professional standards authority
for Health and Social Care

performance review 2019/20

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.

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 2019/20

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 pharmacy professionals and premises in Great Britain.

As at 31 March 2020, the GPhC was responsible for a register of:

57,651 pharmacists, 23,705 pharmacy technicians and 14,181 registered pharmacies

Annual registration fee is: £257 for pharmacists; £121 pharmacy technicians; and £262 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 2019/20 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 Pharmaceutical Council

Executive summary

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

This report sets out the findings of our annual performance review of the General Pharmaceutical Council (GPhC), which 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. We revised our Standards in 2019; this is the first performance review of the GPhC under the new Standards.

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 also sought information from the GPhC where we considered this necessary.

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 2019/20

From our initial review, we required further information about the GPhC's work in relation to its approach to feedback from external stakeholders, how it addresses poor performance in the registration assessment, the registration process for pharmacy premises and the action plan and activities being undertaken to address our concerns from last year. Following a targeted review, we concluded that the GPhC has not met Standards 15, 16 and 18.

General Standards

When we revised the Standards, we introduced a new set of General Standards covering a range of areas including: providing accurate, accessible information to registrants and

[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).

the public; clarity of purpose; equality, diversity and inclusion; reporting on performance and addressing organisational concerns; and consultation and engagement with stakeholders to manage risk.

The GPhC uses its website as its primary means of providing information about its work. This year it launched a new inspections website to publish information relating to its premises inspection and enforcement work. The new website includes inspection reports and a knowledge hub with searchable examples of good, excellent and poor practice. The GPhC has used its new website to publish independent research it commissioned to identify the key patterns, trends and themes in pharmacy inspection reports. It will also be using the new website to publish reports from themed inspections it undertakes. Information provided by the GPhC about its purpose is clear and tailored appropriately and we have seen evidence of it undertaking activities that are in line with its statutory objectives.

The GPhC collects EDI data on a voluntary basis from stakeholders who interact with it. It has published analyses of the data it holds and has commissioned research in a number of areas which have identified further work that it is taking forward. An analysis of candidate performance in the registration assessment by characteristic led to a recommendation that the new standards for initial and training for pharmacists should include a requirement for schools of pharmacy to have proactive equality and diversity policies which should be reported on through the accreditation process. The GPhC is evaluating the effectiveness of its fitness to practise processes in ensuring fair decision-making and eliminating discrimination.

The GPhC considered the Gosport Independent Panel Report and the Williams review into gross negligence manslaughter in healthcare. It identified actions for itself arising out of the recommendations and is undertaking work resulting from them. It is part of an implementation working group convened by the Department of Health and Social Care in response to the Williams review.

We have seen evidence of the GPhC regularly consulting and working with all relevant stakeholders. It uses a variety of different channels to engage, consult on and publicise the work it is undertaking. The GPhC has agreed Memoranda of Understanding with a number of organisations across the health and social care sector to ensure information pertaining to patient safety is shared when appropriate.

Other key findings

New policy development framework

We had concerns about how far the GPhC was taking feedback from individuals into account when addressing risk and developing its policy. It has launched a new policy development framework for reviewing and developing guidance which provides examples of circumstances which might prompt the GPhC to review or develop guidance and key factors to consider when deciding whether new guidance needs to be produced. The framework does not contain any explicit mention of risk, either as a prompt to develop new guidance or as a factor to consider. The GPhC told us that risk assessment is part of its ‘Project Initiation Document’ and we consider that it is likely that some parts of the

framework may prompt consideration of risk. We understand that the framework is still in development and we consider the finalised framework should ensure that there is explicit consideration of risk.

Standards for initial training and education for pharmacists

The GPhC is continuing work on changes to its standards for the initial education and training of pharmacists. Responses to its consultation raised concerns about the learning outcomes and how the integration of education and training would be funded. The GPhC undertook further consultation and is now finalising the revised standards, with the reforms expected to begin in July 2021.

Registration assessment

The GPhC and the Pharmaceutical Society of Northern Ireland (PSNI), each manage and administer the registration assessment for candidates in their own jurisdiction. This year, the two regulators agreed to introduce a joint four-country wide assessment. The GPhC will primarily manage the arrangements, although the PSNI will continue to administer the examination in Northern Ireland. A partnership agreement has been put in place to ensure that Northern Ireland representatives have input into standards and question-setting and that the PSNI continues to have oversight in respect of quality assurance in Northern Ireland. The first joint assessment will take place in June 2021.

We asked the GPhC about action it had taken this year to address repeated and continued poor performance in the registration assessment. We were satisfied that the GPhC had taken appropriate steps, but noted that the actions described to us by the GPhC did not appear to be supported by a formal, documented process, such as a written policy. Formalising this process would assist consistency and business continuity and also ensure there is ongoing monitoring and follow-up of any issues identified.

Approach to pharmacy inspections

Shortly before the period under review, the GPhC updated its approach to pharmacy inspections. Inspections are now generally unannounced and are of three different types; routine, intelligence-led or themed. The GPhC's new approach involves a move towards more risk-based, intelligence-led approach. The GPhC has reported an increase in enforcement activity this year and attributes this to its new approach to inspections. Inspections undertaken during the period under review identified patient safety concerns in relation to the unsafe supply of high-risk medicines by some online pharmacies. As well as taking action against the individual pharmacies, the GPhC highlighted the issue to all online pharmacy owners and reminding them of the *Guidance on providing pharmacy services at a distance.*

Triage process

Last year we were concerned about the GPhC's triage process because we noted that factors that were not included in its guidance were being considered when decisions were being made. The GPhC did not update its guidance to address this point during the period under review. However, the GPhC has introduced additional oversight of cases closed at triage with no further action. It had already started piloting a further review of cases referred for further investigation. The GPhC's analysis of the impact of the additional oversight indicates that reviewers amend the outcomes originally recommended. This raises concerns about the robustness of the main triage process. The GPhC is reviewing

and redesigning this function. It also updated its triage guidance shortly after the period covered by this report. We will be monitoring this work closely.

Approach to risk assessments

Last year, we were concerned about the GPhC's approach to risk assessments because we could not always establish the reasons for the conclusions reached. The GPhC has begun reviewing its approach, but this work was not completed in the period under review.

Action plan in response to the Authority's 2018/19 performance review

In response to our performance review last year, the GPhC published a wide-ranging action plan designed to address the concerns we reported and improve its timeliness and customer service. We reviewed all the investigating committee decisions made in the last quarter of the period under review and saw evidence that the level of detail and reasoning has improved, warnings are set out explicitly when issued and there were no examples of the decisions heavily reflecting the wording of the GPhC's recommendation to the investigating committee. While we felt that the level of reasoning in the investigating committee decisions could be further improved, we concluded that, in the light of the overall improvements, we no longer have significant concerns about investigating committee decisions. Due to the timing of most of the other work in the GPhC's action plan, and the period covered by this report, our concerns about timeliness, customer service and the transparency and fairness of a number of fitness to practise processes are yet to be resolved. We therefore determined that Standards 15, 16 and 18 were not met.

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

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 its website as its primary vehicle to publish information about its work. The website provides information about the GPhC's different regulatory requirements, such as its education and training requirements and its registration requirements. Publications, including the GPhC's standards and guidance documents, are available to download. Users can also raise a concern or search the GPhC's registers via the website.

1.2 The GPhC has a *Publication and disclosure policy* setting out its approach to publishing information about fitness to practise decisions, inspections and enforcement action, its education-related function and the registers. The policy explains where information will be published and for how long.

1.3 Recent fitness to practise determinations are published in the GPhC's e-newsletter, *Regulate*, which is available on the GPhC's website. There is also a search function on the website for fitness to practise determinations.

1.4 In September 2019, the GPhC launched a new inspections website to publish inspection reports[2] and other information about its inspection work. With the launch of the new website, the GPhC also published two reports resulting from independent research it commissioned to identify the key patterns, trends and themes in pharmacy inspection reports from November 2013 to August 2018. One report was an analysis undertaken by the research company and the second was a report prepared by the GPhC summarising and further analysing the key findings of the research. The website also includes a knowledge hub which contains a searchable list of notable examples of good, excellent and poor practice and will be used to publish reports from themed inspections.

