professional standards authority
for Health and Social Care

performance review 2020/21

GENERAL PHARMACEUTICAL COUNCIL

ABOUT THE PERFORMANCE REVIEW PROCESS

We aim to protect the public by improving the regulation of people who work in health and care. This includes our oversight of 10 organisations that regulate health and care professionals in the UK. As described in our legislation, we have a statutory duty to report annually to Parliament on the performance of each of these 10 regulators.

Our performance reviews look at the regulators' performance against our Standards of Good Regulation, which describe the outcomes we expect regulators to achieve. They cover the key areas of the regulators' work, together with the more general expectations about the way in which we would expect the regulators to act.

In carrying out our reviews, we aim to take a proportionate approach based on the information that is available about the regulator. In doing so, we look at concerns and information available to us from other stakeholders and members of the public. The process is overseen by a panel of the Authority's senior staff. We initially assess the information that we have and which is publicly available about the regulator. We then identify matters on which we might require further information in order to determine whether a Standard is met. This further review might involve an audit of cases considered by the regulator or its processes for carrying out any of its activities. Once we have gathered this further information, we decide whether the individual Standards are met and set out any concerns or areas for improvement. These decisions are published in a report on our website.

Further information about our review process can be found in a short guide, available on our website. We also have a glossary of terms and abbreviations we use as part of our performance review process available on our website.

The regulators we oversee are:

General Chiropractic Council • General Dental Council • General Medical Council • General Optical Council • General Osteopathic Council • General Pharmaceutical Council • Health and Care Professions Council • Nursing and Midwifery Council • Pharmaceutical Society of Northern Ireland • Social Work England

Find out more about our work

www.professionalstandards.org.uk

General Pharmaceutical Council
performance review report 2020/21

At the heart of everything we do is one simple purpose: protection of the public from harm

Contents

The General Pharmaceutical Council

key facts & stats

The General Pharmaceutical Council (GPhC) regulates the pharmacy profession in Great Britain.

As at 31 March 2021, the GPhC was responsible for a register of:

56,851 pharmacists, 24,439 pharmacy technicians and 13,977 registered pharmacies

annual retention is £257 for pharmacists, £121 for pharmacy technicians and £365 for pharmacy premises

The GPhC's work includes:

- Setting standards for the education and training of pharmacists, pharmacy technicians, and approving and accrediting their qualifications and training
- Maintaining a register of pharmacists, pharmacy technicians and pharmacies
- Setting the standards that pharmacists and pharmacy technicians (pharmacy professionals) must meet throughout their careers
- Investigating concerns that pharmacy professionals are not meeting its standards, and, taking action to remove or restrict their ability to practise when it is necessary to protect patients and the public
- Setting standards for registered pharmacies which require them to provide a safe and effective service to patients
- Inspecting registered pharmacies to check they are meeting the standards required.

Standards of Good Regulation met for 2020/21 performance review

General Standards	5/5
Guidance and Standards	2/2
Education and Training	2/2
Registration	4/4
Fitness to Practise	2/5

Meeting, or not meeting, a Standard is not the full story about how a regulator is performing. You can find out more in the full report.

The General Pharmacuetical Council

Executive summary

How the GPhC is protecting the public and meeting the Standards of Good Regulation

This report arises from our annual performance review of the General Pharmaceutical Council (GPhC) and covers the period from 1 March 2020 to 28 February 2021. The GPhC is one of 10 health and care professional regulatory organisations in the UK which we oversee. We assessed the GPhC's performance against the Standards of Good Regulation which describe the outcomes we expect regulators to achieve in each of their four core functions

To carry out this review, we collated and analysed evidence from the GPhC and other interested parties, including Council papers, performance reports and updates, committee reports and meeting minutes, policy, guidance and consultation documents, our statistical performance dataset and third-party feedback. We also utilised information available through our review of final fitness to practise decisions under the Section 29 process[1] and conducted a check of the accuracy of the GPhC's register. We used this information to decide the type of performance review we should undertake. Further information about our review process can be found in our Performance Review Process guide, which is available on our website.

The GPhC's performance during 2020/21

We conducted a targeted review of Standards 3, 4, 9, 10, 11, 12, 14, 15, 16, 17 and 18. Our targeted review included an audit of a sample of closed fitness to practise cases. We concluded that the GPhC did not meet Standards 15, 16 and 18. The GPhC has been implementing a wide-ranging action plan to address concerns we reported under the equivalent Standards in 2018/19.[1] The pandemic delayed some of this work but the GPhC has now completed most of the action plan. We have started to see improvements in some areas. However, there is still work to be done to improve the transparency and clarity of some fitness to practise processes, timeliness of case progression and support for people involved in the fitness to practise process.

Key developments and findings:

The GPhC's response to the COVID-19 pandemic

The pandemic impacted on the GPhC's work throughout the review period. It monitored developments closely and responded by adapting the work it was doing in all of its statutory functions. In particular, the GPhC

- set up a dedicated COVID-19 webpage which it kept regularly updated with FAQs, statements and guidance for registrants and information for members of the public

[1] Each regulator we oversee has a 'fitness to practise' process for handling complaints about health and care professionals. The most serious cases are referred to formal hearings in front of fitness to practise panels. We review every final decision made by the regulators' fitness to practise panels. If we consider that a decision is insufficient to protect the public properly we can refer them to Court to be considered by a judge. Our power to do this comes from Section 29 of the NHS Reform and Health Care Professions Act 2002 (as amended).

- continued its work remotely, where possible, including accreditation visits and fitness to practise hearings
- reduced its revalidation requirements, recognising the impact of the pandemic on registrants' capacity to meet the usual requirements
- set up a temporary register to increase the number of pharmacy professionals able to practise during the emergency
- cancelled the 2020 registration assessments and set up a provisional register for trainees to start practising within certain limits while waiting to sit the rescheduled assessment.

EDI strategy

The GPhC finished developing its EDI strategy and publicly consulted on its proposals. The Strategy is aimed at embedding equality, diversity and inclusion across all the work it does as both a regulator and an employer. As evidence relating to EDI within the specific context of COVID-19 began emerging, the GPhC incorporated this into its Strategy and EDI activities.

Education reform

The GPhC launched its new *Standards for initial training and education for pharmacists* this year. It formed an Advisory Group to work on a transition plan for a phased implementation of the new Standards. The new Standards incorporate training on independent prescribing, which used to be separate, post-graduate training programmes. Part of the transition work is focused on addressing challenges arising from this change. We will continue to monitor this work as it progresses.

Registration assessment

We received considerable feedback about changes to the GPhC's registration assessment and issues that arose when candidates tried to book their sitting. The GPhC cancelled its 2020 sittings of the assessment because of the pandemic and brought forward existing plans to introduce an online format. Prior to the first sitting in March 2021, various issues arose, including with insufficient test centre capacity, particularly in Scotland. The GPhC took steps to rectify the issues promptly and carried out a lessons learned review before the next sittings in July 2021. We considered the feedback we received about the registration assessment and the issues that arose under a number of Standards. They did not lead to any Standards not being met.

The GPhC's response to our 2018/19 performance review

The GPhC is implementing a wide-ranging action plan to address concerns we reported in 2018/19 about timeliness, customer service and the transparency and fairness of a number of fitness to practise processes, together with a new fitness to practise strategy. The pandemic delayed both pieces of work but the GPhC has now completed almost all activities in its action plan and it launched its new strategy in July 2021 after a public consultation.

We have seen evidence of some improvements, including the introduction of new documents and guidance to aid transparency about voluntary agreements and IC warnings. We have also seen more information being provided to parties at the initial

stages of an investigation. We welcome these improvements, which suggest a positive direction of travel.

The GPhC is working to improve its risk assessments. However, our audit this year did not find significant improvements. At triage, very few risk assessments were recorded. During investigations, risk assessments were not always completed when they should have been and they did not always identify or analyse the risks arising. We are concerned that the improvement work is taking so long to progress, given that it directly relates to how risks are identified and managed.

We still have concerns about the transparency of certain processes, in particular triage decision-making. Our audit this year found that most triage outcomes were reasonable but we could not always see what factors had been considered because they were not usually recorded. We continue to be concerned about the transparency of the process and whether it ensures consistency in decision-making.

We also found that parties were still not routinely updated on the investigation and, in some cases, were not notified of the outcome of their case. Timeliness has deteriorated further since last year. We know the pandemic will have contributed to this but some median timeframes have increased significantly. We therefore concluded that Standards 15, 16 and 18 were not met.

The GPhC acknowledges that further improvement is needed and continues to work towards this. For some of the changes, it will take time to see evidence of their impact. We will continue to closely monitor the evidence as it becomes available.

How the General Pharmaceutical Council has performed against the Standards of Good Regulation

The GPhC's registration assessment

A large number of individuals raised concerns with us about the GPhC's handling of its registration assessment in 2020. The matter potentially affected our assessment of several Standards, so we have looked at the event as a whole here. We will assess how these matters affect the individual Standards in our discussion of the relevant Standards.

