General Pharmaceutical Council

Standards of good regulation

Professional Standards Authority (PSA)

13 February 2025 – 8 May 2025

GPhC Response

The GPhC welcomes the opportunity to respond to this first-stage consultation on reviewing the Standards of Good Regulation. As a regulator, we have restricted our responses to the questions relating to the Standards of Good Regulation rather than the Standards for Accredited Registers.

We support the primary question in the consultation document, namely whether the PSA is looking at the right things for the benefit of the public. Given that the regulators have four main statutory functions in relation to education and training; registration; standards and guidance; and fitness to practise, we would wish to see the standards continue to focus primarily on those areas. We would also support making the standards clearer, more accessible and transparent for the benefit of the public and the regulators who are working towards them, assuming that the fundamental requirements of the standards would remain (albeit with a possible shift of emphasis towards prevention).

Standards as an effective way of assessing performance

In relation to q.13, we agree that standards can be helpful in defining expectations but take the view that they should be focussed on *outcomes* for patients, regulators and stakeholders that ensure public protection, rather than on *outputs*. The aim of the regulators should be to regulate well and therefore meet the Standards, not to regulate to meet the Standards.

We are also of the view that standards which apply to multiple organisations can only be fair and effective if they are measured equitably. There is a need for recognition in the Standards that all the regulators have slightly different remits and work under different Rules. This means that we do not all regulate in the same way, but this is not necessarily recognised in the way that we are measured.

Keep, change, add or remove

As mentioned above, we would like to see the Standards focus more on outcomes (whether regulation is delivering public protection) and less on quantitative outputs of operational delivery. While it is important that those who come into contact with the regulators in any context receive a good service, this could be looked at through a wider lens with an increased focus on the fairness and quality of the decisions made by the regulator through its various processes.

Making the Standards fit for the future

We would like to see the Standards take into account changes in healthcare practice and delivery such as multi-disciplinary team working, innovations including the use of AI and the ways that regulators are dealing with these issues and the associated risks.

Alignment

We agree that the Standards of Good Regulation and the Standards for Accredited Registers should be aligned insofar as they should both be focussed on outcomes rather than outputs.

We also agree that the guidance and evidence framework underpinning the Standards should be clear on how to meet a standard and offer flexibility in how a standard can be met. However, we would not wish to see the guidance inadvertently introduce additional requirements, as happened with the early iterations of the guidance on Standard 3.

Clarity on how the Standards are assessed

We feel that it would be beneficial to have greater clarity about how the PSA makes its judgements on the quality of evidence provided in the performance review process, the decision on whether a standard is met or not met and the recommendations to the panel. Regulators would also benefit from a greater understanding of whether and, if so, how the PSA compares performance across regulators and whether everyone is held to the same standard and/or whether contextual factors are taken into account when reaching a decision.

This is particularly relevant in relation to Standard 15 where fairness, proportionality and timeliness of decision making are considered together. While we do not necessarily advocate for splitting the standard (see below), we do think that there is scope for the PSA to consider whether the timeliness element of a decision was proportionate to the case.

Merging standards 14 and 18

We do not agree with the proposal to merge Standards 14 and 18. The two standards look at very different things – standard 14 is about whether there are barriers to raising a concern with us while standard 18 relates to how people are supported once they have done so and how other parties in the issue are supported. These are two separate issues about which parties could have very different perceptions, which would make it difficult to fairly assess both under one standard. Although standards 14 is nearly always met, it remains important as ease of access for those wishing to raise a concern is a fundamental aspect of good regulation.

Splitting standard 15

There are pros and cons to splitting standard 15, separating fair and proportionate decision making from timeliness. It could be helpful in the sense that failing standard 15 on the timeliness element (as several regulators repeatedly do) can detract from public confidence in the regulator's ability to make fair and proportionate decisions because the standard shows as failed overall. However, separating them gives more prominence to the timeliness rather than the quality of the decisions, whereas we would prefer to see the PSA give more emphasis to the handling of cases and the fairness and proportionality of the outcomes. Overall, we would be against splitting the standard as timeliness is an element of quality, although we would emphasise that the judgement on timeliness should be proportionate to the complexity of the case.

That said, we do have some concerns about timeliness as it is currently assessed. A significant issue is that timeliness appears to be subjective and there are no clear benchmarks. We understand that the criteria applied are not the same across the regulators.

Going forward, we would like to see timeliness measured consistently across the regulators and for the way in which timeliness is assessed to be shared with transparent benchmarks.

New standards on governance, leadership, and culture

The systems by which a regulatory organisation operates, the quality of its leadership and the strength of its culture can all help to ensure that regulation works in the public interest by delivering a focus on openness, accountability, and transparency. Overall, we support the introduction of a standard related to governance, however, we do have some concerns that the PSA has not clearly articulated the issues which could be remedied by creating additional standards, making it difficult to fully assess the proposed changes. In particular, we would like to know more about how any additional standards would be measured. It may be helpful for the PSA to look at examples from other areas when considering how any new standard should be framed and what it would measure that would help to support patient protection.