1.5 The GPhC also uses other channels to promote and publicise its work and the method used is tailored according to the piece of work it relates to. For example, prior to the launch of the inspections website, the GPhC provided face-to-face and written briefings to key stakeholder organisations and when the GPhC introduced new guidance for pharmacist prescribers in November 2019, all pharmacist prescribers and superintendent pharmacists were sent a targeted email in addition to the guidance being more generally publicised online. These key engagement and communications activities are reported to the GPhC's Council on a quarterly basis.

[2] In May 2018, changes to the Pharmacy Order 2010 took effect which gave the GPhC the power to publish outcomes of inspections.

1.6 The GPhC has a YouTube channel, a Twitter feed and a Facebook page. Videos about revalidation and inspections are available to view on the YouTube channel and live updates about Council discussions and Council decisions are published on the GPhC's Twitter feed.

1.7 The GPhC's main website and its inspections website both use the accessibility tool ReciteMe. The software enables users to customise the website to their needs, including a text to speech function, dyslexia software, an interactive dictionary and a translation tool with over 100 languages.

1.8 The GPhC told us that when it was developing its inspections website, it commissioned the Shaw Trust[3] to test the accessibility of the website. The feedback from the Shaw Trust led to a number of improvements being made prior to the launch of the website.

1.9 The GPhC has quality assurance processes in place to ensure the information it publishes is accurate. It also has an ongoing auditing process to ensure that documents on its website are accurate and up-to-date. We have not identified any examples of inaccurate information being published during the period under review.

1.10 Based on the evidence we have seen, we are satisfied that this Standard is met and consider that the GPhC has taken important and very valuable steps in improving the transparency of the information available to patients and the public. We commend this.

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.

Clarity of purpose

2.1 The GPhC's objectives and principal functions are set out in the Pharmacy Order 2010. Its over-arching objective is the protection of the public, which involves pursuit of objectives to:

- protect, promote and maintain the health, safety and wellbeing of the public
- promote and maintain public confidence in the professions regulated under the Order
- promote and maintain proper professional standards and conduct for members of those professions
- promote and maintain proper standards in relation to the carrying on of retail pharmacy businesses at registered pharmacies.

2.2 The GPhC's principal functions are:

- to establish and maintain a register of pharmacists, pharmacy technicians and premises at which a retail pharmacy business is, or is to be, carried on

[3] The Shaw Trust is a charity which employs people with a wide range of disabilities and accessibility needs and supports organisations in checking the accessibility of their websites.

- to set and promote standards for the safe and effective practice of pharmacy at registered pharmacies
- to set requirements by reference to which registrants must demonstrate that their fitness to practise is not impaired
- to promote the safe and effective practice of pharmacy by registrants (including, for example, by reference to any code of conduct for, and ethics relating to, pharmacy)
- to set standards and requirements in respect of the education, training, acquisition of experience and continuing professional development that it is necessary for pharmacists and pharmacy technicians to achieve in order to be entered in the Register or to receive an annotation in the Register and to maintain competence
- to ensure the continued fitness to practise of registrants.

2.3 The GPhC's strategic and business plans for 2017-20 are linked to its objectives and principal functions and the GPhC's Council has oversight of progress against each of the strategic objectives through quarterly reports and through papers on relevant pieces of work. For example, the reports resulting from consultations conducted by the GPhC this year on its guidance for pharmacist prescribers and its guidance for pharmacies providing services at a distance explained how the work being consulted on was linked to the GPhC's strategic objectives.

Conflicts of interest

2.4 In September 2019, the GPhC updated its *Conflicts of interest policy* to include new guiding principles for identifying, managing and recording conflicts of interest. This was one of a number of policy updates completed by the GPhC as part of its regular reviews of its governance framework to ensure policies remain in line with relevant legislation and good practice. Council members and Directors continue to be asked to provide updated declarations of interests in March and September and are expected to provide updated information as soon as possible following a change in circumstances. The declarations are published on the GPhC's website and are also reported to the GPhC's external auditors as part of the year end processes.

2.5 The *Conflicts of interest policy* sets out what should be declared and how. Details of how conflicts will be managed in certain circumstances are set out through other policies and procedures, for example in its Standing Orders of the Council. The GPhC told us that guiding principles in the overarching policy provide it with the flexibility to respond appropriately to individual circumstances.

2.6 The GPhC told us about two examples of declarations that were made during the period under review and explained how they were managed. We did not identify any concerns about the way in which the declarations were managed.

Application of policies

2.7 The GPhC told us that it uses a flexible approach and a variety of different methods, such as different types of training and cross-team activities, when

embedding new policies. The methods used are dependent on the policy being implemented.

2.8 The GPhC then uses a range of tools to monitor the application of policies after they are introduced. These tools include internal quality assurance groups and external auditors and legal firms which conduct assurance audits and 'critical friend' reviews.

Application of learning

2.9 Between January and April 2019, the GPhC consulted on changes to the initial education and training for pharmacists. The consultation is discussed in further detail under Standard 5. However, we noted that the proposals incorporated a recommendation from the paper *Learning from the Registration Assessment 2010-18*[4] that the revised initial education and training standards for pharmacists should require schools of pharmacy to have proactive equality and diversity policies which should be reported on through the accreditation process.

2.10 The GPhC has also set out its intention to use learning from research it has conducted or commissioned to inform its wider work. The learning from the analysis of inspection reports, mentioned under Standard 1, will be used to inform the development of the GPhC's new fitness to practise strategy, as well as its approach to inspections. And the GPhC's policy and operational work will be informed by an analysis of an online registrant survey which ran from June to July 2019. The purpose of the survey was to gain insight into pharmacy professionals' work, training, job satisfaction, professional practice and future plans. A similar survey was conducted in 2013 and the GPhC intends to run it again in future on a cyclical basis so that changes in these areas can be identified.

2.11 We have seen evidence of the GPhC undertaking activities that are in line with its statutory objectives, that it uses a mixture of internal and external resources to assure itself that policies are being applied appropriately and it uses learning from different areas of its work to inform others. 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 is developing an Equality, Diversity and Inclusion (EDI) Strategy which it plans to consult on in 2020. It currently has an *Equality, Diversity and Inclusion Statement* and an *Equality, Diversity and Inclusion Policy (HR)* which set out:

- the GPhC's commitment to EDI
- the EDI work the GPhC has planned

[4] The paper was presented by the GPhC to its Council in July 2018.

- how the GPhC will ensure that unlawful discrimination does not occur in its interactions with its employees or any of its service users, including members of the public and registrants.

3.2 The GPhC is a member of the Business Disability Forum, Wharfability Disability Network,[5] Stonewall and building a case for Disability Confident. It also told us that it has established internal networks for staff to promote an inclusive workplace. These include Black, Asian and minority ethnic (BAME), women's, LGBT+ and disability networks. The GPhC has an EDI leadership group with representation from across the organisation which monitors and provides assurance on EDI practice.

3.3 The GPhC collects EDI data on a voluntary basis from people and groups that interact with it, such as students, registrants, partners, witnesses in fitness to practise proceedings and respondents to consultations.

3.4 We have seen examples of how the GPhC then uses and reports on this data. As mentioned under Standard 2, the GPhC conducted an analysis of candidate performance in the registration assessment by characteristic and identified recommendations relating to EDI practices, which the GPhC is currently taking forward. The GPhC will continue to report on candidate performance, including breakdowns by characteristic where this is possible without leading to individuals being identifiable.

3.5 The GPhC's Assurance and Appointments Committee (AAC) reports annually on its work and this includes an equality data analysis of the GPhC's associates and partners.[6] The AAC reports data on six of the nine characteristics protected under the Equality Act 2010[7] and provides a comparison of the associate and partner populations against both the UK and registrant populations.

3.6 The GPhC reported that its last recruitment campaign for associates and partners, which took place in Spring of 2018, was designed to attract applicants from as diverse a range of backgrounds and sections of the community as possible. The AAC reported that in 2017/18 the proportion of non-white panellists had risen since 2015, from 21 per cent to 25.9%. There has been no recruitment since the 2017/18 report, so the report for 2018/19 contains largely similar data.

3.7 The GPhC told us about the combination of tools it uses to ensure its processes do not impose inappropriate barriers or otherwise disadvantage people who share protected characteristics. The GPhC:

- provides regular EDI training to staff and associates, which includes equality and unconscious bias training, disability awareness training and mental health awareness training
- uses multiple and joint decision-makers
- conducts quality assurance of decisions

[5] A network based specifically in Canary Wharf, where the GPhC's offices are located.
[6] The GPhC's associates and partners are involved in different areas of the GPhC's work, including assessing applications to join the register and making fitness to practise decisions.
[7] The data reported is on sex, disability, race, age, religion or belief and sexual orientation.