Before the pandemic, the GPhC held two in-person, paper-based sittings of the registration assessment[2] each year:

- one in June held across six or seven large conference venues, typically taken by around 3,000 candidates
- one in September held across a smaller number of usually the same venues, typically taken by around 1,000 candidates.

The dates of the assessments were confirmed around 12 months in advance.

After the announcement of the national lockdown in March 2020, the GPhC consulted with stakeholders then cancelled both 2020 sittings of the registration assessment and explored alternative options. In the interim, it introduced provisional registration[3] to allow trainees to start working while waiting to sit the rescheduled assessment.

The GPhC identified four key principles to take into account when considering changes to pre-registration training and the registration assessment:

- maintain standards and protect patient safety
- support NHS and community pharmacy
- safeguard students and trainees
- minimise blockages or gaps for qualified new registrants to join the profession.

The GPhC initially planned to introduce an online assessment that candidates could sit remotely. However, it later chose a hybrid approach, with candidates sitting at a test centre unless there was a medical or other reason for them to sit remotely. This enabled the GPhC to secure increased capacity and reduce the risk of candidates being affected by unreliable internet connectivity at home. The GPhC's chosen supplier, Pearson VUE, had 164 test centres across Great Britain. It also had test centres either owned directly or operated through third parties in all the countries where overseas candidates were based.

[2] The registration assessment is an exam that all trainees must pass after completing their qualification and training in order to register with the GPhC.
[3] The provisional register initially ran from 1 July 2020 to 1 July 2021 but was later extended to 31 January 2022.

On 30 November 2020, the GPhC announced that assessments would take place on 17 and 18 March 2021.[4] From 5 January 2021, candidates could register for the assessment. From 25 February 2021, candidates could book their slot at a test centre. A total of 2,670 candidates sat the March 2021 assessment; 2,587 at test centres and 83 remotely.

When the system for booking a slot at a test centre went live, a number of issues arose:

- some candidates were notified later than others that booking had opened
- there was insufficient capacity at test centres for candidates in Scotland
- both sittings were in the morning but some candidates were able to book afternoon slots in error
- some candidates booked places for both sittings, which the system should have prevented.

We were contacted by people who had concerns about what happened and about the GPhC's overall management of the registration assessment. The GPhC also received concerns directly. The GPhC carried out a lessons learned review of what happened and implemented changes as a result.[5]

People told us they had concerns about:

- the GPhC's decision to retain the registration assessment rather than consider alternative means of assuring itself that candidates met the requirements for registration
- the GPhC making decisions without consulting or listening to stakeholders
- candidates having to travel to test centres during a pandemic, contrary to initial indications from the GPhC that the assessment would be sat remotely
- decisions about whether overseas candidates could sit the assessment remotely
- the quality and frequency of the GPhC's communications about the registration assessment
- the issues that arose when the booking system went live
- the reasonable adjustments process

The GPhC's approach to the registration assessment

The four principles followed by the GPhC when making its decisions prioritised patient safety while taking account of other appropriate factors. We did not identify risks to the public arising from its approach or decisions. The GPhC consulted and considered the views of representative bodies, employers, education and training bodies, trainees, patients and members of the public. We therefore do not have concerns about the GPhC's decision to retain the registration assessment.

Although holding the assessment in test centres meant candidates had to travel during the pandemic, this approach meant more capacity could be secured and technical issues

[4] In order to accommodate social distancing within venues, two sittings were arranged.
[5] Due to the timing of the issues that arose, the GPhC completed the lessons learned review and resulting changes after the current review period. However, we have taken account of the actions taken by the GPhC were we considered it relevant.

could be minimised. The GPhC's decision to change course from its initial plan of holding a remote assessment was reasonable in the circumstances.

Overseas candidates

The GPhC made a number of incorrect assumptions about test centres and did not explore options for overseas candidates until late in the process.[6] This led to several changes of decision as to where and how these candidates could sit the assessment. Overseas candidates were first told they would be able to sit the assessment remotely. Candidates with a time difference of more than six hours were subsequently told they would not be able to sit the assessment.[7] After being contacted by candidates and stakeholders about this decision, the GPhC explored alternative options and was able to find a way for all overseas candidates to sit the assessment remotely without affecting the integrity of the assessment. Its lessons learned review identified the need to ensure arrangements for overseas candidates are confirmed much earlier in the process to allow such issues to be identified and resolved. There were no reports of similar issues arising for overseas candidates sitting the July assessment.

Communications

After announcing the cancellation of the 2020 registration assessments, the GPhC issued almost monthly updates. The GPhC increased the frequency of its communications in the two months before the first sitting. However, some people thought the updates were infrequent and provided little substantial information. They did not feel fully or properly informed about the changes to the registration assessment. People told us this had an impact on their mental health during an already stressful time.

The GPhC attempted to keep people informed through regular communications but it recognised that its communications did not have the intended effect for all candidates. The GPhC explored how it could improve its communications through its lessons learned review. It committed to providing more regular updates on a clear schedule and to keeping candidates regularly informed when problems or issues arise. After the current review period, the GPhC liaised with employers and student representative bodies to improve the tone and content of communications.

Booking system issues

Different factors led to the problems that arose when the booking system went live:

- some notification emails were sent later than others because the GPhC had to re-send a small proportion of data files to Pearson VUE
- the GPhC did not carry out a detailed exercise mapping candidates' addresses to test centre capacity so did not identify there was insufficient capacity for candidates in Scotland before the system went live

[6] The GPhC decided to prioritise arrangements for candidates already in the UK, partly because pandemic restrictions reduced the likelihood of people being able to travel to the UK.

[7] The assessment is in two parts and lasts a total of five and a half hours. A time difference of six hours meant some candidates would be starting the assessment after others had finished, making it possible for details of questions to be discussed, thereby affecting the overall integrity of the assessment.

- a technical error led to candidates being able to book afternoon slots and the booking system did not have a mechanism to prevent candidates from booking places on both days.

The GPhC took prompt remedial action and within a week, it had secured more places in Scotland and rebooked all candidates who had booked an afternoon slot in error. It also tried to re-allocate candidates to more convenient centres if they were booked a significant distance from home. On the exam dates, 86% of candidates sitting at test centres did so within 50 miles of their home address. The GPhC reported that most candidates had shorter distances to travel than in previous years when fewer, but larger, venues were used.

The GPhC's lessons learned review identified the need to:

- carry out a detailed mapping exercise of candidates' addresses and test centre capacity prior to the July 2021 sittings
- work with Pearson VUE to identify the best way to share data and arrange a more effective booking process so candidates have a more equal opportunity to book the test centre of their choice.

We did not identify any reports of booking issues arising for the July 2021 sittings.

Reasonable adjustment process

The communications issued by the GPhC about the reasonable adjustment process included guidance on its website and direct emails to candidates the process for booking for candidates requiring adjustments. Candidates could apply for adjustments to the process between 18 December 2020 and 11 January 2021. They were allowed a further five working days to provide additional information if their application was incomplete. The GPhC's lessons learned review did not identify any improvements related specifically to the booking process for reasonable adjustments but identified more generally that communications could be provided more regularly and on a clear schedule. We consider that the GPhC's reasonable adjustment process was appropriate.

The issues mentioned above, and the GPhC's response, are relevant to our assessment of several of our Standards. We have mentioned them under Standards 1, 3, 4 and 9.

Overall, however, we considered that:

- The pandemic and lockdown created an unprecedented and unforeseen situation which affected all organisations. We do not criticise the GPhC for being unprepared for it
- The GPhC's response to the pandemic took account of the right principles, but did not fully consider the implications of its approach for all of those affected and led to several unnecessary unforeseen consequences which caused avoidable concern for candidates
- The GPhC responded quickly and flexibly to the concerns raised and, ultimately, we had no evidence of candidates being disadvantaged
- The GPhC appropriately instituted a 'lessons learned' exercise and we considered that its findings were appropriate and transparent.

General Standards

Standard 1: The regulator provides accurate, fully accessible information about its registrants, regulatory requirements, guidance, processes and decisions.

1.1 The GPhC uses various channels to provide information about its work, including its website, social media and emails.

1.2 The GPhC made several changes and adaptations in response to the Covid-19 pandemic:

- it launched a dedicated Covid-19 webpage that it frequently updated with statements, guidance, Frequently Asked Questions (FAQs) and signposting to resources and information published by other organisations
- no inspection reports were published between mid-March and mid-June 2020[8] but the GPhC continued to collate, publish and publicise examples of notable practice identified through its inspection activities
- stakeholder events, such as forums and focus groups, continued but were held virtually.

Customer Contact Centre

1.3 The GPhC sought to remain accessible by telephone and email throughout the pandemic. However, the pandemic created unprecedented challenges, particularly in the earlier stages. Staff had to adapt to home-working without access to their usual facilities. The complexity of queries increased, leading to an increase in the average call length. Unsurprisingly, there was a decline in the GPhC's performance against its Key Performance Indicators (KPIs) for answering calls and responding to emails. Performance subsequently improved and the GPhC met its KPIs in the last financial quarter of 2020/21.

1.4 Making allowances for the pandemic, we decided the temporary decline in performance did not adversely affect our assessment of the GPhC's performance against this Standard.

