General Pharmaceutical Council (GPhC) Performance Review – Monitoring year 2021/22



Our performance review process

We have a statutory duty to report annually to Parliament on the performance of the 10 regulators we oversee. We do this by reviewing each regulator's performance against our Standards of Good Regulation and reporting what we find. Our performance reviews are carried out on a three-year cycle; every three years, we carry out a more intensive 'periodic review' and in the other two years we monitor performance and produce shorter monitoring reports. Find out more about our review process here.

This report covers the period 1 March 2021–30 June 2022.

Key findings

- The GPhC demonstrated its commitment to equality, diversity and inclusion (EDI) in its work as a regulator and an employer with the launch of its new EDI strategy. Activity arising from the strategy this year included its public consultation on draft equality guidance for pharmacies.
- Work continues on the GPhC's education reforms and we received positive feedback about the way it is engaging with stakeholders in this area. The GPhC adapted its quality assurance process to allow time for education providers to introduce changes arising from the new education standards launched last year. Early feedback about the changes to the process is positive.
- Concerns have been raised about whether the GPhC's remit and approach to pharmacy inspections sufficiently address the risks in this area. The GPhC is engaging with the concerns and exploring how they can be addressed so we will be monitoring how it responds and manages the risks identified.
- Two separate sets of issues arose with the June 2022 sitting of the registration assessment this year. The delays on the day of the sitting, and the impact on candidates, were concerning but the GPhC is treating them seriously and taking a range of actions to remediate what happened and prevent it from happening again.
- The GPhC completed the action plan it developed to address our concerns about its fitness to practise function. It also launched its new fitness to practise strategy. We recognise the GPhC's continued commitment to address our concerns and the direction of travel remains positive. However, the timing of activities this year, coupled with the time it takes to demonstrate the impact of changes, means we have not yet seen tangible evidence that our remaining concerns have been addressed. We cannot yet say that Standards 15, 16 and 18 are met.

Standards met 2021/22



	8
General Standards	5/5
Guidance and Standards	2/2
Education and Training	2/2
Registration	4/4
Fitness to Practise	2/5
Total	15/18

GPhC standards met 2019-21

 2020/21
 15/18

 2019/20
 15/18



86,250 professionals on the register (as at 30 June 2022)

13,849 premises on the register (as at 30 June 2022)

General Standards

The GPhC met all five General Standards this year.

These five Standards cover a range of areas including: providing accurate, accessible information; clarity of purpose; equality, diversity and inclusion; reporting on performance and addressing organisational concerns; and consultation and engagement with stakeholders to manage risk to the public.

Equality, diversity and inclusion (EDI)

The GPhC is working hard to improve EDI in its work as a regulator and as an employer. This year it:

- launched its new five-year EDI strategy¹
- launched its new five-year fitness to practise strategy which has EDI considerations built into it and recognises the need to address overrepresentation of registrants from Black, Asian and Minority Ethnic backgrounds in fitness to practise proceedings
- implemented a Diversity Action Plan to support the recruitment process for its new Chair
- started reporting to its Workforce Committee on its ethnicity pay gap alongside ongoing reporting on its gender pay gap
- consulted on draft equality guidance for pharmacies
- continued to recognise there is differential attainment² in its registration assessment and made EDI a focus of accreditation visits while exploring how it can further understand the causal and contributing factors in order to address them.

We are currently reviewing our approach to assessing Standard 3 as part of our own organisational EDI action plan 2022/23.

Stakeholder engagement

This year, the GPhC:

- held five consultations, routinely reporting on the responses received and how it will act on those responses
- set up an 'online public panel' for non-registrants to understand what people think about pharmacy services and the GPhC's work.

Several organisations sent us positive feedback about the way the GPhC has engaged and worked with them. The GPhC was described as constructive, responsive, collaborative and willing to listen to concerns and suggestions for solutions. One organisation commented that a previously difficult relationship is now much improved.



"We believe, particularly as the sector navigated the uncharted pandemic experience, that the GPhC have appropriately approached the challenges faced with a mindset of joint problem solving."

Guidance and Standards

The GPhC met both Standards for Guidance and Standards this year.