- removes identifiable information within its registration assessment processes.

3.8 The GPhC's consultation documents and Council papers include a section on the EDI implications of the work being proposed or undertaken, for example, the quarterly engagement and communications reports presented to Council.

3.9 The GPhC has also developed a toolkit which provides internal guidance on when an Equality Impact Assessment (EIA) should be completed and what it should include. Detailed EIAs are usually completed during the development of new policy, practice or guidance documents. During the period under review, the GPhC published the EIAs it had completed when updating its *Guidance for pharmacist prescribers* and for the changes proposed to the initial education and training standards for pharmacists.

3.10 The GPhC has completed, or commissioned, various pieces of research work relating to EDI in different areas of its core functions.

3.11 Following an initial scoping exercise on EDI in fitness to practise, the GPhC reported in September 2018 that it would be:

- completing a further quantitative analysis of the EDI data it holds on fitness to practise processes
- evaluating its fitness to practise processes and developing a model to measure and evaluate their effectiveness at ensuring fair decision-making and eliminating discrimination
- reviewing work undertaken or commissioned by other regulators to understand if, and how, limitations in data and meaningful analysis were overcome.

3.12 A report on this work was due to be presented to Council in December 2019 alongside recommendations for any improvements identified. However, this report has been delayed. The GPhC reported that the work to understand the unintended impact of the fitness to practise process started later than planned although a logic model of the fitness to practise process has been developed. The model will be tested with internal colleagues and will feed into the development of the GPhC's wider fitness to practise strategy, which is discussed further under the Fitness to Practise Standards.

3.13 In October 2019, the GPhC published *Barriers and enablers to the pharmacy technician profession*, a report on research commissioned to explore pharmacy technicians' perceptions of the profession, understanding of the professional standards and possible barriers and enablers to the profession. The GPhC is using this research to identify any areas where it might be able to act or influence in response to the findings.

3.14 The GPhC also commissioned a registrant survey which ran from June to July 2019. The survey included a number of EDI questions and a separate EDI report was prepared and published alongside the main report in December 2019. The GPhC intends to use the findings from both reports to inform its ongoing work.

3.15 One of the priorities in the GPhC's business plan for 2017-20 is the development of its data and insight strategy and we have seen evidence of the GPhC conducting internal analyses of its own data, as well as availing itself of external resources, such as becoming members of disability groups and commissioning research, in order to better understand the diversity of individuals and groups it interacts with.

3.16 The GPhC publishes EDI data and research reports and it has committed to using this information, as well as research undertaken by other health and social care regulators, to inform its work going forward.

3.17 The GPhC has incorporated EDI considerations into its documents to ensure that they are embedded in all aspects of its work and it has a range of mechanisms in place designed to ensure its processes do not impose inappropriate barriers or otherwise disadvantage peoples with protected characteristics. It is continuing to develop its understanding through a number of ongoing pieces of work aimed at identifying any further action it may be able to take in this area.

3.18 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 were contacted by a small number of individuals who told us about corporate complaints they had raised with the GPhC. We were aware that the GPhC was reviewing its corporate complaints policies so we carried out a targeted review to better understand the GPhC's approach to considering feedback from external stakeholders.

4.2 For the period under review the GPhC's approach to handling complaints and feedback from external stakeholders was set out in its *Customer service feedback procedure* and *Complaints and Feedback Management Policy*. Shortly after the period under review, the GPhC replaced the *Complaints and Feedback Management Policy* with a *Guide to giving feedback or making a complaint about our service.* The new guide does not change the complaints process but is designed to provide clearer information about how to provide feedback and how feedback will be handled.

4.3 The GPhC has a separate *Raising concerns* policy for internal stakeholders, such as staff and committee members, to use. It covers whistleblowing and provides for escalation to the Chief Executive & Registrar, the Chair of Council or the Chairs of the Committees. The policy does not provide a similar escalation route for external stakeholders but it is not an outlier amongst the regulators in this regard. The GPhC's Council maintains oversight of complaints through quarterly monitoring reports, which provide a breakdown of the number of complaints by theme, allowing any trends to be identified. We have not identified any significant concerns about the approach being taken.

4.4 As part of our assessment of this Standard, we also looked at evidence of the GPhC reporting on its own performance and considering the implications for it of findings of public inquiries and other relevant reports about healthcare regulatory issues.

4.5 The Pharmacy Order 2010 requires the GPhC to annually report on its EDI arrangements, fitness to practise information and a strategic plan. In addition to this, the GPhC provides quarterly performance monitoring reports and quarterly annual plan progress reports to its Council. The performance monitoring reports include information on operational performance against internal key performance indicators. The work of the GPhC's three statutory[8] and four non-statutory committees[9] is also reported to Council through meeting minutes and annual reports.

4.6 After the publication of the Gosport Independent Panel Report and the Williams review into gross negligence manslaughter in healthcare, the GPhC identified actions for itself arising out of the recommendations. Both reports were published in June 2018 and the GPhC completed a number of actions prior to the period under review, including producing a reflection and learning resource for registrants[10] and developing new guidance for staff on undertaking parallel investigations. The GPhC continues to liaise and work with the Department of Health and Social Care (DHSC) on the report's recommendations and it is part of an implementation working group which is consolidating expertise in gross negligence manslaughter in healthcare and developing an agreed and clear explanatory statement of the law in this area.

4.7 Last year, we reported concerns about a number of different aspects of the GPhC's fitness to practise function. The GPhC responded very constructively and quickly and published an action plan designed to address the concerns identified. The work being undertaken as part of the action plan is discussed in further detail under the relevant Fitness to Practise Standards.

4.8 There is clear evidence that the GPhC regularly reports publicly on its performance, beyond what is required by its legislation. It looks at the implications for it of the findings of public inquiries and other relevant reports about healthcare regulatory issues. The GPhC has identified and completed pieces of work in light of findings from public inquiries and it has put an action plan in place to address the concerns we identified about it through our performance review last year.

4.9 We are satisfied that this Standard is met.

[8] Investigating Committee; Fitness to practise Committee; Appeals Committee
[9] Audit and risk Committee; Remuneration Committee; Assurance and Appointments Committee; Finance and planning Committee (previously the Efficiency and Effectiveness Assurance and Advisory Group).
[10] The GPhC led on the development of this resource, working in collaboration with the Royal Pharmaceutical Society and the Association of Pharmacy Technicians UK.

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.

5.1 The GPhC works with a wide range of stakeholder groups and organisations, including representatives of patients and registrants. It provides quarterly reports to its Council on its communications and engagement activities. The reports show that the GPhC uses a variety of channels to engage and consult with its stakeholders and publicise the work it is undertaking. This year, the GPhC's activities have included:

- stakeholder events and speaking engagements
- patient focus groups
- webinars
- social media and direct email campaigns
- press releases
- media interviews.

5.2 The GPhC has a structured process in place to consult with stakeholders. During this review period, we saw the process in operation when the GPhC consulted on changes to its *In practice: Guidance for pharmacist prescribers* and its initial education and training standards for pharmacists. The GPhC reported on the consultation responses it received and how those responses were taken into account.

5.3 Following the consultation on the *In practice: Guidance for pharmacist prescribers*, the GPhC strengthened the information in the guidance about remote prescribing and access to medical records, particularly where a patient lacks capacity. The finalised version was published in November 2019.

5.4 Last year we reported on the GPhC's consultation on proposed changes to its standards for the initial education and training for pharmacists, which ran from January to April 2019. We noted that in light of the responses, the GPhC was undertaking further work and engagement with stakeholders before finalising its proposals. The GPhC has since reconvened a working group to finalise the revised standards and the reforms are expected to begin in July 2021 using a phased approach to implementation.

5.5 The GPhC has Memoranda of Understanding (MoUs) in place to aid and govern information-sharing with a number of organisations across the health and social care sector.[11] All of the MoUs are published on the GPhC's website and explicitly refer to patient safety as one of the aims of the information-sharing arrangements.