What we heard from stakeholders

1.5 We received positive feedback about the communications issued by the GPhC during the pandemic. However, some people were critical of the quality and frequency of the GPhC's communications about the registration assessment. The GPhC took this feedback on board and identified ways to improve its communications.

Conclusion against this Standard

1.6 The feedback we received shows the GPhC's communications about the registration assessment could have been better. The GPhC recognised this and we welcome the steps it took as a result to improve the information it provides.

[8] The GPhC placed routine inspections on hold during lockdowns.

1.7 However, we have also received positive feedback about the GPhC's communications in other areas. We saw it provide information about its work through its usual channels, particularly its website and social media. Frequent communications were issued throughout the pandemic and engagement activities which would have usually been held in person were not cancelled but were instead conducted remotely.

1.8 We concluded that, overall, the information provided by the GPhC across all of its work and functions was accurate and accessible and that this Standard is met.

Standard 2: The regulator is clear about its purpose and ensures that its policies are applied appropriately across all its functions and that relevant learning from one area is applied to others.

2.1 This year, the GPhC:

- set its strategic plan for 2020-2025 and set out its vision for the next ten years in its Vision 2030. Both documents are centred around the purpose of ensuring 'safe and effective pharmacy care at the heart of healthier communities'
- continued to carry out activities in line with its statutory objectives. It had to change how some activities were done because of the pandemic, for example holding meetings and hearings remotely rather than in person
- shared information across its functions to identify learning or where action needed to be taken, particularly in response to pandemic-related issues.

What we heard from stakeholders

2.2 We received feedback that questioned the GPhC's clarity of purpose because of statements it published on:

- profiteering
- rapid antibody testing kits.

2.3 In March 2020, the GPhC issued a statement on profiteering[9] in response to reports of raised prices and locum rates during the pandemic. We received feedback arguing that a regulator should not comment on registrants' hourly rates. However, the GPhC's statement was about profiteering and how this can impact public confidence in the profession, which is clearly within the GPhC's remit. We therefore did not consider the statement suggested any lack of clarity about the GPhC's role.

2.4 In July 2020, the GPhC wrote to all pharmacy owners and superintendent pharmacists and issued a statement on Covid-19 rapid antibody tests.[10] Based on the public health advice at the time, the GPhC's position was that it was not appropriate for these tests to be sold in community pharmacies or recommended by pharmacy professionals.[11] Again, some groups argued that the GPhC should not seek to limit the products sold by its registrants. We considered that the statement

[9] https://www.pharmacyregulation.org/news/profiteering-difficult-times
[10] https://www.pharmacyregulation.org/news/gphc-position-COVID-19-rapid-antibody-tests
[11] When the public health advice later changed, the GPhC updated its position to reflect this. https://www.pharmacyregulation.org/standards/guidance/qa-coronavirus/COVID-19-supply-tests-pharmacies

was entirely appropriate. The GPhC was following the guidance at the time which was directly relevant to its role in protecting the public.

Conclusion against this Standard

2.5 The GPhC continued to discharge its statutory objectives this year, albeit with some changes to how it did so because of the pandemic. We were satisfied that the statements which caused concern were within its remit and focused on public protection. We are satisfied that this Standard is met.

Standard 3: The regulator understands the diversity of its registrants and their patients and service users and of others who interact with the regulator and ensures that its processes do not impose inappropriate barriers or otherwise disadvantage people with protected characteristics.

3.1 The GPhC progressed various pieces of work relating to Equality, Diversity and Inclusion (EDI):

- **EDI Strategy**: the GPhC continued to develop its EDI Strategy, which is aimed at embedding equality, diversity and inclusion in its work as a regulator and an employer. As evidence relating to EDI within the specific context of Covid-19 began emerging, the GPhC incorporated this into its strategy and EDI activities. It launched a public consultation on the strategy shortly after the current review period and the final version was launched in November 2021
- **EDI requirements in new *Standards for the initial education and training of pharmacists***: the new Standards were launched in January 2021 and include strengthened EDI requirements for course providers
- **Council member diversity**: the GPhC updated its Diversity Action Plan, which is aimed at further diversifying Council membership, as well as updating its approach to appointments and reappointments for Council members to ensure a clear and positive emphasis on EDI.

3.2 In addition to the above, the GPhC is:

- exploring the need for equality guidance for pharmacy owners to help them meet their obligations under the Equality Act and the Human Rights Act
- carrying out a pilot of anonymous decision-making by the Investigating Committee[12]
- improving equality monitoring data for staff and Council members.

What we heard from stakeholders

3.3 We heard from a representative body that questioned what action the GPhC is taking to:

- ensure and demonstrate its fitness to practise processes are free from bias

[12] The pilot was delayed because the pandemic led to the diversion of resources towards remote hearings and ensuring the safe resumption of in-person hearings. In addition, further preparatory work was identified and the GPhC also carried out further work to refine the scope of the pilot. It will start in 2022 and the GPhC will evaluate it on a monthly basis with a more comprehensive evaluation after six months.

- address:
    - differential attainment in the registration assessment
    - overrepresentation of BAME registrants in fitness to practise
    - the lack of diversity in panels.

3.4 We know there is still work to be done in these areas. However, we are satisfied that the GPhC recognises this and has demonstrated a commitment to addressing them by the work it is doing to identify, pilot and implement new approaches and mechanisms. We will continue to monitor the work it is doing and its impact.

3.5 We considered the feedback we received about the registration assessment under this Standard, particularly the concerns about the booking process, the reasonable adjustments process and the decisions relating to overseas candidates.

3.6 The overall process for agreeing to reasonable adjustments process appeared to us to work appropriately. However, we were concerned about the issue with test centre capacity in Scotland and the late reversal of decisions about overseas candidates because these issues were potentially preventable and had an impact on the affected candidates. The GPhC rectified the issues and identified the causes through its lessons learned review. It implemented changes after that review and there were no reports of similar issues arising for the July 2021 sittings of the assessment.

Conclusion against this Standard

3.7 The GPhC collects and analyses EDI data about its registrants and other people that interact with it. It is using this data to improve its processes and it has launched an EDI Strategy. It is progressing work that is aimed at ensuring its processes do not impose inappropriate barriers or otherwise disadvantage people who share protected characteristics.

3.8 The issues that arose with the registration assessment meant that some candidates were initially disadvantaged. It is clear from the feedback we received that these issues had an impact on the candidates affected, although we have not seen evidence that people with protected characteristics were specifically disadvantaged.

3.9 We balanced the issues that arose on the registration assessment with the following factors:

- the GPhC was introducing a new format for the registration assessment and making decisions during the unprecedented and rapidly changing circumstances created by the pandemic
- the GPhC took prompt corrective action to reduce the impact for candidates sitting the March 2021 assessments
- the GPhC implemented measures to avoid similar issues arising for the July 2021 sittings which appear to have been effective
- the issues arose in one discrete area of the GPhC's work and there is wider, positive work it is doing on EDI.

3.10 In the light of these considerations, we are satisfied that this Standard is met.

Standard 4: The regulator reports on its performance and addresses concerns identified about it and considers the implications for it of findings of public inquiries and other relevant reports about healthcare regulatory issues.

4.1 We have no concerns about the way the GPhC reports on its performance. It continues to do this regularly in a variety of ways, including its annual report and through operational updates at public Council meetings.

4.2 The GPhC considered and acted on public inquiries and other events in the healthcare regulatory landscape, including:

- Brexit
- the Cumberlege report
- the Paterson inquiry.

4.3 The GPhC also carried out a significant amount of Covid-19-related activity in response to external events or emerging issues. For example, it:

- asked employers to review their risk assessments in light of Public Health England's (PHE's) report on *Disparities in the risk and outcomes of COVID-19*
- worked with Hestia, a charity running the UK SAYS NO MORE campaign, to encourage pharmacies to participate in the 'Safe Spaces' initiative.[13]

Corporate complaints

4.4 The GPhC reports on and analyses data on corporate complaints it receives. It identifies and shares learning through an established process.

4.5 In response to the pandemic, the GPhC changed its approach to managing Stream 1 fitness to practise cases.[14] Its new approach means Stream 1 cases are logged and closed. In anticipation that this would lead to an increase in corporate complaints about closed Stream 1 cases, the GPhC decided to streamline its approach to considering such complaints. The complaints are still logged by the Governance team and passed to the fitness to practise directorate for review and response. However, the review stage is carried out by a more junior member of the fitness to practise team.[15]

4.6 The new approach to corporate complaints about Stream 1 cases was not used during the review period because no corporate complaints of this type were received. We therefore cannot assess its impact.

Registration assessment

4.7 When the GPhC became aware of the concerns about the registration assessment process, it acted promptly to address these and carried out a lessons learned review to identify any other improvements it could implement for future sittings. The GPhC convened an additional Council meeting in June 2021 to publicly report the

[13] https://uksaysnomore.org/
[14] The GPhC's new approach is discussed further under the fitness to practise Standards.
[15] Prior to the pandemic, the review was carried out by the Head of Function or Manager but under the new process, the review is carried out by a senior member of the triage team.

findings from its lessons learned review. There were no reports of similar issues arising for the July 2021 sittings.

