly research by the GMC has shown that older male doctors are over-represented in FtP proceedings. There may be a pattern of older male registrants being over-represented across all regulators but only a thematic review could identify whether this was the case.

Over the last 30 years all the healthcare professions have seen huge increases in female registrants. The role of the regulator (at education level) and the culture and leadership (as demonstrated in Guidance and Standards documents) of the profession is certainly an area which would benefit from a thematic review.

References:

(1) **Regulation of Health Care Professionals Regulation of Social Care Professionals in England**
http://www.lawcom.gov.uk/app/uploads/2015/03/lc345_regulation_of_healthcare_professionals.pdf

(2) **Professional Standards Authority for Health and Social Care performance review 2018/2019 GENERAL PHARMACEUTICAL COUNCIL**
https://www.professionalstandards.org.uk/docs/default-source/publications/performance-review---gphc-201819.pdf?sfvrsn=78c17720_0

(3) **Council meeting 12 October 2017 14:00 to 15:30 approx. Council Room 1, 25 Canada Square, London E14 5LQ**
https://www.pharmacyregulation.org/about-us/who-we-are/our-governing-council/council-meetings/2017-council-meetings/council-meeting-12

(4) **The GPhC identified major patient safety concerns in 667 pharmacy inspections**.
https://www.the-pda.org/the-gphc-identified-major-patient-safety-concerns-in-667-pharmacies-across-great-britain/

(5) **Regulatory performance assessments The process**
https://www.legalservicesboard.org.uk/what_we_do/consultations/closed/pdf/2017/08122017_Regulatory_Performance_Process_Document.pdf

The Pharmacists' Defence Association, The Old Fire Station, 69 Albion Street, Birmingham. B1 3EA
General enquiries: 0121 694 7000 | Incident reporting: 0121 694 7007 | fax: 0121 694 7001 | web: www.the-pda.org | e mail: enquiries@the-pda.org