5.6 The GPhC works closely with the regulator for pharmacists and pharmacies in Northern Ireland, the Pharmaceutical Society of Northern Ireland (PSNI),

[11] Examples include the Pharmaceutical Society of Northern Ireland, the Medicines and Healthcare Regulatory Agency, the Care Quality Commission, the Joint Council for Cosmetic Practitioners, NHS England, Healthcare Inspectorate Wales and the majority of Trusts in Scotland.

particularly in education and training for pharmacists. During the period under review, the GPhC and PSNI agreed to introduce a joint four-country registration assessment which will replace the current arrangement of the GPhC managing and administering a registration assessment in Great Britain and the PSNI managing and administering a registration assessment in Northern Ireland. The new arrangements will be governed by a partnership agreement between the two regulators. The introduction of the four-country registration assessment is discussed in further detail under Standard 9.

5.7 There is clear evidence of a number of pieces of work that demonstrate the GPhC consulting and working with stakeholders to identify and manage risks to the public in respect of its registrants. 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 *Standards for pharmacy professionals* were introduced by the GPhC in May 2017. They are not yet due for review as the GPhC's ongoing programme of cyclical reviews are generally carried out on a five-year cycle. There have been no developments in the regulatory landscape during the period under review that would prompt the need for an early review of the standards.

6.2 We have not seen any evidence that the *Standards for pharmacy professionals* have become outdated or that they fail to prioritise patient or service user centred care and safety.

6.3 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 The GPhC publishes a range of guidance documents to support registrants in meeting the *Standards for pharmacy professionals* and the *Standards for registered pharmacies*. During this review period, the GPhC published *In practice: Guidance for pharmacist prescribers* and *Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet*.

7.2 The GPhC's *Regulatory Standards Policy*, which set out the GPhC's approach to developing, publishing, monitoring and reviewing standards and guidance, and which was published on its website, has been in place since 2013.

7.3 We carried out a targeted review of this Standard because we wanted to further understand the GPhC's approach to developing new guidance and how it takes account of feedback from external stakeholders as part of its process. We had

received an example where the GPhC had not appeared to consider concerns raised by an individual about poor practice so we asked for further information to understand how the GPhC had responded when the concerns were initially raised.

7.4 In respect of the individual concern, the GPhC provided us with a detailed chronology of its interactions with the stakeholder, which included a number of discussions and meetings. The GPhC told us that the issues are complex as they encompass several parts of the wider health and social care system, and this required the GPhC to work carefully in conjunction with other relevant stakeholders. We agree with this analysis. Nonetheless, having regard to the chronology, we felt that the GPhC could have acted sooner to consider what should be done about the matters raised. The GPhC has started taking work on the issue forward.

7.5 The GPhC has launched and implemented a new policy development framework which replaced the *Regulatory Standards Policy* that had been in place since 2013. This was part of a piece of work to update the GPhC's approach to managing policy development across the whole organisation and will be developed further.

7.6 The framework sets out examples of what might prompt the need for guidance to be reviewed or developed, including when a gap or need is identified by the GPhC or other stakeholders. The framework also lists key factors the GPhC considers when deciding whether guidance needs to be produced.

7.7 The new framework does not contain any specific mention of guidance being used to address areas of risk. The GPhC told us that risk assessment is part of its 'Project Initiation Document'. We also considered that some of the drivers and key factors listed by the GPhC in the framework may identify risks. The framework documents provided by the GPhC do not indicate the timeframes for scheduled reviews of Standards or policies. The GPhC told us that it aims to review documents a year after publication and then between three and five years after their publication. The GPhC also told us that the new framework is still being developed and further elements will be added, including additional information about the general principles underpinning its approach to regulatory standards. We consider the finalised framework should ensure that there is consideration of risk, irrespective of the source of the information.

7.8 Overall, the evidence we have seen does not give rise to concerns about the guidance the GPhC currently has in place. The new policy development framework should ensure any new or revised guidance is up to date and prioritises patient and service user centred care and safety, as it refers to the need to ensure guidance is up to date and includes a reminder that patients and service users also use guidance published by the GPhC. We are therefore 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 the past two years we have reported on work that the GPhC has been undertaking to review its standards of education and training for the whole pharmacy team. The GPhC has continued this work.

8.2 In May 2019, the GPhC published an evidence framework to accompany the *Standards for the education and training of pharmacist independent prescribers*, which were revised in January 2019. The evidence framework aims to support pharmacist independent prescribers, their designated prescribing practitioners and course providers.

8.3 In December 2019, the GPhC's Council approved new education and training requirements for unregistered pharmacy support staff. This followed feedback received by the GPhC that its involvement in approving the training requirements was valued by stakeholders due to its independence. The requirements will come into effect in October 2020 and changes include:

- broadening the scope from two community-oriented roles to all staff who support registered pharmacy professionals in the provision of pharmacy services, including dispensing, supply and giving of advice
- strengthened criteria for approving courses, for example in respect of EDI.

8.4 Last year we reported that the GPhC was consulting on changes to its standards for the initial education and training for pharmacists, which included revising the learning outcomes so that they are set around four domains:

- person-centred care
- professionalism
- professional knowledge
- skills and collaboration.

8.5 The Authority did not respond to the GPhC's consultation as we have not identified any concerns about the changes the GPhC has proposed. The proposed learning outcomes reflect a number of the GPhC's *Standards for pharmacy professionals*, including the first standard, which is to provide patient-centred care.

8.6 As we noted under Standard 5, prior to finalising its proposals the GPhC intends to undertake further stakeholder engagement in light of the responses it received to its consultation. We will continue to monitor the GPhC's work in this area and review the final proposals it puts forward.

8.7 The GPhC has also been monitoring the implementation of the revised *Standards for the initial education and training standards for pharmacy*

technicians, which it introduced in October 2017. No concerns have been identified about their implementation.

8.8 The GPhC has continued its programme of work to review its standards for education and training to ensure they are up-to-date and fit for purpose. The activity we have seen this year includes examples of the GPhC taking account of stakeholders' views, publishing an evidence framework to assist course providers in understanding and meeting the standards and monitoring the implementation of the revised standards it has introduced. We have not identified any concerns about the current standards or the changes the GPhC is proposing to make to its standards in terms of whether they prioritise patient and service user centred care and safety. 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 There have been no changes to the GPhC's process for quality assuring education programmes and the GPhC continues to publish reports from approval visits on its website.

9.2 We carried out a targeted review of this Standard to understand how the GPhC addresses continued or repeated poor performance in the registration assessment. This was because the GPhC reported that it had contacted five universities to discuss low pass rates for the June 2019 registration assessment and some of the schools were reported to have previously been in a similar position.

9.3 The GPhC told us that where the information from the registration assessment indicates a low pass rate for candidates who attended particular universities, it contacts the university to understand the reasons for the results and confirm that actions are being taken to address any reasons identified.

9.4 The GPhC also told us that the information it obtained through these discussions is being used to inform its ongoing review of the initial education and training standards for pharmacists and a wider review of its accreditation methodology.

9.5 The activity described to us by the GPhC does not appear to be supported by a formal, documented process, such as a written policy explaining the steps the GPhC may take if it identifies repeated or continued poor performance in the registration assessment. Having a formal process assists consistency and business continuity and also ensures there is ongoing monitoring and follow-up of any issues identified.

Four-country registration assessment

9.6 Under Standard 5 we noted that the current arrangements for the registration assessment, whereby the GPhC and PSNI each manage and administer the

examination in their own jurisdiction, will be replaced by a joint four-country registration assessment.

9.7 The PSNI and GPhC already collaborate on several aspects of their education and training functions, including the accreditation of courses leading to registration. The new arrangements will be governed by a partnership agreement between the two regulators.

9.8 The joint assessment will be managed by the GPhC on behalf of both regulators, including questions and standards-setting and the handling of enquiries and appeals. However, the PSNI will continue managing the Northern Ireland examination venue, invigilation and handling and communication of results. The introduction of the joint assessment does not make any substantive changes to the quality assurance process the GPhC has in place or the level of oversight it will have in terms of standard and question-setting. The first sitting of the joint registration assessment will take place in June 2021.

9.9 We have seen evidence of the GPhC monitoring performance relating to its education and training function and also using the data to inform both its quality assurance activities and the development of its registration requirements. 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 No concerns about the integrity of the register have been reported during this review period.

10.2 We conducted a check of the GPhC's register by selecting a random sample of the appealable decisions reported to us during the period under review and the pharmacies with an inspection report published about them during the period under review.

10.3 We did not identify any inaccuracies and the information published for each entry, including any restrictions, was as expected and in line with the GPhC's *Publication and disclosure policy*.