Conclusion against this Standard

4.8 During a year where the pandemic presented significant challenges for the regulators, the GPhC continued reporting on its performance, took action in response to public inquiries and other reports on healthcare regulatory issues and identified learning to address concerns about it.

4.9 The GPhC's response to the issues that arose with the registration assessment is a clear example of it identifying and addressing concerns. We are satisfied that the GPhC learned from the issues that arose and took effective steps to rectify the concerns. We are satisfied that this Standard is met.

Standard 5: The regulator consults and works with all relevant stakeholders across all its functions to identify and manage risks to the public in respect of its registrants.

Consultations

5.1 The GPhC consulted on:

- increasing registration fees for pharmacy premises
- proposals to expand the types of evidence it will accept for English language competence
- its new fitness to practise strategy: *Managing concerns about pharmacy professionals: Our strategy for change.*

5.2 After each consultation, the GPhC reported on the responses received and how the responses were taken into account.

Fitness to practise strategy

5.3 The GPhC's consultation proposed a number of changes to its approach. We responded, expressing concerns about the transparency and effectiveness of some of the proposals.

5.4 The GPhC's consultation report acknowledged the feedback it received. It has now launched its new strategy. We will be monitoring its implementation and impact.

Changes to the GPhC's procedure rules

5.5 The GPhC also carried out an expedited consultation exercise on changes to its procedure rules for its fitness to practise hearings to take account of the restrictions in place because of Covid-19. All the changes were temporary, with the exception of the changes allowing electronic service of documents.

5.6 The changes were in effect for two months and expired on 1 May 2021. We recognise that, in the emergency, the consultation needed to be expedited. The GPhC recently launched a public consultation on remote hearings, which includes proposals for a permanent change to its procedure rules to enable remote hearings. We will monitor the consultation and its outcome.

Working with stakeholders

5.7 The GPhC continued working closely with the PSNI on the new *Standards for the initial education and training of pharmacists* and the introduction of a joint four-country registration assessment. To finalise the *Standards for the initial education and training of pharmacists*, the GPhC re-convened a working group with education and training organisations in each country, professional and student representative bodies, trade unions and employers.

5.8 The pandemic led to increased engagement and collaboration amongst the regulators and their stakeholders. The GPhC:

- met regularly with:
    - the other health and social care regulators to discuss matters arising, provide information about changes or challenges and exchange learning
    - primary care clinical stakeholders
    - national pharmacy stakeholders
- issued joint statements with a range of stakeholders on topics involving potential risks to the public in respect of its registrants, such as:
    - the sale of rapid antibody tests and the advice at the time that they may have an adverse impact on wider public health
    - the introduction of the test and trace system and the impact this might have on business continuity in the event a whole pharmacy team, or large part of it, had to self-isolate.

Conclusion against this Standard

5.9 The GPhC continued to consult and work with stakeholders during the pandemic. We are satisfied that this Standard is met.

Guidance and Standards

Standard 6: The regulator maintains up-to-date standards for registrants which are kept under review and prioritise patient and service user centred care and safety.

6.1 The GPhC aims to review documents a year after publication and then between three and five years after publication.

6.2 The *Standards for pharmacy professionals* were introduced in May 2017 so now fall within the three to five year window for review.

6.3 The GPhC did not amend the *Standards for pharmacy professionals* in response to the pandemic. It published a joint statement with the other health and social care regulators explaining that the existing regulatory standards are designed to be flexible and provide a framework for decision-making in a wide range of situations. The regulators highlighted the key principles that should be followed.

6.4 We received no information to suggest that the *Standards for pharmacy professionals* were not flexible enough to apply appropriately to the unprecedented circumstances of the pandemic. We will monitor any work to review these standards but have no concerns about their suitability at present.

6.5 We are satisfied that this Standard is met.

Standard 7: The regulator provides guidance to help registrants apply the standards and ensures this guidance is up to date, addresses emerging areas of risk, and prioritises patient and service user centred care and safety.

7.1 Last year the GPhC began exploring the need for new guidance on the use of Multi-compartment Compliance Aids. This work was delayed by the pandemic but has now resumed and we will continue to monitor it.

7.2 In response to the pandemic, the GPhC published additional guidance and statements to help registrants understand how the *Standards for pharmacy professionals* applied in the circumstances. The GPhC identified emerging areas of risk on the basis of reports it was receiving. Guidance and statements were published about:

- the GPhC's approach to regulation, fitness to practise (including hearings) and inspections during the pandemic
- profiteering and pricing during the pandemic
- the sale of rapid antibody tests
- the temporary register, including guidance for employers and the GPhC's approach to concerns about temporary registrants
- operating pharmacies in emergency situations
- the use of NHS volunteers to deliver medicines
- new legislation relating to controlled drugs
- business continuity plans following the rollout of test and trace
- review of employer risk assessments in light of report findings on the impact of Covid-19 on BAME groups
- provisional registration, including guidance for employers and provisional registrants
- reports of employers under-reporting exposure to Covid-19 in community pharmacies.

7.3 The GPhC also continued to publish examples of notable practice on its inspections website. Covid-19-related examples were included and the search function of the inspections website was updated to enable users to search for examples related to Covid-19.

7.4 We consider that the GPhC responded very strongly to the pandemic and provided relevant and suitable guidance for its registrants. We are satisfied that this Standard is met.

Education and Training

Standard 8: The regulator maintains up-to-date standards for education and training which are kept under review, and prioritise patient and service user centred care and safety.

8.1 In recent years, the GPhC has been updating its standards of education and training for the pharmacy team.

8.2 This year the GPhC launched its new *Standards for the initial education and training of pharmacists* in January 2021,[16] replacing the previous standards from 2011. We have not identified any concerns about the new standards in terms of patient care and safety. The new standards incorporate training on independent prescribing (which was previously covered by post-graduate training programmes) and enable pharmacists to independently prescribe from the point of registration.

8.3 The GPhC is developing an evidence framework to accompany the new standards. In the meantime, it published FAQs on its website with other supporting resources to explain the changes that are being made.

8.4 The new standards will be implemented in phases. The GPhC has formed an Advisory Group to develop an implementation transition plan. The Advisory Group's work will address a number of challenges that have been identified, particularly those arising from the incorporation of independent prescribing training.

8.5 We received feedback that raised concerns about:

- the speed at which the new standards were being introduced and the risks arising from this, especially around prescribing
- whether the previous education and training standards were fit for purpose and whether the requirement to pass a standardised national registration assessment was outdated.

8.6 We are satisfied that the GPhC has given consideration to these points. It has identified potential areas of future risk arising from the implementation of the new standards and is working to address them. The work done by the GPhC to review and update its standards is aimed at ensuring they are up-to-date, fit for purpose and forward-looking.

8.7 The GPhC has worked throughout the year with stakeholders to ensure the standards reflect current practice and are forward-looking, and we note the work done with the Royal Pharmaceutical Society to ensure the learning outcomes are aligned with post-graduate training as far as possible.

8.8 We will continue to monitor the GPhC's work as it progresses. The GPhC continues to work with relevant stakeholders and has identified potential areas of future risk which it is working to address.

[16] The launch followed a public consultation and engagement work with a range of stakeholders which we reported on last year.

8.9 We have not identified any concerns about the work done to date. We are satisfied that this Standard is met.

Standard 9: The regulator has a proportionate and transparent mechanism for assuring itself that the educational providers and programmes it oversees are delivering students and trainees that meet the regulator's requirements for registration, and takes action where its assurance activities identify concerns either about training or wider patient safety concerns.

9.1 As a result of the pandemic, the GPhC:

- changed the way it conducted accreditation visits
- cancelled its 2020 sittings of the registration assessment and brought forward plans to introduce an online assessment
- introduced provisional registration.

Accreditation visits

9.2 The GPhC took different approaches to accreditation visits during the pandemic; some visits went ahead remotely, some were postponed and in some cases, accreditation was extended for one year.

9.3 When deciding which approach to take, the GPhC took account of the type of course[17] due for accreditation and the type of visit[18] due. It also considered the risks arising from extending accreditation without carrying out a visit. The GPhC mitigated the risks by asking all accredited course providers to submit information about any temporary changes made to their courses during the pandemic, together with assurance of how teaching and assessment would continue to address all the learning outcomes. These appeared to us to be relevant considerations.

9.4 This approach enabled it to obtain a level of assurance that the programs and providers it oversees continued to meet its standards, within the constraints of the national restrictions.

Registration assessment

9.5 We considered the events connected to, and the feedback we received about, the GPhC's registration assessment under this Standard.

9.6 We are concerned by the issues that arose when the booking system went live. However, we were satisfied that the GPhC took account of appropriate factors and stakeholders' views in deciding to retain the registration assessment. We were also satisfied that its decision to change from remote sittings to a hybrid approach was reasonable in the circumstances.

[17] The GPhC accredits different types of course, including MPharm, independent prescribing and pharmacy technician courses. Teaching and assessment methods vary according to the type of course.
[18] The GPhC carries out different types of accreditation visits, including full accreditation visits and interim monitoring visits.