The GPhC delayed its planned reviews of its *Standards for pharmacy professionals* and *Standards for registered pharmacies* so that the reviews can take account of new rules and standards³ it will be creating for Chief pharmacists, Superintendent pharmacists and Responsible pharmacists. The delay to the planned reviews is reasonable in the circumstances but we will monitor any further delays.

The GPhC continues to identify and respond to emerging areas of risk by providing information to help registrants apply its standards. It updated its *Guidance on providing pharmacy services at a distance, including on the internet* and it publicised guidance on areas of risk, such as online prescribing services, the sale of codeine linctus and supplying valproate. It published new resources on the duty of candour, with input from leading providers of professional indemnity insurance. It is also carrying out work on the guidance available on the use of Multicompartment Compliance Aids and we are monitoring this work as it progresses.

Education and Training

The GPhC met both Standards for Education and Training this year.

Education reform

The GPhC is carrying out extensive work to implement reforms to the education and training of pharmacists. This year, it started the transition to its new *Standards for the initial education and training of pharmacists*, which launched in January 2021. It also introduced an interim set of learning outcomes for the new Foundation Training Year that started in July 2021.

The GPhC's Advisory Group is working closely with stakeholders across the UK to make sure areas of risk are identified and addressed and to ensure regular and consistent information is shared about the work. The Advisory Group is currently focused on:

- how training on independent prescribing will be incorporated into training programmes under the new Standards⁴
- quality assurance

- the evidence framework to support the new Standards
- the future of the registration assessment

We received largely positive feedback about the way the GPhC is engaging with stakeholders about the education reforms, although one stakeholder commented on the delay in introducing the evidence framework to support the new Standards.⁵ The GPhC published other supporting resources in the meantime and we will monitor the work on the evidence framework together with the wider work being done by the GPhC on education reform.

Changes to the quality assurance process

The GPhC adapted its quality assurance process so that the reaccreditation of existing courses against its new Standards is done in a proportionate way. Instead of using single reaccreditation events, the adapted methodology uses a two-stage process spread over a longer period of time to allow course providers time to implement the changes needed to meet the new Standards. It also takes into account that course providers are yet to receive confirmation of funding arrangements for delivering enhanced clinical activities, which may impact the approach taken by providers.

The GPhC will be evaluating the changes made to the process. We received early feedback that the adapted methodology is an improvement on the previous process.

Registration assessment

June 2022 sitting of the registration assessment

Last year we reported on issues that arose when the booking system went live for the March 2021 sitting of the GPhC's registration assessment.

The GPhC held several sittings of the registration assessment this year without similar incidents, including the first sitting of the common registration assessment with the Pharmaceutical Society of Northern Ireland (PSNI). However, two separate sets of issues arose for the June 2022 sitting, which was the first sitting run by a new provider:

May 2022: despite successful system testing, when the booking system went live, technical issues meant it had to be taken down soon after. This led to a 24-hour delay in candidates being able to book a place and some test centres were overbooked, so 109 candidates had to be re-located.

The issues were rectified by the GPhC reasonably quickly and 2,900 candidates booked a place. The GPhC told us 'the overwhelming majority of candidates, including those who needed to be re-located, will be sitting the assessment at a test centre within reasonable travelling distance, most within 50 miles of their home.'

June 2022: on the day of the sitting, technical issues caused delays at six test centres ranging from 45 minutes to seven and a half hours. After the sitting, candidates also reported several other types of concerns, such as individual allegations of cheating and background noise at test centres. The GPhC is investigating these reports.

How did the GPhC respond to the issues with the June 2022 sitting of the registration assessment?

The GPhC recognised the seriousness of what happened and the impact it would have on candidates. It has so far responded in a range of ways, including:

- issuing several public apologies and signposting candidates to sources of wellbeing support
- convening an urgent Council meeting and establishing a new Council Committee on Quality and Performance Assurance to have oversight of the registration assessment⁶
- confirming candidates who experienced delays of 30 minutes or more will receive a full refund and the delays will automatically be accepted for grounds of appeal for candidates who did not pass
- re-opening provisional registration for candidates who had delays of more than 30 minutes or for candidates who successfully appeal on the basis of other procedural issues
- conducting a Serious Incident Review and commissioning an external audit of the registration assessment processes and contract with the new assessment provider
- meeting with a delegation of students who protested outside the GPhC offices and holding listening sessions for candidates to discuss their experience.