10.4 We are satisfied that this Standard is met.

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

11.1 For our assessment of this Standard, we considered the GPhC's registration processes for pharmacy professionals and for pharmacy premises separately. We carried out a targeted review of this Standard to obtain further information about the process for pharmacy premises.

Pharmacy professionals

11.2 The GPhC continues to efficiently process applications from pharmacists and pharmacy technicians, with the median timeframe in 2019/20 being under one week.

11.3 In January 2020, the GPhC launched a new online application process for UK-qualified pharmacy technicians. It does not change the way the GPhC makes decisions about the applications it receives but enables applicants to submit part of their application electronically through the myGPhC portal.

Pharmacy premises

11.4 Information about the registration process for pharmacy premises is published on the GPhC's website. Applications are reviewed by a GPhC inspector and assessed against the *Standards for registered pharmacies*. The assessment may involve an inspection of the proposed premises, following which the inspector will make a recommendation to the GPhC as to whether the application should be accepted or refused or whether further information should be obtained before a decision is made. The process can take up to three months. If an application is refused, this decision is appealable to the GPhC's Appeals Committee.[12]

11.5 Some of the documents relating to the registration process for pharmacy premises were updated during the period under review.

11.6 We were concerned by evidence from an appeal hearing which suggested that the processes for recording and communicating inspectors' recommendations may not have been robust. We also saw one case where the GPhC appears to have offered to reconsider an application rather than have the matter appealed. We asked the GPhC to provide further information about its processes for the registration of pharmacy premises, and any changes to those processes.

11.7 The information provided by the GPhC confirmed that, although the guidance about the registration process was updated during the period under review, this was simply to provide further detail and the process itself did not change.

11.8 We did not have concerns about the GPhC's documented processes for the registration of pharmacy premises. The GPhC has a template recommendation form for inspectors to record and communicate their recommendation and reasons to the GPhC. It requires inspectors to record which standards would not have been met, and why, if they recommend that registration be refused. This addressed our concern about the GPhC's approach to recording and communicating inspectors' recommendations.

11.9 The GPhC confirmed that, in line with its legislation, a refusal decision is appealable to the Appeals Committee so we were concerned by the GPhC's offer to reconsider an application that had been refused. However, the GPhC subsequently told us that where an applicant presents new information, it may reconsider the application without requiring the applicant to proceed through a formal appeal. Where new information is submitted by an applicant, it appears to be proportionate for the GPhC to consider the application afresh, provided

[12] Under Articles 39 and 40 of the Pharmacy Order 2010.

that the applicant is informed of the different routes available to them and the distinction between submitting an appeal and a new application. We considered that the GPhC's processes for registration operate proportionately, fairly and efficiently.

11.10 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 reported taking any action in respect of non-registrants or premises using a protected title during the current period under review. From previous reviews, we know that the GPhC has taken action in the past and the GPhC has not reported a change in its approach or policy to managing risks resulting from non-registrants using a protected title.

12.2 The introduction of the Investigatory Powers (Codes of Practice and Miscellaneous Amendments) Order 2018 in July 2018 made changes to the Regulation of Investigatory Powers Act 2000 (RIPA) which provided powers to the GPhC to use general surveillance and covert (directed) surveillance in its investigations providing certain statutory tests are met. The legislation does not authorise the GPhC to use covert human intelligence sources, such as using an informant or someone acting undercover.

12.3 The GPhC has started developing a governance framework around the use of its new powers, including a *Regulation of Investigatory Powers (RIPA)* policy which:

- sets out the definitions of different types of surveillance
- states what the GPhC has the power to do and what it does not have the power to do
- explains the circumstances when authorisation for the use of RIPA powers is needed and when it is not needed
- provides examples of the surveillance activities which are available to the GPhC and which are not.

12.4 In May 2019, the Investigatory Powers Commissioner's Office (IPCO)[13] examined the arrangements the GPhC has in place to secure compliance with the legislative provisions governing the use of covert surveillance. The IPCO report was complimentary about the arrangements put in place by the GPhC and a further visit is expected to take place approximately 18 months after the first one.

12.5 We will continue to monitor implementation of the governance framework. We are satisfied that this Standard is met.

[13] The IPCO has responsibility for reviewing the use of investigatory powers by public authorities to ensure compliance with Home Office Codes of Practice.

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

13.1 In April 2018, the GPhC introduced revalidation for pharmacy professionals. As part of its evaluation of the policy, the GPhC checked whether this had led to a significant number of registrants seeking removal from the register. Its work did not suggest that this was the case.[14] The GPhC will be undertaking and reporting on further evaluation activities in 2020/21 and 2021/22.

13.2 The GPhC's quarterly performance monitoring reports provide ongoing data on revalidation, including the number of registrants entered into revalidation remediation and the number of registrants removed from the register. There are currently no identifiable trends or patterns in the data which give rise to concerns about how revalidation is working or the impact it is having. We will continue to monitor the reports and evaluation activities being undertaken by the GPhC.

13.3 For pharmacy premises, the GPhC conducts inspections to assess whether they continue to meet the *Standards for registered pharmacies*.

13.4 Shortly before the period under review, the GPhC updated its approach to regulating registered pharmacies. Inspections are now generally unannounced and are of three different types: routine; intelligence-led; or themed.

13.5 A 2015 study commissioned by the GPhC reported that pharmacy professionals found inspection reports and inspector feedback useful in helping them to meet the standards and improve services. The GPhC has continued making these resources available to registrants and pharmacy owners. As we noted under Standard 1, the GPhC has also started publishing all inspection reports on its new inspections website, which it also uses to publish notable examples of practice and reports from themes arising from the inspections completed.

13.6 Should an inspection identify concerns about a pharmacy, there are a range of enforcement options available to the GPhC:

- Improvement action plans
- Conditions
- Improvement notices
- Disqualification of a pharmacy owner
- Removal of the premises entry from the register
- Suspension of the premises entry from the register.

13.7 The GPhC's *Registered pharmacies enforcement policy* sets out how the GPhC will decide which enforcement tool to use, if any. Decisions are guided by the following five principles:

- proportionality
- consistency

[14] Only 0.6% of registrants who provided a reason for requesting voluntary removal cited revalidation as their reason.

- transparency
- targeting
- accountability.

13.8 Improvement action plans will generally be the GPhC's first response to concerns. It will follow these up to ensure the improvements have been made and the standards fully met before the action plan is removed.

13.9 The GPhC reports data on its inspection and enforcement activity in its quarterly performance monitoring reports and its annual report. In 2019/20, the GPhC inspected 2,892 pharmacies. Action plans were agreed with 430 pharmacies.[15] As of quarter three of the 2019/20 financial year,[16] the GPhC reported issuing six improvement notices and imposing conditions on 16 premises. The GPhC reported that there has been an increase in enforcement activity, which it said was an expected consequence of its new risk-based, intelligence-led approach to inspections.

13.10 During the period under review, pharmacy inspections undertaken by the GPhC identified patient safety concerns in relation to the unsafe supply of high-risk medicines by some online pharmacies. As well as taking action in respect of the individual pharmacies, the GPhC published an article reminding pharmacy owners of its *Guidance on providing pharmacy services at a distance*, which was updated in April 2019.

13.11 After the updated guidance was published, the GPhC wrote to all online pharmacy owners to highlight the changes and ask that they inform the GPhC how they planned to meet the guidance. Following the concerns highlighted by the pharmacy inspections, the GPhC wrote a further letter to all online pharmacy owners asking those who had not already responded to provide a copy of their risk assessment of online services and information about any changes they had made to ensure compliance with the guidance. The GPhC intends to use the responses to inform and prioritise its inspection programme.

13.12 From the evidence we have seen, we are satisfied that the GPhC has proportionate requirements in place to satisfy itself that its registrants, including premises, continue to be fit to practise.

13.13 We are satisfied that this Standard is met.

[15] These data relate to the financial year 2019/20 so some of the activity took place after the period under review.
[16] At the time of writing, the GPhC had not yet published its quarter four data.

Fitness to Practise

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

14.1 Last year we concluded that the equivalent Standard[17] was met, although we reported concerns about the GPhC deviating from its documented triage process in making decisions.

14.2 In response to our audit findings from last year, the GPhC introduced peer review of triage decisions to take no further action. It developed an action plan to address the concerns we reported last year which included a quality assurance audit of these decisions.