Provisional registration

9.7 When the GPhC cancelled the 2020 sittings of the registration assessment, it introduced provisional registration so that eligible trainee pharmacists could start practising while waiting to sit the rescheduled registration assessment. We discuss the provisional register in more detail under Standards 10 and 11.

Conclusion against this Standard

9.8 We do not have concerns about the GPhC's accreditation activities during the pandemic, because it adapted them in a reasonable and proportionate way. We have also not identified any concerns about the GPhC's approach to provisional registration.

9.9 We are concerned by the issues that arose with the registration assessment. It is clear from the feedback we received that the issues had an impact on candidates during an already stressful time. Some of the issues were avoidable and public protection could have been affected if the issues had resulted in fewer registered pharmacists. However, we saw no evidence that this happened and, as with the other Standards, we took account of the action the GPhC took to resolve the problems and of the fact that the pandemic had created an unprecedented situation.

9.10 We therefore do not think the issues that arose with the registration assessment are serious enough to suggest that the GPhC did not meet this Standard. We are satisfied that this Standard is met.

Registration

Standard 10: The regulator maintains and publishes an accurate register of those who meet its requirements including any restrictions on their practice.

10.1 In response to the pandemic, the GPhC set up two new registers:

- a temporary register so that eligible[19] former registrants could join the workforce during the emergency situation created by the pandemic
- a provisional register so that eligible trainee pharmacists could start practising while waiting to sit the rescheduled registration assessment.

Provisional register

10.2 The provisional register was initially open from 1 July 2020 to 1 July 2021 but was later extended to 31 January 2022.

10.3 The GPhC set eligibility criteria for provisional registration.[20] We were contacted by people who had concerns about the criteria set by the GPhC and these are discussed further under Standard 11.

[19] Pharmacy professionals who had left the register in the last three years without fitness to practise issues were eligible for temporary registration.
[20] The GPhC published criteria for provisional registration in May 2020. https://www.pharmacyregulation.org/sites/default/files/document/initial-education-and-training-standards-for-pharmacists-criteria-for-registering-provisionally-june-2021.pdf

10.4 The GPhC recognised the risks of allowing individuals to practise before they had demonstrated that they meet the standards for registration by passing the registration assessment. To mitigate these risks, the GPhC required provisional registrants to practise under the guidance and direction of a senior pharmacist and prevented them from working as locums, Superintendent Pharmacists or Chief Pharmacists.

10.5 The GPhC conducted a survey of provisional registrants and used the responses to identify concerns about employers' risk assessments or registrants' access to clinical guidance and support. The GPhC contacted employers to ensure steps were taken to address these concerns and, where necessary, its inspection team followed up with the pharmacies concerned.

Accuracy of the registers

10.6 We saw no evidence of inaccuracies in the main register or the provisional register. One person was added to the temporary register in error because the exclusion parameters used to identify non-eligible registrants did not capture their circumstances. The error was identified when the GPhC received a query from the person concerned. The GPhC removed them from the register and updated their exclusion parameters.

10.7 The GPhC acted promptly and effectively to meet the workforce needs created by the pandemic. We had no concerns about this Standard and are satisfied that it is met.

Standard 11: The process for registration, including appeals, operates proportionately, fairly and efficiently, with decisions clearly explained.

11.1 The GPhC has not made any significant changes to its registration processes for pharmacy professionals or pharmacy premises.

11.2 It continues to process applications for registration efficiently. The median processing time:[21]

- for normal registration was less than one week
- for provisional registration was two days.

11.3 We received feedback about the GPhC's criteria for provisional registration, in particular the decisions to:

- exclude those who had completed their training prior to 2020 or who had failed the registration assessment from eligibility for provisional registration
- restrict provisional registrants from being able to locum.

11.4 People were concerned about the impact these restrictions would have on candidates' abilities to obtain employment and progress their careers.

11.5 Under Standard 9, we have listed the key principles the GPhC followed when making decisions about the registration assessment and provisional registration.

[21] The data reflects the median time taken from receipt of completed application to approval decision in 2020/21.

The GPhC balanced its aim of minimising delays for newly qualified registrants to join the profession with the need to maintain standards. The GPhC published its Equality Impact Assessment (EIA) on provisional registration which recognised that the policy may impact those with protected characteristics and identified actions to mitigate those impacts. The EIA also addressed concerns raised by stakeholders[22] about other groups that may be affected by the GPhC's approach to provisional registration, including resitters and those who needed flexibility in their work patterns.

11.6 We recognise that some groups disagreed with the decisions made by the GPhC because of the impact on them. However, we are satisfied that, before making its final decision, the GPhC:

- engaged with a range of stakeholders, including those impacted by the criteria
- took account of appropriate factors
- considered the potential impacts of the process it was implementing and how they could be mitigated.

11.7 The criteria set by the GPhC appeared to balance these considerations appropriately.

11.8 We are satisfied that this Standard is met.

Standard 12: Risk of harm to the public and of damage to public confidence in the profession related to non-registrants using a protected title or undertaking a protected act is managed in a proportionate and risk-based manner.

12.1 The GPhC has not changed its approach to managing risks related to non-registrants using a protected title. We have been satisfied with these in previous years and have no reason to believe that it needs to change.

12.2 In July 2018, the GPhC was given powers to use general surveillance and covert (directed) surveillance in its investigations providing certain statutory tests are met. Last year we reported it was developing a governance framework for the use of its new powers. We said we would monitor this work and the use of its powers.

12.3 The GPhC has not yet used its new surveillance powers and intends to use them in very limited cases. It made some minor updates to its policy and procedures to reflect good practice advice it received from the Investigatory Powers Commissioner's Office (IPCO). The IPCO inspected the GPhC remotely this year and was satisfied the governance framework is compliant with law and the GPhC was demonstrating good practice in a number of areas.

12.4 We are satisfied that this Standard is met.

[22] The EIA includes appendices with information about the different stakeholder engagement events carried out by the GPhC and the stakeholders which engaged, including the RPS, NPA, PDA, BPSA, Pharmacy Schools Council, Patients Association and the Black Pharmacists' Association.

Standard 13: The regulator has proportionate requirements to satisfy itself that registrants continue to be fit to practise.

Revalidation for pharmacists and pharmacy technicians

13.1 To revalidate, registrants are normally required to submit records of their CPD, peer discussion and a reflective account when they renew their registration each year.

13.2 In recognition of the impact of the pandemic, the GPhC reduced its revalidation requirements. Registrants are currently only required to submit a reflective account. The GPhC intends to resume full revalidation once the emergency powers for the pandemic introduced by the Secretary of State for Health and Social Care are removed, but will keep its position under active review. The GPhC may wish to consider whether the change in the requirement has any adverse impacts on registrants' performance or competence and, in the light of that, consider how the process should work in the future.

Premises inspections

13.3 The GPhC's inspections activity was significantly impacted by the pandemic. Intelligence-led inspections continued throughout but routine inspections were paused during national lockdowns. Inspectors were deployed in a supportive capacity, contacting pharmacies to provide advice and support. The GPhC also provided indemnity cover for inspectors who returned to practise as pharmacists during the pandemic.

13.4 The GPhC gathered examples of good practice in the context of the pandemic and shared them on its knowledge hub, publicising them through its social media channels. It also publicised enforcement action taken against pharmacies as a result of its inspection activity.

Conclusion against this Standard

13.5 The GPhC's usual activities were constrained by the pandemic this year but we saw it adapt its methods of gathering information, prioritise activity where potential risks had been identified and take action where necessary.

13.6 In the circumstances of the pandemic, where the GPhC's registrants were working as part of the front-line response, the approach taken by the GPhC was proportionate.

13.7 We are satisfied that this Standard is met.

Fitness to Practise

Standard 14: The regulator enables anyone to raise a concern about a registrant.

14.1 Last year, we reported having significant queries about the robustness of the GPhC's triage process. This year, we carried out a targeted review, with an audit, of this Standard because we wanted to understand:

- if the high proportion of cases closed at triage and low proportion of decisions made by the Investigating Committee (IC) indicated that cases were being closed sooner in the process than appropriate[23]
- the GPhC's new approach to managing its Stream 1[24] cases.

Triage processes and guidance

14.2 In 2018/19, we reported concerns about the GPhC deviating from its guidance when making triage decisions. The guidance required an assessment of whether the complaint was within the GPhC's remit based on four criteria. We found that the GPhC was considering additional criteria when making triage decisions. We were concerned about the transparency of this.

14.3 The GPhC is redesigning its triage function, moving towards undertaking more preliminary enquiries which enable a more holistic assessment. The Concerns Oversight Panel (OP)[25] and Closure Review Forum (CRF),[26] which were introduced as pilots in December 2018 and December 2019 respectively, will remain a part of the process for now. The GPhC also plans to introduce Case Examiners.

14.4 The GPhC updated its triage guidance to include:

- new sections explaining the roles of the OP and CRF
- factors to consider when deciding whether a voluntary agreement is appropriate
- examples of the types of further enquiries that can be conducted at triage
- changes to the process for cases relating to mental health so it is the same as the process for cases relating to physical health
- changes in some terminology.