It is important that the GPhC avoids a repeat of what happened. We expect the GPhC to reflect on what happened and consider the outcome of the Serious Incident Review to identify where the failures occurred. We also expect the GPhC to consider whether the delays disproportionately impacted any candidates who share protected characteristics.

The issues that arose will likely have impacted confidence in the GPhC but we note they did not give rise to risks to public protection. We are satisfied that the GPhC responded to the emergency as well as it could have. We also note that this was the first sitting run by a new provider and other sittings took place during the review period without incident. What happened, and the impact on candidates, was serious, but the GPhC is taking steps to remediate this and prevent a recurrence. Consequently, we decided that Standard 9 was met.

Candidate performance in the registration assessment

After each sitting of the registration assessment, the GPhC publishes an analysis of candidate performance by various categories, including schools of pharmacy and protected characteristics. The GPhC uses this analysis to identify concerns about education and training.

This year's data show ongoing concerns in two separate areas: differential attainment and the performance of one school of pharmacy. The GPhC is taking action in respect of both and we will be monitoring this activity. It is:

- as mentioned under the General Standards, working to understand the factors behind differential attainment so that measures can be taken to address it
- engaging with the school in question about improvements needed and considering whether any further action is necessary.

Registration

The GPhC met all four Standards for Registration this year.

Provisional register and temporary register

The GPhC closed its provisional register⁷ on 31 January 2022 and will close its temporary register⁸ on 30 September 2022. The GPhC

notified registrants of the planned closures in advance and encouraged them to apply for full registration to continue practising. This clear communication was important to ensure continuity of registration for those who wanted to keep practising.

The GPhC's registration processes

The GPhC registers pharmacy professionals and pharmacy premises. We were told about some examples where people had a poor experience of the registration processes, in particular how long it took. These experiences do not appear to reflect the GPhC's overall performance during the review period because:

- the median time taken to process pharmacist applications from receipt of online application to approval was 29 days in Q4 2020/21 but was then within the GPhC's 28-day performance standard throughout 2021/22
- the median time taken to process premises applications from receipt of completed application to registration decision was two weeks for 2020/21 and 3.3 weeks for 2021/22.9

We will continue to monitor the GPhC's performance data, but we recognise the data in isolation does not always give a full picture of performance. Next year we will be interested in hearing more about people's experiences of the GPhC's registration processes.

Revalidation

After reducing its revalidation requirements in response to the pandemic, the GPhC has put registrants on notice that it will be reintroducing the full requirements in October 2022. We will be monitoring any evaluation the GPhC undertakes of its revalidation requirements.

Pharmacy inspections

The GPhC inspects pharmacies to ensure they meet its *Standards for pharmacies*. It reports on any enforcement action it takes and acts on any trends identified. This year, it:

- raised awareness of action it was taking against pharmacies in relation to the supply of codeine linctus
- updated its guidance for online pharmacies in response to a disproportionately high number of fitness to practise referrals received about these types of pharmacies.

Our register check identified instances of pharmacies meeting the Standards but having enforcement action taken against them. The GPhC explained there are several different circumstances where this situation might arise. ¹⁰ It has guidance in place to help it make consistent decisions about enforcement action. The GPhC's approach appears to be a reasonable and proportionate way of managing the risks in these situations. However, we encourage it to consider publishing information to explain why some pharmacies have met the Standards but are still subject to enforcement action.

We received feedback that raised concerns about whether the GPhC's remit and approach to pharmacy inspections address the risks arising in this area, with some examples highlighted to us:

- concerns that an investigation handled by the corporate owner of a pharmacy did not fall within the GPhC's remit
- clinical checks on prescriptions issued in instalments for periods up to 12 months not being carried out as they should be
- the use of artificial intelligence to replace pharmacist checks.

The GPhC is engaging with these concerns and responding to them by exploring how it can address them, both in the short and long term. We will be monitoring how it responds and manages the risks identified.

Fitness to Practise

The GPhC met two of five Standards for Fitness to Practise. The GPhC met Standards 14 and 17 and did not meet Standards 15, 16 and 18.