14.3 The GPhC did not change its internal triage guidance significantly during the period under review, but it reported an increase in the number and proportion of cases closed at triage and a decrease in the number of cases considered by the investigating committee (IC), despite receiving an increased number of referrals. The GPhC attributed the increase in closures at triage to the use of other mechanisms to dispose of cases, such as the passing of soft intelligence to its inspectorate team, and the introduction of additional senior oversight of cases recommended for further investigation.

14.4 We carried out a targeted review of this Standard to better understand why fewer cases are progressing through the GPhC's fitness to practise process and the implications this might have for individuals trying to raise a concern about a registrant.

14.5 According to the GPhC's guidance, at triage there are two overarching outcomes; cases can be closed or they can be referred for further investigation. Each of these outcomes have different options within them.

14.6 Cases can be closed with:

- no further action
- signposting
- guidance
- follow-up or pre-IC undertakings (in health cases).

14.7 Cases that are referred for further investigation are referred via one of two routes:

- Stream 1 for investigation by the GPhC's inspectorate team[18]
- Stream 2 for investigation by the GPhC's professionals regulation team.[19]

[17] Standard 1 of the previous Fitness to Practise Standards
[18] Cases that are assessed as being unlikely to meet the threshold criteria for referral to the IC are referred to Stream 1.
[19] Cases that are assessed as meeting, or likely to meet, the threshold criteria for referral to the IC are referred to Stream 2. Cases can be cross-referred between the two streams as enquiries progress. Protection of title concerns are managed through this investigation stream.

14.8 The GPhC introduced additional oversight measures relating to two types of triage decisions; closures with no further action and referrals to Stream 2.

14.9 Decisions to close cases with no further action were initially verified through a peer review process. This was later replaced by a Closure Review Forum (CRF), where the full Monitoring and Concerns team considers cases that have been recommended for closure. A case officer from the professionals regulation team also attends the CRF to assist with the consideration of cases.

14.10 Recommendations for further investigation via Stream 2 are reviewed by a Concerns Oversight Panel (COP) which consists of senior members of the fitness to practise directorate.

14.11 After introducing the peer review process, the GPhC conducted a quality assurance audit of triage decisions to close cases with no further action. This led to the peer review process being replaced by the CRF, which was also reviewed after its introduction to assess its impact. The GPhC provided information to us about both of these reviews and it also provided data on the outcomes of cases considered by the COP, together with a copy of the COP's Terms of Reference.

14.12 The quality assurance audit of triage decisions to close cases with no further action took place in December 2019 and looked at almost half of the decisions made between 1 October and 7 November 2019. The audit found that just over half of the cases reviewed were appropriately closed at triage. It found good examples of well-maintained case files and further enquiries being carried out, but the GPhC told us that it also found a number of cases where further enquiries or improved signposting would have been preferable. The GPhC told us that it found only three cases which it considered were closed inappropriately and it took action to address each of these cases. Through the audit, the GPhC also identified a number of areas for improvement and as a result decided to replace the peer review process with a pilot of the CRF.

14.13 The CRF was introduced in December 2019 and a sample of the cases it considered were reviewed by the GPhC in March 2020. The GPhC told us that the review found that the CRF is having a positive impact on decision-making, with most recommended closures being approved, although some cases were approved for closure with signposting or forwarded to inspectors as soft intelligence to consider at future inspections[20] rather than being closed with no further action. The CRF disagreed with 12% of the cases proposed for closure and directed that further enquiries be conducted before a decision could be made. It also decided that 5% of cases recommended for closure would be more appropriately referred to Stream 1. The GPhC told us that its review of the CRF identified additional areas for improvement and it is taking these forward as part of a redesign of its triage function.

14.14 The GPhC told us that the COP was introduced as a pilot in December 2018 to give senior oversight and assurance that triage decisions to make a referral to Stream 2 were appropriate and proportionate and that there was consistency in the approach. It was also designed to pilot the type of enquiries that could

[20] We note that this is not an outcome listed in the GPhC's triage guidance.

appropriately be made at triage to ensure that the GPhC used the right regulatory levers and only used the investigation route when necessary. It told us that this means that some of its decisions will go beyond the triage guidance.

14.15 According to the Terms of Reference, the COP makes its decisions by considering whether the information suggests potential grounds for investigating whether a pharmacy professional's fitness to practise may be impaired. Examples of the type of information the COP can consider include:

- information provided by an employer
- accompanying evidence such as a clear and logical narrative, copies of notes and statements or documentary records of any admissions made
- evidence of remediation and insight
- whether there is an available alternative that is proportionate in the circumstances.

14.16 The Terms of Reference also state that where an employer is undertaking an investigation and there is no immediate public safety or public interest risk, the GPhC may decide to close the case and ask the employer to contact them again and provide a copy of the investigation report once the investigation has concluded.

14.17 The GPhC told us that during this reporting period, the COP reviewed 127 cases that were recommended for further investigation under Stream 2, which resulted in:

- 16 cases (13%) closed with no further action
- 17 cases (13%) referred to Stream 1
- 56 cases (44%) referred to Stream 2
- 38 cases (30%) referred back to the triage team for further enquiries to be conducted.

14.18 We were concerned by the findings of all of the GPhC's internal reviews because the reviewing bodies amend or revise a high number of initial decisions. While the changes may not be significant, they suggest that the first level of decision is not as robust as it should be.

14.19 We were also concerned that the COP's Terms of Reference allowed consideration of remediation and insight at triage and the possibility of cases being closed when employers' investigations are ongoing.

14.20 When we responded to the GPhC's consultation on its new threshold criteria,[21] we expressed concerns about consideration of remediation and insight at that stage of the process as it is our view that this may allow cases to be closed prematurely with the potential to result in public protection risks. The GPhC appears to have now informally introduced consideration of these factors at an even earlier stage of its process.

[21] The GPhC consulted on its proposals between December 2016 and March 2017 and introduced its new threshold criteria in February 2018.

14.21 Closing cases while an employer's investigation is ongoing might lead to public protection risks because the GPhC may not be notified of changes in risk and employers may not subsequently re-refer cases when necessary. The GPhC told us that its most recent internal review of the COP had also identified this as a risk and it is reviewing how to ensure it is appropriately managed in these cases.

14.22 We considered whether the observations we have set out above, when combined, suggest that the GPhC's approach is presenting barriers to concerns being raised, either directly or indirectly.

14.23 We have significant queries about the robustness of the GPhC's triage process. However, we have not seen evidence that this is leading to cases being closed when they should not be, as opposed to one type of closure being recommended when another would be more appropriate. We have taken account of the fact that our audit last year did not find that cases were being inappropriately closed at triage and we note that, this year, the GPhC's internal reviews did not find that significant numbers of cases were being closed inappropriately.

14.24 We are reassured that the GPhC is actively reviewing and redesigning its triage function. It has put some control mechanisms and processes in place, such as the CRF, which are identifying issues and are preventing cases being closed inappropriately. We note that there are early indications that the introduction of the CRF has improved decision-making at triage.

14.25 The GPhC confirmed that its triage guidance was updated in line with the timeframe set out in its action plan, which was by the end of March 2020. This falls outside the current period of review so will be assessed in next year's performance review.

14.26 We have concluded that the Standard is met, but we considered the decision to be finely balanced. We will be closely monitoring the triage data and the work of the CRF and the COP and this Standard may be subject to a more detailed review next year if we continue to have concerns.

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 carried out a targeted review of this Standard to obtain further information about the work the GPhC is doing to address the concerns we reported last year about the timeliness, transparency and fairness of the GPhC's fitness to practise process.

15.2 We were concerned about the timeliness of the process because improvements we were expecting to see in the overall end to end timeframe for concluding

cases had not materialised[22] and our audit found avoidable or unexplained delays in a high proportion of the cases we reviewed.

15.3 Last year, we were concerned about the transparency and fairness of the process because our audit found the following:

- **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 In response to our findings, the GPhC put an action plan in place and began implementing a range of measures to address our concerns, including reviewing and updating the guidance associated with each of the processes listed above. The content of template letters and forms related to IC warnings were also being reviewed.

15.5 With the exception of the guidance for pre-IC undertakings, which was published in February 2020, all of the reviews and updates were due to be completed by the end of March 2020 which is after the period under review.

15.6 The guidance for pre-IC undertakings, which have been renamed 'voluntary agreements', is aimed at both staff and external stakeholders, such as registrants and their representative bodies. It explains the purpose of voluntary agreements and when they may apply. It also explains that the agreements are voluntary and differ from IC undertakings because IC undertakings are statutory whilst agreements are not.