14.5 The GPhC has not changed the remit assessment criteria so we remain concerned that there is a discrepancy between the criteria in the guidance and the criteria considered in practice. The OP, which is making triage decisions, has its own Terms of Reference. The test applied by the OP involves asking whether there are potential grounds for investigation. The inconsistencies between the guidance, the factors considered in practice and the OP's Terms of Reference means that different thresholds may be applied to triage decisions. This is not transparent and does not appear to support a consistent understanding of what factors can or should be considered when making triage decisions.

[23] The proportion of cases closed at triage this year is comparable to last year so there has not been a significant change in the data, but it remains relatively high.
[24] One of two investigation routes used by the GPhC if a fitness to practise concern progresses past triage. Cases which are assessed as unlikely to meet the threshold criteria after further investigation are investigated via Stream 1, which is managed by the GPhC's inspectorate team.
[25] A panel of senior members of the fitness to practise directorate which considers cases that have been recommended for a Stream 2 investigation and decides whether Stream 2, or another outcome, is appropriate.
[26] A forum that considers cases that have been recommended for closure and decides whether closure, or another outcome, is appropriate. The forum consists of the full Monitoring and Concerns team and a case officer from the Professionals Regulation team.

New approach to Stream 1 cases

14.6 Before the pandemic, cases referred to Stream 1 of the GPhC's investigation process were managed and investigated by its inspectorate team. From 26 March 2020, the GPhC stopped allocating Stream 1 cases to the inspectorate so that inspection-related activity could be prioritised.

14.7 Cases that were identified as Stream 1 at triage were closed but passed to the inspectorate for an additional risk assessment and review. An inspector reviews the case to decide which of the following actions is necessary:

- no further action
- prioritise future inspection when programme of inspections resumes
- contact Superintendent Pharmacist/owner or visit pharmacy to discuss concern and seek assurance
- telephone call or visit to the pharmacy (as part of the 'pandemic support' calls/visits being undertaken)
- partial intelligence-led inspection to review specific systems and procedures (as a minimum, a partial intelligence-led inspection will always involve an assessment against the six key standards that drive performance)
- full intelligence-led inspection.

14.8 Inspectors can challenge the triage decision if they think the case should have been referred to Stream 2 for investigation. This happened in four cases during the review period, which is comparable to the seven cases that were cross-referred from Stream 1 to Stream 2 in 2019/20.

14.9 Between 26 May 2020 and 31 March 2021, the GPhC closed 864 concerns at triage under its new Stream 1 approach. The GPhC carried out a full or partial intelligence-led inspection in response to 30 of those concerns.

14.10 The GPhC monitored its new approach, carrying out three internal audits and implementing improvements as a result. Our audit sample included nine cases closed under the new approach.

Audit findings

14.11 We audited 69 cases closed by the GPhC during the review period. All of the cases had a triage decision made on them, although 19 of the triage decisions were made before the review period. Our main audit findings at triage were:

- **Record-keeping**: reasons for decisions were not always recorded. We noticed an improvement in the recording of decisions during the review period compared to decisions made before the review period. However, reasons were still not recorded in 40% of the triage decisions we looked at that were made during the review period. In some cases, there was no record that they had been considered by the OP or CRF

- **Decision-making**: some decisions were based on flawed reasoning[27] but this did not necessarily lead to inappropriate outcomes. We disagreed with the closure decision in four cases because the concerns were minimised or not fully explored and, as a result, it was not clear that closure was the appropriate decision. However, most of the outcomes we saw were reasonable
- **Customer service**: parties were not always notified of the outcome of the case or there was a delay in providing updates
- **Risk assessment**: very few cases had a risk assessment recorded at triage
- **Cases closed under the GPhC's new approach to Stream 1 cases**:
    - the triage decision was reasonable in all cases, although the reasons were not always recorded
    - most of the outcomes identified by inspectors were reasonable and sufficient for public protection
    - most of the cases were progressed and reviewed by an inspector without avoidable or unexplained delays.

14.12 The record-keeping made it difficult for us to assess decision-making at triage because we could not see what factors had been considered or how they were balanced. It also meant we could not see whether the GPhC's triage guidance had been correctly and consistently applied. However, in each case we were still able to form a view on the outcome itself.

14.13 Most of the triage outcomes we saw were reasonable, even in cases where the reasoning was flawed. Where we disagreed with the closure decision, we could not always be certain that the outcome was sufficient for public protection because the concerns had not been fully explored before the case was closed. However, this was in a small number of cases and we saw no evidence to suggest wider concerns about the system. We also saw no evidence of cases being inappropriately closed under the GPhC's new approach to Stream 1 cases. Based on our audit findings and the low number of Stream 1 cases that led to inspections, we were also reasonably confident that high risk cases were not being inappropriately referred to Stream 1.

Conclusion against this Standard

14.14 We do not have concerns about the GPhC's triage process but we remain concerned about the transparency and clarity of the GPhC's triage guidance because it does not properly reflect all of the criteria that are considered.

14.15 The record-keeping at triage meant that we could not assure ourselves of the quality of the GPhC's decision-making. This includes decisions made by the OP and CRF, which are supposed to act as control mechanisms to ensure appropriate triage decisions are being made. It is therefore difficult for us to be assured that this additional scrutiny is having the intended effect.

[27] For example, they did not accurately reflect the concerns raised, were unclear or did not take account of relevant factors such as previous fitness to practise history.

14.16 However, we cannot say these factors are leading to cases being closed inappropriately because most of the triage outcomes we saw were reasonable. The GPhC's triage function is going through a period of flux as new processes are being implemented. This may explain some of our audit findings.

14.17 Our audit also allayed our potential concerns about the high proportion of cases being closed at triage because most of the triage outcomes were reasonable. We did not see evidence to suggest that the GPhC is routinely closing cases inappropriately at triage. We will continue to monitor the data.

14.18 On balance, we are satisfied that this Standard is met. We will be closely monitoring triage and the changes that are being made, in particular to the guidance.

Standard 15: The regulator's process for examining and investigating cases is fair, proportionate, deals with cases as quickly as is consistent with a fair resolution of the case and ensures that appropriate evidence is available to support decision-makers to reach a fair decision that protects the public at each stage of the process.

15.1 We looked at three areas of the GPhC's work:

- its progress towards completing its action plan to address our concerns from 2018/19
- the changes it made in response to the pandemic
- timeliness of case progression, including the impact of the pandemic and how the GPhC planned to manage this.

15.2 We took account of our audit findings where relevant.

The GPhC's action plan

15.3 The GPhC has been implementing a wide-ranging action plan to address the following concerns, which we reported in 2018/19:

- **The triage process**: the process being operated deviated from the GPhC's internal guidance for staff because it took account of factors that were not set out in the guidance
- **The pre-IC undertakings process**: there was no guidance in place on the circumstances in which it would be appropriate to offer pre-IC undertakings to registrants
- **The process for health cases**: outcomes were being used that were not described in the guidance and registrants were asked to provide further health information or agree to pre-IC undertakings without being provided with full and transparent information about this request
- **The 'informal guidance' process**: the GPhC issued 'informal guidance' to registrants without telling them it was such and without explaining what the future consequences might be

- **The process for IC warnings**: registrants were not provided with full and transparent information when invited to comment on or accept a warning issued by the IC.

15.4 The GPhC had to re-prioritise and adapt its plans because of the pandemic but has managed to complete almost all of its planned actions.

15.5 Last year, we reported that the GPhC introduced new guidance on voluntary agreements (formerly known as pre-IC undertakings) in December 2019. The guidance explains the purpose of these agreements and when their use may be appropriate. We are satisfied that this addresses our concerns about pre-IC undertakings.

15.6 The GPhC has also taken steps to address our concerns about the process for IC warnings by introducing a new process, guidance and templates in August 2020. The information provided to registrants is clearer and it is made clear that the IC should draft the wording for warnings. Further templates to support the new process were introduced in February 2021. The changes took effect in months eight and 12 of the review period so they do not impact the full year.

15.7 We remain concerned about the other elements of the process and whether they are operating in a fair way because:

- as detailed under Standard 14, the GPhC has not updated the assessment criteria described in its triage guidance
- while the GPhC's guidance does not mention proportionality as a factor to consider, our audit found that triage decisions on health cases routinely take account of proportionality. This is not inappropriate, but it gives rise to concerns about transparency. Importantly, almost all of the closure decisions we saw in health cases were reasonable. We also no longer saw outcomes being used that are not described in the guidance.

15.8 In addition, the GPhC's internal guidance has not been updated in relation to the issuing of 'informal guidance'. After our review, the GPhC confirmed that in March 2020 it updated its outcome letter template to include clearer information about the impact of informal guidance on registration and how the GPhC may take it into account if further concerns are raised. The GPhC also provided training to staff in February and July 2020. We did not see evidence of the impact of these changes in the cases we audited so we will continue to monitor this area for evidence of improvements. We will also monitor the impact of work completed by the GPhC shortly after this review period, including further training and the introduction of an informal guidance bank in April 2021.