The GPhC's action plan

This year the GPhC completed the wide-ranging action plan it developed to address the concerns we reported about its fitness to practise function in 2018/19. Last year we saw evidence of some improvements, but we were yet to see evidence that the GPhC had fully addressed our concerns about:

- the transparency and clarity of its triage process and the impact of this on the fairness of the process and the quality of triage decisions
- the quality of threshold criteria decisions
- the timeliness of fitness to practise investigations
- the support provided to parties to participate in the process.

Activities completed by the GPhC this year included introducing:

- new *Initial assessment guidance* for the triage process
- senior sign-off and decision recording at triage for cases progressing to investigation, which are designed to improve recording of risk assessments and reasoning for decisions
- stand-alone decisions for cases closed at the end of the investigation stage, which are designed to improve the reasoning for decisions
- a new Investigation Planning and Report Form (IPRF) for use during investigations which is designed to support better recording

of risk assessments and reasons for decisions, including reasons for threshold criteria decisions

its new fitness to practise strategy for managing concerns.

We recognise and welcome this work, which demonstrates a clear and continued commitment to addressing our concerns. However, we also recognise that it takes time to embed changes and demonstrate they have had the desired effect on performance. Next year we will assess in detail the impact of the GPhC's changes.

Triage process

In recent years, we have been monitoring the triage stage of the GPhC's fitness to practise process because a high proportion of cases are closed at this stage and the GPhC's triage guidance did not properly reflect the process it was operating. The GPhC has been redesigning its triage function as part of its overall improvement work in fitness to practise.

We were pleased to see the GPhC introduce its new *Initial* assessment guidance as it more accurately reflects the GPhC's triage process. This should therefore address our concerns about the transparency and clarity of the process. However, the guidance only came into effect in the last month of the review period, so has had a limited impact on this year's performance review.

We received a small amount of feedback this year about the early stages of the GPhC's fitness to practise investigations, but we did not identify evidence of widespread concerns about the process. We will be interested in hearing more about stakeholders' experience of the process next year to help us assess the impact of the GPhC's improvement activity and new guidance.

New fitness to practise strategy

The GPhC launched its new five-year fitness to practise strategy in July 2021. 11 It has four strategic aims designed to improve the fitness to practise process, the time taken to conclude investigations and the experience for participants. It is too early to see evidence of the impact of this wide-ranging work, but it demonstrates the GPhC's ambitions and ongoing commitment to improving performance in its fitness to practise function. We will monitor its impact in the coming years. One area of particular interest is the GPhC's intention to manage concerns outside its formal processes, such as through voluntary agreements. It is important that the GPhC uses these informal processes in way that is fair to registrants.

Time taken to progress cases

The GPhC is still taking too long to progress fitness to practise investigations. Figure 1 shows that performance against the median end-to-end timeframe declined this year, although there were improvements in the timeliness of other stages of the process.

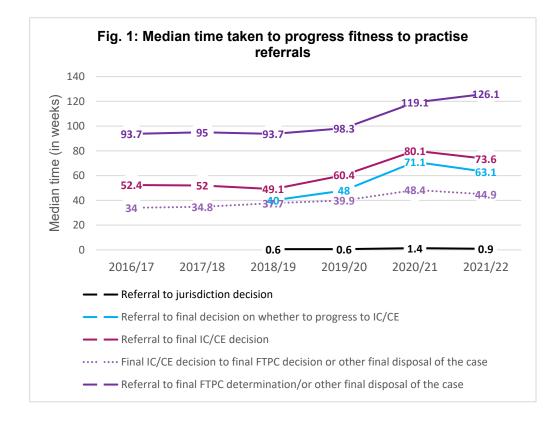
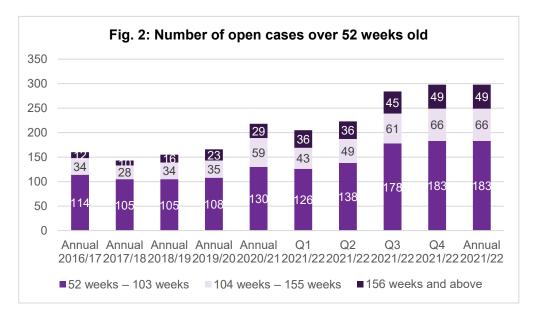


Figure 2 shows that the number of older cases also increased this year, despite an initial improvement in the first quarter of the financial year.