15.7 The introduction of these guidance documents is a positive step but given the timing of the changes made, there has been a limited impact on performance in the period under review. The changes therefore do not significantly affect our assessment of this Standard.

[22] In our 2015/16 performance review the GPhC told us that its focus on disposing of its oldest cases had led to an increase in its median timeframe from receipt of complaint to the final fitness to practise committee (FtPC) decision. We accepted this was a short-term consequence and reported that we expected to see improvements in the overall timeframe. Subsequent reports noted sustained rather than improving performance.

15.8 In terms of timeliness of the GPhC's fitness to practise process, the table below shows the key timeliness data we ask regulators to provide.

Measure	2015/16 Annual	2016/17 Annual	2017/18 Annual	2018/19 Annual	2019/20 Annual
Median time (in weeks) from:					
Receipt of referral to final IC decision	48.4	52.4	52	49.1	60.4
Final IC decision to final FtPC decision	34	34	34.8	37.7	39.9
Receipt of referral to final FtPC decision	96.6	93.7	95	93.7	98.3
Number of open cases older than:					
52 weeks	106	114	105	105	108
104 weeks	37	34	28	34	35
156 weeks	10	12	10	16	23

15.9 The median timeframes have increased for all three of the key stages of the fitness to practise process.

15.10 There has also been a small increase in the total number of cases older than 52 weeks old. We do not consider the increase to be large enough to be significant at this time but we note that there was a similar-sized increase last year and we will continue to monitor this.

15.11 As part of our targeted review, we asked the GPhC to provide copies of the IC decisions from the last quarter of the period under review. These are discussed in more detail under Standard 16, however, of relevance to this Standard, we noted that in a number of decisions the IC explicitly commented on significant delays in the GPhC's investigation. Two cases were rescinded, in part because of the length of time that had passed without further reported incidents. We recognise that this is a small number of cases and there were other reasons involved, such as the disengagement of witnesses. However, we were concerned by this evidence of delays affecting the viability of allegations, and potentially the continued engagement of witnesses, and the impact this could have on public protection. We will monitor this closely.

15.12 The GPhC's action plan includes a programme of training and development aimed at improving both timeliness and customer service. It is developing its existing case monitoring tools, such as its case review process,[23] to highlight cases which are not progressing within key performance indicators. The GPhC also told us that it is making more proactive use of exception reporting. However, these activities have clearly not yet resulted in any improvement in timeliness overall.

[23] Senior oversight of cases is maintained through case review meetings which take place at least once a month between the Case Officer and Senior Case Officer where case progression is reviewed and discussed.

15.13 The GPhC is undertaking a significant amount of work to address the concerns we raised last year. However, this has yet to demonstrate any tangible improvements during the period under review and there has been a decline in the timeliness of case progression. We have therefore concluded that this Standard is not met. We will continue to monitor and review the progress and impact of the GPhC's action plan.

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 We carried out a targeted review of this Standard to obtain further information about the work the GPhC is doing to address concerns we raised last year about the reasoning and consistency of decisions made at the initial stage of the GPhC's fitness to practise process.

16.2 The GPhC has three main decision-making points at the initial stage of its fitness to practise process; triage, the conclusion of an investigation and IC.

16.3 Last year, our audit found that decisions at all three points were not always accompanied by full, clear, accurate and appropriate reasons. As we have noted under Standard 14, we found that triage decisions were being made based on criteria which were not described in the GPhC's guidance. We also reported that when the IC issued advice or a warning, it did not usually specify the wording of the advice or warning to be provided to the registrant and we were concerned by a number of IC decisions we saw which heavily reflected the wording of the GPhC's recommendation[24] with little or no evidence of the IC's independent consideration of the factors in the case.

16.4 We have set out in detail under Standard 14 the reasons why we continue to have concerns about the GPhC's triage process. The GPhC's internal reviews indicate that the triage decisions being recommended are not consistently in accordance with its own processes. We also note that the triage decisions made may have continued to deviate from the guidance because the guidance for staff was not significantly updated during the period under review.

16.5 In February 2020, the GPhC reported the findings from an evaluation it had conducted of the impact of its new threshold criteria, which were introduced in February 2018. The evaluation looked at all threshold criteria decisions made in February 2019. The findings reflected those of our audit last year, which had included a sample of threshold criteria decisions made between March 2018 and February 2019.

16.6 In light of the findings, the GPhC provided scenario-based training to staff and planned to provide further training and guidance on giving good reasons. It also planned to amend the template form used to capture decisions in order to support better recording of reasons. The progress and impact of this work will

[24] When making a referral to the IC, the GPhC's regulations enable it to make a recommendation to the IC for the disposal of the case.

be monitored through the GPhC's quality assurance programme. Most of the improvement activities resulting from the GPhC's evaluation commenced after the period under review. This means that our concerns about the threshold criteria stage of the process remain.

16.7 Prior to our audit, the GPhC had identified that its IC decisions required improvement and had begun work in this area. The work was incorporated into the action plan the GPhC published in response to our performance review last year. Training was provided to statutory committee members in June, July and November 2019 so we asked the GPhC to provide all, or a sample of, the IC decisions made in December 2019, January 2020 and February 2020 together with the accompanying recommendations made by the GPhC to the IC. The GPhC provided all 17 of the IC decisions made during this three-month period and the accompanying recommendations.

16.8 We did not identify any concerns about the IC decisions made and we noted a number of improvements. In all but one of the cases where the IC decided to issue a warning, the wording of the warning was explicitly set out in the decision and none of the decisions heavily reflected the wording of the GPhC's recommendation. We also considered that the IC decisions contained an improved level of detail and reasoning as in most of the decisions the allegation was clear, the evidence considered was clear and the decision explained why the IC considered there was a realistic prospect of the facts alleged being found proven.

16.9 However, in our view the decisions lacked reasoning for other aspects of the IC's consideration, namely the reasons for deciding:

- there was a realistic prospect of impairment being found (separate to why the IC considered there was a realistic prospect of the facts being found proven)
- the behaviour could not be addressed by advice (where relevant)
- a warning was considered to be the proportionate outcome (in cases where a warning was imposed).

16.10 The GPhC's *Good decision making: Investigation committee meetings and outcomes guidance* sets out that the IC should first consider whether there is a real prospect of the facts being proven and, if so, then separately consider whether there is a real prospect of impairment being found. The IC decisions we reviewed appeared to conflate these two tests, with only one set of reasons being given for both.

16.11 Although there are still aspects of the IC decisions which could be further improved, on the basis of the improvements we have seen, we no longer have significant concerns about the IC decisions. Moreover, the GPhC told us that the sample of IC decisions we reviewed predates further improvements it has introduced, including the use of new guidance on warnings and a number of new templates. We will review these changes next year.

16.12 While we have not identified concerns about the final hearing decisions made by the GPhC during the period under review or seen evidence which suggests that the concerns we have identified are leading to incorrect decisions being

made, we remain concerned that the processes underlying triage and threshold criteria decisions are not ensuring that those decisions are made in accordance with the processes and are consistent and fair. We have therefore concluded that this Standard is not met and we will continue to monitor the improvement work that the GPhC is undertaking.

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 We carried out a targeted review of this Standard to obtain further information about three areas of the GPhC's work; risk assessments, interim orders and cases placed on hold.

Risk assessments

17.2 Last year, the equivalent Standard[25] was met, but we said that we would monitor the GPhC's approach to risk assessments because our audit found that the way they were documented[26] meant that we could not always establish the reasons for the conclusions reached. We also found that in linked cases[27] involving more than one registrant, the risk assessment was completed on one form which did not always separately assess the risk presented by each registrant.

17.3 In response to our audit findings, and prior to the publication of our report last year, the GPhC told us it had instructed staff to complete separate risk assessments for each registrant in linked cases and reminded staff of the importance of including further information in the risk assessment so that the issues considered can be identified. Since then, the GPhC has made a number of changes to its case review process which are aimed at supporting improvements in case progression including a requirement for a risk assessment to be completed during the case review meeting if one has not been completed since the last meeting.

17.4 In addition, the GPhC told us that it has begun the review of its approach to risk assessments as part of a wider review of the document it uses to record details of the investigation conducted. This work was not completed during the period under review so, while it is clear that work has happened and is taking place, our concerns about the GPhC's approach to risk assessments have not yet been addressed.