Changes made in response to the pandemic

15.9 The pandemic and associated restrictions had an impact on the GPhC's fitness to practise processes in a number of ways:

- **Investigations**: as mentioned under Standard 14, the GPhC changed the way it managed Stream 1 cases because of the pandemic. Other investigations proceeded as normal although the GPhC advised that progress may be delayed because of the pandemic
- **Committee meetings and hearings**:

- Investigating Committee meetings continued remotely
- interim order applications, interim order reviews and principal reviews were prioritised and considered on the papers, where parties consented
- listed principal hearings were initially postponed but subsequently resumed remotely

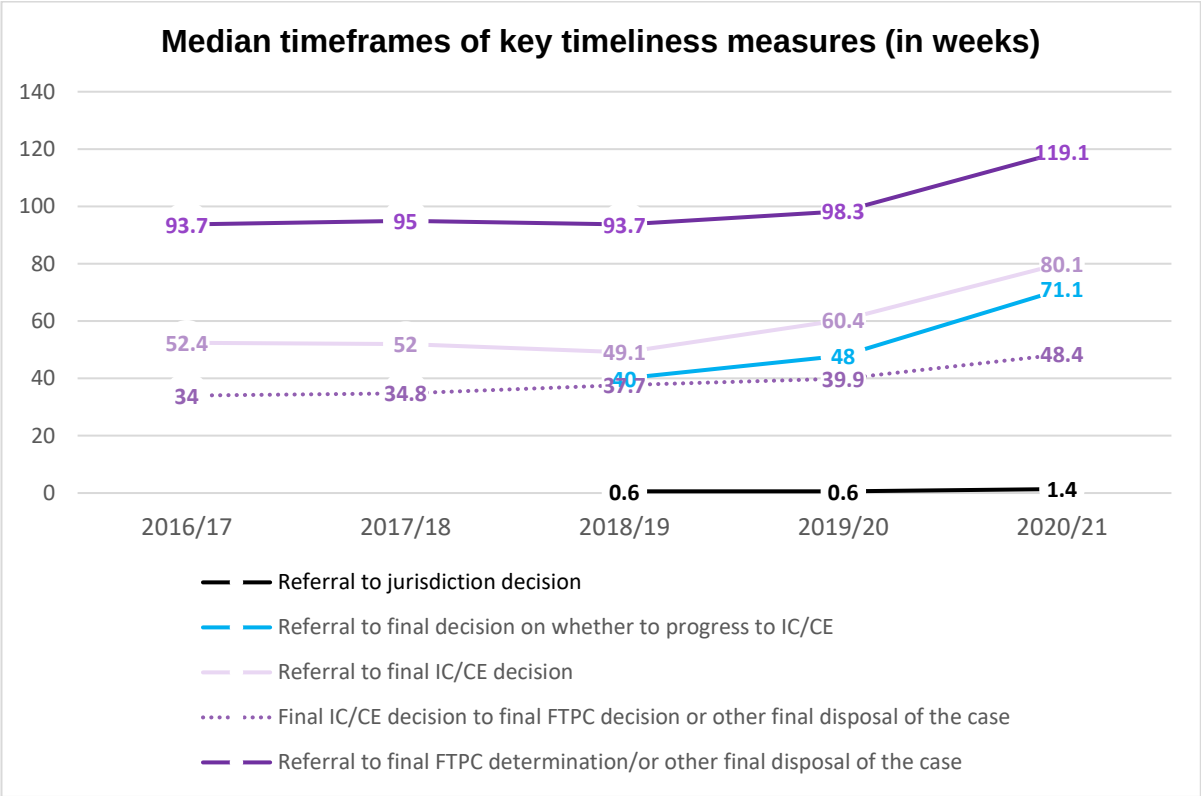
- **Procedure rules**: the GPhC was granted temporary changes to its procedure rules to facilitate remote hearings and electronic service of hearing notices and documents
- **Temporary register**: the GPhC developed a separate risk-based approach to managing concerns about temporary registrants, based on the grounds on which an interim order can be sought
- **Provisional register**: the GPhC applied its usual fitness to practise processes and policies to consider concerns raised about provisional registrants.

15.10 We did not identify any significant concerns about the changes made by the GPhC in response to the pandemic. In November 2021 it launched a public consultation on proposed permanent changes to its procedural rules. We will be monitoring any permanent changes it introduces.

Timeliness of case progression

15.11 The time taken for the GPhC to progress cases was deteriorating before the pandemic. Part of the GPhC's action plan was aimed at addressing this. The chart below shows that timeliness declined again in 2020/21.[28]

[28] Before 2018/19 we did not collect data on the median timeframe from referral to jurisdiction decision or referral to final decision on whether to progress to IC/CE.



15.12 The pandemic affected the GPhC's resources, logistics and ability to obtain information from third parties and hold hearings. These challenges contributed to the deterioration in timeliness this year, but we cannot quantify the extent of this. We do not know whether we would have seen improvements in timeliness had it not been for the pandemic.

15.13 Nonetheless, the deterioration in timeliness is significant as all of the median timeframes have increased, three of them by nearly 20 weeks or more.

15.14 The GPhC acknowledges that its timeliness needs to be improved. In addition to the actions it was already taking, it has identified further improvement measures, including:

- embedding its updated case review processes and ensuring more regular case reviews of cases over ten months old
- launching a new Investigation Report Form (IRF)
- securing additional support with the taking of evidence, providing case direction, undertaking advocacy and report writing
- creating a new administrative role to assist case officers in progressing cases and ensuring good customer care.

15.15 We will monitor the implementation and impact of these measures.

Conclusion against this Standard

15.16 The GPhC made significant progress with its action plan this year whilst also responding to the challenges of the pandemic. Our concerns about the processes for pre-IC undertakings and IC warnings have been addressed, although the latter was only addressed in the last quarter of the review period.

15.17 We still have concerns about the transparency and clarity of certain elements of the fitness to practise process and the GPhC's decision-making. In addition, timeliness was poor last year and has significantly deteriorated this year. We have taken account of the pandemic and the improvements implemented by GPhC. However, our concerns have led us to conclude that this Standard is not met.

Standard 16: The regulator ensures that all decisions are made in accordance with its processes, are proportionate, consistent and fair, take account of the statutory objectives, the regulator's standards and the relevant case law and prioritise patient and service user safety.

16.1 The GPhC has four main decision-making points in its fitness to practise process:

- triage
- threshold criteria stage
- Investigating Committee
- Fitness to Practise Committee.

16.2 Last year, we had no significant concerns about decisions made by the Investigating and Fitness to Practise Committees. However, we remained concerned that the processes underlying triage and threshold criteria decisions did not ensure that those decisions are made in accordance with the GPhC's processes and are consistent and fair. In considering the Standard this year, we took account of our audit findings where relevant.

Triage processes and guidance

16.3 The GPhC is redesigning its triage function and will be implementing new guidance to accompany its new approach. We have referred to our concerns about the lack of transparency in its guidance and inconsistencies in threshold in our discussion Standard 14. As mentioned there, our audit found that reasons for triage decisions were not always recorded. In these cases, we could not properly assess the decision-making because we could not see if decisions were based on the GPhC's processes and guidance or whether the various criteria were considered in a fair and consistent way.

Threshold criteria decisions

16.4 Our audit sample included 12 cases where threshold criteria decisions were made. In just over half of the cases, we found the reasons for the decision were not always fully and accurately recorded or they were flawed in some way. For example, in some cases it was recorded that there was a lack of evidence when there was a conflict of evidence. We had no concerns about decisions in the remainder of the cases.

16.5 The GPhC delivered training in 2020 which included:

- sessions on 'giving good reasons' in July and August, with a refresher in April 2021
- specific training on the threshold criteria in September 2020.

16.6 There was no marked difference between the threshold criteria decisions we saw that were made before and after the training. However, we saw a relatively small number of decisions made after the training was delivered so have not drawn any firm conclusions from this.

16.7 The GPhC carried out its own internal review of threshold criteria decisions. It found that 'decisions generally contained clear and detailed assessment of the available evidence, identified conflicts in the evidence and evidential weaknesses' but that there was a need to 'review the structure of decisions to include clearer analysis of risks and behaviours and highlight the most serious issues in order to reflect the weight of evidence and risk.'

16.8 These findings provide evidence of improvements in the quality of threshold criteria decisions. However, our audit findings suggest our concerns have not yet been fully addressed.

Conclusion against this Standard

16.9 We continue to have concerns about decisions at the triage and threshold criteria stages. While we have not seen inappropriate or unsafe decisions being made, the GPhC's poor record-keeping made it difficult to properly assess its decision-making and meant we could not always see the link between the reasoning and the decision. In these circumstances, we cannot be assured that the processes in place are ensuring good decision-making.

16.10 We welcome the evidence of improvements so far. This suggests the direction of travel is positive. However, there is still work to be done to fully address our concerns and we have therefore concluded that the Standard is not met.

Standard 17: The regulator identifies and prioritises all cases which suggest a serious risk to the safety of patients or service users and seeks interim orders where appropriate.