The GPhC recognises that it needs to improve the timeliness of case progression. It introduced several initiatives this year aimed at doing so, including:

- recruiting additional case officers and using additional administrative support to enable case officers to focus on progressing cases
- using external law firms to provide direction on complex cases
- completing an analysis to aid more accurate forecasting.

The GPhC has further work planned to improve timeliness and we welcome its commitment to this.

Risk assessments

We have been concerned by the GPhC's documenting of risk assessments for a number of years. The GPhC accepts its risk assessments need to improve and we have reported in recent years on the steps it is taking to achieve this. Some of the changes mentioned above were also designed to assist improvements here, such as the new IPRF and the changes made for cases progressing to investigation. The GPhC also delivered training this year to its investigation teams on risk assessments and on giving good reasons.

The GPhC is monitoring and evaluating the impact of the changes it has made. It told us that a recent internal audit of closure decisions found improvements in risk assessments at triage.

We will continue to monitor the GPhC's risk assessments but have not seen evidence this year, or in previous years, that the issue is resulting in the GPhC failing to identify risks or serious cases. The data shows that the GPhC continues to promptly apply for interim orders after receiving information suggesting that one may be necessary.

Support for parties to the fitness to practise process

The GPhC has been working to improve the support it provides to those involved in the FtP process since we reported concerns about this area in our 2018/19 report. The GPhC's plans were delayed by the pandemic, but it has now implemented a range of changes to improve customer service, including the launch of its new fitness to

practise strategy. We saw some improvements last year but some of our concerns remained.

The GPhC carried out a dip sample this year to look at the quality of its customer service. The findings suggest a positive direction of travel, but this is offset by what appears to be a small decline in performance since the introduction of the new investigation planning and report form. We also note that the sample size was relatively small and mostly focused on the earlier stages of the fitness to practise process, so we are not yet assured that our concerns have been fully addressed. We will continue to monitor the impact of the GPhC's changes as more evidence becomes available.

We recognise and welcome the GPhC's continuing commitment to addressing our concerns about its FtP process. These will take time to embed and we will assess their impact in detail next year. However, we concluded that Standards 15, 16 and 18 are not met this year.



Quick links/find out more

- Find out more about our performance review process
- ▶ Read the GPhC's 2020/21 performance review
- ▶ Read our Standards of Good Regulation

errors-and-organisational-governance/outcome/rebalancing-medicines-legislationand-pharmacy-regulation-programme-consultation-outcome

4 Under the previous standards, independent prescribing training courses were

¹ <u>Delivering equality, improving diversity and fostering inclusion: Our strategy for change 2021-2026</u>

² A difference in the average performance of groups who share a protected characteristic and those who do not share the same characteristic.

³ The government is introducing two Section 60 Orders that will give the GPhC powers to create these new rules and standards: https://www.gov.uk/government/consultations/pharmacy-legislation-on-dispensing-

⁴ Under the previous standards, independent prescribing training courses were standalone post-graduate courses.

⁵ The GPhC's new *Standards for the initial education and training of pharmacists* were launched in January 2021 and the evidence framework was to be discussed by

the Advisory Group in September and October 2021 but the framework has not yet been published.

- ⁶ The new Committee will also have oversight of other areas. Subject to Council approval, the draft Terms of Reference include the quality and performance of significant workstreams and improvement initiatives and the development of performance measures and data to provide meaningful updates to Council on the GPhC's performance and compliance with targets and plans.
- ⁷ In response to the pandemic, the GPhC cancelled the 2020 sittings of the registration assessment. It then introduced a provisional register so that eligible trainee pharmacists could start practicing while waiting to sit the rescheduled assessment.

- ⁸ In March 2020, the GPhC set up a temporary register so that eligible former registrants could join the workforce during the emergency situation created by the pandemic.
- ⁹ The GPhC's guidance on applying to register pharmacy premises says it takes up to three months to process applications.
- ¹⁰ For example, an inspection may result in a pharmacy not meeting standards and having conditions imposed on it, then at the follow-up inspection, the ongoing conditions continue to restrict certain activities but the pharmacy may be found to meet the standards in the areas that aren't restricted.
- ¹¹ <u>Managing concerns about pharmacy professionals: Our strategy for change 2021-</u> <u>26</u>