The general standards (standards 1-5) already cover transparency, policy development, EDI, reporting and stakeholder relations so while we agree that it is valid for the PSA to explore good governance, we would like to know more about what any future standard would assess and how that would work. The PSA already sees all public Council papers, attends Council meetings, and meets with the regulators after Council meetings to discuss issues in more detail. The reporting of committee minutes to Council and the publication of committee annual reports also gives the PSA insight into the work of the non-statutory committees that support the work of the Council. Continuing the point made in the paragraph above, we would like to know whether a new standard on governance would focus on governance itself (and, if so, which aspects) or the Council's assurance of governance.

We would also like to know more about the level of organisational leadership that the PSA would be assessing and to understand more about how it proposes to do this. The PSA currently scrutinises the appointment and re-appointment of our Council Chair and members and has sight of the ways that the Council assures itself of organisational performance, through performance reports, Board Assurance Frameworks and so on. It would be particularly helpful to know whether the aim would be to look at the quality of the leadership provided to the organisation or the way in which the organisation provides leadership within the relevant sector.

We have similar questions about the introduction of a standard on organisational culture – namely how it would be assessed and in what context. We would like to understand more about how the PSA would both define and measure culture as both of these could be done in many different ways, as well as how they would propose to establish a baseline. We would be interested to know whether the PSA believes that having such a standard in place could have helped them to identify the issues that took place at the NMC.

We would want to see the PSA focus on holding the Councils of the regulators to their task of assuring themselves that the culture of their organisation is aligned with their values and strategy, and with patient protection. We would not want to see the PSA substituting its own judgement on organisational culture (for example) for confidence that the Councils are taking appropriate actions to assure themselves in the relevant areas.

One suggestion could be to assess whether the regulators have accessible policies and procedures in place in relation to, for example, raising concerns and grievances; and apply them consistently and well (although Standard 2 already looks at whether our policies are applied appropriately across all our functions).

Collaboration

We strongly support effective collaboration between the regulators and between the regulators and other organisations such as the CQC, HEIW, HIS, the Medicines and Healthcare products Regulatory Agency, the Advertising Standards Authority, and the Statutory Education Bodies. Collaboration is a key element of our new strategic plan, in the context of health and social care becoming much more integrated, joined-up and interdependent and the need for regulation to do likewise.

Our one note of caution here would be that collaboration should not mean all the regulators doing the same thing. We have repeatedly advocated for the PSA to do more around sharing good practice examples, but we would not want this to lead to an expectation that all other regulators should follow them, regardless of context, size, and available resources.

Criminal record checks

The question references registrants but we are assuming that it also refers to applicants for registration.

As we noted in our response to the recent PSA survey on safeguarding, applicants for registration with the GPhC must complete a declaration relating to (among other things) any criminal convictions. The declaration makes clear that applicants cannot withhold information about convictions which might otherwise be considered spent and that failure to disclose could result in disciplinary action. Registrants who apply to renew their registration must confirm that they still have no convictions.

The protection and safety of patients and the public is a priority for all regulators but cannot be assured solely by the disclosure of convictions to the regulator. Healthcare professionals are already subject to guidance and employers (where they exist) are in the best place to decide on the efficacy of criminal record checks within their environment.

Each regulator will have different contexts for this question, but we do not feel that it is for the regulators to assess whether registrants are in a patient-facing role which would require a DBS check. In roles where a check is appropriate, the check only provides assurance at a single point in time, whereas the regulators already have requirements that their registrants inform them of any relevant criminal proceedings as they arise.

We note that the UK government has not yet responded to the Independent Review of the Disclosure and Barring Regime and so we question whether this is the appropriate time for the PSA to impose requirements in this area.

There would also be a number of issues around introducing such a requirement, including but not limited to the viability for regulators who have a large number of self-employed registrants; the cost to registrants working in financially pressured sectors and/or on low incomes; the cost to the regulators, which may have to be passed on to registrants through fees; and the fact that a check requires five years of UK-based addresses, which could disadvantage overseas-qualified registrants.

Factors to be considered in planning for the implementation of changes

We understand that a further consultation is planned on any revisions to the Standards and would strongly encourage this to give stakeholders chance to share more detailed feedback once these initial responses have been reviewed.

It will be important that we have sufficient advance notice before the new Standards are implemented, an understanding of how they will be measure and a clear explanation of how implementation will work in relation to performance reporting years, especially for those regulators who may have part of a reporting year under one set of standards and part under another.

If you would like to discuss the points raised in this response, or any other aspect of the GPhC's work, please do not hesitate to contact us.

General Pharmaceutical Council

8 May 2025