17.1 Last year, this Standard was met but we said we would monitor three areas of the GPhC's work:

- cases placed on hold
- interim orders
- risk assessments.

17.2 This year, we carried out a targeted review, with an audit, of this Standard because we wanted to better understand how the GPhC assesses and manages risks.

Cases placed on hold

17.3 Last year, the GPhC carried out a review of all on-hold cases[29] which found that further work was needed to embed its *Undertaking parallel investigations* guidance. A repeat review was planned but was delayed due to the pandemic and did not take place during the review period.

[29] These are cases where the GPhC pauses its investigation in certain circumstances, for example to avoid prejudicing an ongoing police investigation.

17.4 Our audit sample included seven cases that were placed on hold at some stage of the investigation. We did not identify any concerns about the reasons these cases were placed on hold and found that investigations were resumed promptly when it was appropriate to do so.

Interim orders

17.5 We identified some concerns about how the GPhC manages interim order cases because:

- the GPhC reported[30] issues on four cases:
    - there was a delay in applying for an IO in one case because the recommendation for an application was missed
    - an IO lapsed because it was not reviewed in time
    - the High Court refused an application to extend the IO on two linked cases
- the number of applications to the High Court for IO extensions has increased in recent years.

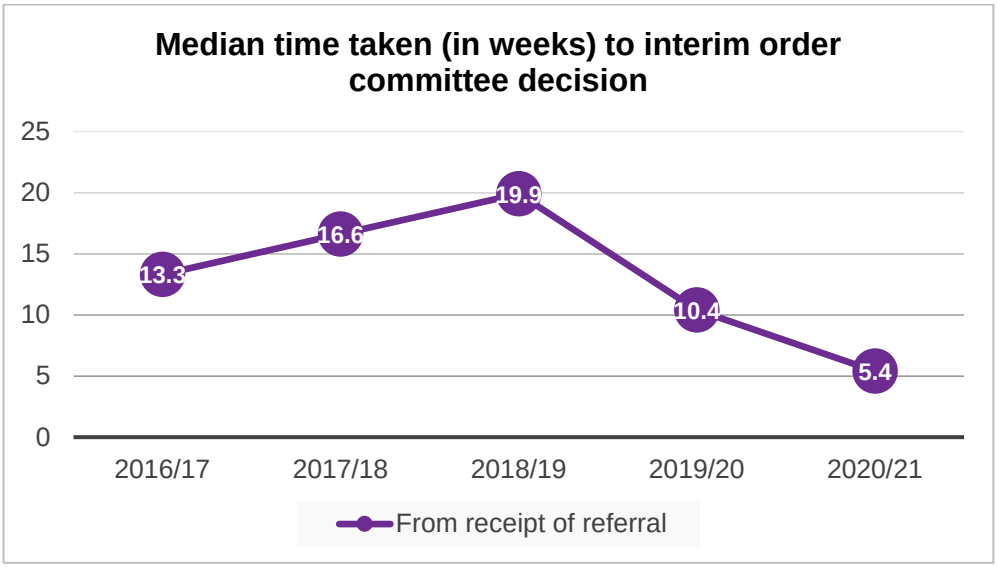
17.6 We sought further information from the GPhC about the four cases where it reported issues. We were satisfied that the GPhC reviewed what happened in each case to identify the cause(s) and put measures in place to prevent further recurrences. The GPhC also provided evidence that the measures were effective.

17.7 Our audit sample included seven IO cases. Due to the nature of IO cases, most of the activity we saw on these cases occurred before the review period. However, we were concerned by what we saw because we found:

- avoidable or unexplained case progression delays in four cases
- avoidable delays in applying for an IO in two cases.

17.8 Since the delays we identified in these cases, the GPhC has changed its IO process to ensure IO applications are made promptly. It has also implemented a range of measures to improve timeliness of case progression. As mentioned under Standard 15, the GPhC's timeliness of case progression has deteriorated this year.[31] However, the chart below shows that during the review period there was a significant improvement in the time taken to apply for an IO from receipt of the referral. This suggests the changes to the GPhC's IO process have improved the timeliness of IO applications.

[30] The information was reported to Council in the GPhC's performance monitoring reports.
[31] We do not collect separate data on the progression of IO cases so cannot separate them from the overall timeliness data.



Risk assessments

17.9 Last year, we said we were concerned because the GPhC had not yet addressed the points we raised in 2018/19 about its approach to documenting risk assessments. They were not documented at triage and at investigation stage they were documented on Yes/No checklists with little, if any, accompanying explanation.

17.10 The GPhC told us its approach to documenting risk assessments 'is an ongoing and progressing area of activity' but some of its planned work was delayed by the pandemic. It continues to use Yes/No checklists during investigations but now documents risk assessments at triage. An internal review by the GPhC found 'significant improvements in the consistency with which risk assessments are recorded' at that stage.

17.11 However, our audit did not find significant improvements in the risk assessments carried out by the GPhC during the review period. We found:

- at triage, very few risk assessments were recorded
- during investigations, risk assessments:
    - were not always completed when they should have been
    - did not always identify or analyse the risks arising.

17.12 The GPhC accepted that its recording of risks and frequency of risk assessments can be improved. It is working to improve various aspects of its risk assessments and we accept that the pandemic has caused delays in this work. However, we are concerned that this work is taking so long to progress, given that it directly relates to how risks are identified and managed.

Conclusion against this Standard

17.13 We reported concerns about the GPhC's risk assessments in our last two performance reviews and have seen no significant change in performance this year.

17.14 The GPhC accepts its risk assessments need to improve and has a number of actions in progress aimed at addressing this. We did not see evidence of the GPhC

failing to identify the need for an IO or failing to apply for an IO when it should have. We also note that the time taken from referral to Interim Order Committee decision has improved.

17.15 We are satisfied that this Standard is met this year. However, we will be seeking evidence of improvement in the GPhC's risk assessments next year.

Standard 18: All parties to a complaint are supported to participate effectively in the process.

18.1 In 2018/19, our audit found that:

- parties were not kept updated on their cases
- processes were not being clearly explained
- outcomes were not always sent
- there were avoidable or unexplained delays on a significant number of cases
- parties were given short response deadlines.

18.2 This Standard was not met last year as we were not assured that the GPhC had addressed the concerns identified from our 2018/19 audit. The GPhC is addressing these concerns through two pieces of work:

- a new Fitness to Practise strategy: *Managing concerns about pharmacy professionals*
- its Communications Forum action plan.

18.3 The pandemic delayed this work but most of it has now been completed, albeit that some was completed after the current review period.

18.4 The GPhC's new Fitness to Practise strategy was launched in July 2021, after a public consultation. During the review period, the GPhC progressed elements that were not dependent on the consultation and are aimed at being more person-centred. For example, it launched a new witness page on its website and delivered workshops for staff on being more person-centred.

18.5 The Communications Forum action plan has four main elements:

- **Service promises**: these were introduced after the review period as part of the new Fitness to Practise strategy
- **Glossary of terms**: these were introduced after the review period, in March 2021
- **FAQs**: these were introduced after the review period, in March 2021
- **Review of template documents**: revised templates were introduced during and after the review period and this piece of work is ongoing.

18.6 This Standard was not subject to audit this year. However, some of our audit findings are relevant to this Standard. Our audit found improvements in the information provided to participants:

- the acknowledgement template includes information about next steps, anticipated timeframes and signposts complainants to independent sources of support
- when registrants were contacted, they were routinely signposted to Pharmacist Support.

18.7 However, we also found that:

- participants were not routinely provided with regular case updates
- in some cases, participants were not notified of the outcome.

18.8 The GPhC's own internal reviews looked at outcome correspondence sent after decisions made by the Closure Review Forum. Approximately two thirds of the correspondence reviewed addressed the complainant's concerns, had clear reasons, was person-centred and displayed sensitivity. We would expect to see good quality correspondence on a higher proportion of cases. The GPhC also acknowledged that more work is needed at the investigation stage of its process to embed person-centred communications. It told us about the following future activity it has planned, which we will monitor:

- a new online concerns form
- updated information leaflets for witnesses
- exploring other forms of support for witnesses, which will be informed by asking witnesses for their views.

Conclusion against this Standard

18.9 Although the pandemic delayed some of the GPhC's plans, most of the improvement work has now been completed. Our audit found evidence of some improvements but they relate only to the initial stages of the fitness to practise process. There is still work to be done to ensure parties are supported to participate throughout the process.

18.10 We recognise the progress made by the GPhC this year, particularly in the circumstances of the pandemic. While we have seen improvements, we still have some concerns that were not addressed within the review period, which means we have concluded that this Standard is not met.

Useful information/links

The nature of our work means that we often use acronyms and abbreviations. We also use technical language and terminology related to legislation or regulatory processes. We have compiled a glossary, spelling out abbreviations, but also adding some explanations. You can find it on our website.

You will also find some helpful links below where you can find out more about our work with the 10 health and care regulators.

Useful links

Find out more about:

- the 10 regulators we oversee
- the evidence framework we use as part of our performance review process
- the most recent performance review reports published
- our scrutiny of the regulators' fitness to practise processes, including latest appeals

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