Interim orders

17.5 In last year's report we noted that there had been increases in:

[25] Standard 4 of the previous Fitness to Practise Standards
[26] Risk assessments were completed using a Yes/No checklist with little or no accompanying narrative to explain the answers given.
[27] Cases against different registrants are sometimes linked and investigated together or in parallel when they relate to the same incident(s).

- the median time taken to obtain an interim order from receipt of information indicating the need for an interim order
- the number of applications made by the GPhC to the High Court for interim orders to be extended

17.6 We accepted that a number of cases with interim orders were subject to a complex investigation being undertaken by the Medicines and Healthcare products Regulatory Agency (MHRA) and this had contributed to the increase in the number of High Court applications. We also noted that all of the applications were granted by the court, which provided some assurance that the investigations in these cases were not being delayed unnecessarily by the GPhC.

17.7 The data from this year is set out in the table below.

Median time (in weeks) to make Interim Order decisions:	**2016/17 Annual**	**2017/18 Annual**	**2018/19 Annual**	**2019/20 Annual**
From receipt of complaint	13.3	16.6	19.9	10.4
From receipt of information indicating the need for an interim order	2	2.1	2.9	3.1
Number of High Court extensions to interim orders:				
Applied for	16	17[28]	24	30
Granted	15	16	24	30
Rejected	1	0	0	0

17.8 The data shows that there have again been small increases in the median time taken to obtain an interim order from the receipt of information indicating the need for one and the number of High Court applications for interim order extensions. However, this is contrasted by a significant reduction in the time taken by the GPhC to apply for an interim order from receipt of the referral, which suggests that the GPhC continues to identify and prioritise serious cases. We also note that all of the High Court applications were granted.

Cases placed on hold

17.9 In certain circumstances, for example where there is a real risk of prejudicing external concurrent proceedings, the GPhC may decide to place its own investigation on hold. The GPhC reports the number of cases it has on hold, and the reasons why, in its quarterly performance monitoring reports.

17.10 We asked the GPhC for further information about some of the reasons why cases were on hold. We also asked the GPhC about the outcome of a review it conducted of all its on-hold cases against its *Undertaking parallel investigations* guidance, which was introduced in December 2018.

[28] One of the High Court extension applications made in 2017/18 was withdrawn following the revocation of the interim order by the GPhC's FtPC.

17.11 We were satisfied by the GPhC's response that it only puts cases on hold where it is necessary to await the outcome of an external investigation before progressing with fitness to practise proceedings.

17.12 The GPhC told us that the review of all on-hold cases took place in January 2020 and found that further work was needed to embed the *Undertaking parallel investigations* guidance. In February 2020, the GPhC introduced a new form to be used during case review meetings which includes a reminder that cases on hold should be reviewed against the guidance. The GPhC had planned to undertake a repeat review in March 2020 to further assess progress in embedding the guidance; however this was delayed due to the Covid-19 pandemic. The GPhC also intends to use a planned internal quality assurance audit of the new case review arrangements to assess progress in embedding the guidance.

17.13 The GPhC's own review appears to have identified an issue with some cases in this category not being progressed as swiftly as possible. However, we note that the GPhC is taking steps to address this so we will continue to monitor this work and will consider the outcomes of the GPhC's further reviews next year.

17.14 We were concerned that the points we raised last year about the GPhC's approach to risk assessments have not yet been addressed but we acknowledge that the GPhC is taking steps to do so.

17.15 Our audit last year did not find that serious cases were not being identified or prioritised by the GPhC and, overall, the data on interim orders this year suggests that the GPhC continues to identify and prioritise serious cases.

17.16 We have concluded that this Standard is met but we will continue to monitor the work being done by the GPhC and we will also continue to closely monitor the dataset measures.

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

18.1 We carried out a targeted review of this Standard to obtain further information about the activities the GPhC has planned in order to address the concerns we reported about customer service last year and the anticipated timeframes for completion.

18.2 Last year, the GPhC did not meet the equivalent Standard[29] because 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.

[29] Standard 7 of the previous Fitness to Practise Standards.

18.3 The GPhC will be using two overarching pieces of work to improve its customer service, both of which commenced prior to the publication of our 2018/19 report; a Communications Forum[30] and a new fitness to practise strategy.

18.4 The Communications Forum has developed an action plan setting out a programme of work aimed at improving the GPhC's front-end fitness to practise communications. This will include work to review the template letters used and the introduction of documents such as a glossary of terms, FAQs and a set of fitness to practise 'promises' explaining what stakeholders can expect from the GPhC throughout the process. In developing these documents, the GPhC intends to seek input from people who have been through the fitness to practise process.

18.5 Prior to our audit last year, the GPhC had started to develop a new fitness to practise strategy. The GPhC told us it will be using the learning from our audit to inform the development of a more person-centred approach as part of this wider fitness to practise strategy work. The work includes training, workshops and events with staff. In the last quarter of the period under review, the GPhC delivered training sessions in handling conversations with vulnerable stakeholders and held a workshop with staff, which included hearing from a registrant who had been a witness in a fitness to practise hearing.

18.6 Unsurprisingly, the timeframes for both overarching pieces of work have been impacted by the Covid-19 pandemic. The Communications Forum action plan was initially expected to be completed by Autumn 2020. The bulk of the activity has now been delayed with activities scheduled to continue during the summer and beyond, although the scope may be dependent on restrictions being lifted. The GPhC is also exploring alternatives to face-to-face training where feasible.

18.7 The GPhC told us that it originally intended to implement its new fitness to practise strategy this year, after a consultation in Spring 2020. However, it continues to develop the strategy and the GPhC currently expects to present it to Council for approval in September 2020, with a public consultation to follow. The implementation of the strategy is unlikely to commence before early 2021, although the GPhC told us that elements which are not dependent on the consultation have already commenced.

18.8 We welcome the GPhC's commitment to addressing our concerns about customer service. Its work in this area is focused on improving its communications with parties and the clarity and transparency of those communications, which we consider are key to ensuring parties are supported to participate effectively in the process. However, most of the work the GPhC is undertaking has yet to be completed so its impact will not have been seen during the period under review. Consequently, we have concluded that this Standard is not met. We will continue to monitor progress of the GPhC's activities in this area.

[30] This was previously named the Customer Service Forum.

Useful information

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 this glossary below, spelling out abbreviations, but also adding some explanations.

Below the glossary you will find some helpful links where you can find out more about our work with the 10 regulators.

Glossary

A

Accreditation	The GPhC accredits training programmes which meet its standards for initial education and training. Once full accreditation is granted, the programme is subject to the full reaccreditation process every six years, with an interim visit every three years.
Appeals Committee	An independent committee of the GPhC which considers appeals against certain types of registration decisions made by the GPhC.
Assessment	In our **performance reviews**, the assessment is the first stage, where we decide the scope of our review. You can find more information about our performance review process on our website.
Assurance and Appointments Committee	The AAC is one of the GPhC's non-statutory (not required by law) committees. It is responsible for the selection, recruitment training and development of statutory committee members. It reports to the GPhC's Council on its work.
Audit (of FTP cases)	A review of a sample of fitness to practise cases closed by the regulator, to assess how its processes operate in practice and whether the decisions made protect the public and maintain public confidence in the regulator and profession. The audit involves us accessing the regulator's systems and looking at how cases have been managed. We may decide to carry out an audit as part of a targeted review. We can also audit other areas of the regulator's work, such as its registration function. You can find more information about our performance review process on our website.

C

Case to answer	A professional has a case to answer about their **fitness to practise** if the regulator decides that there is a reasonable chance that a serious concern about the professional might be found proved at a hearing.
Closure Review Forum (CRF)	A forum introduced by the GPhC to review all cases which are potentially suitable for closure with no further action at triage. The forum consists of the full Monitoring and Concerns team and a member of staff from the Professionals Regulation Team.
Concerns and Oversight Panel (COP)	A panel introduced by the GPhC to review all cases that are recommended for further investigation via Stream 2. The panel consists of senior members of the fitness to practise directorate.
Consultation	A formal process by which an organisation invites comments on proposed changes to how it works.
Corporate complaint	A complaint to a regulator about something the regulator has done, for example a service it has provided.
Council	The GPhC's Council is responsible for ensuring that the GPhC fulfils its statutory objectives. It sets the strategic direction for the organisation and oversees the implementation of that strategy and the performance of the organisation.

D

Designated Prescribing Practitioners (DPP)	A pharmacist prescriber who is responsible for overseeing a trainee pharmacist prescriber during their period of learning in practice.

E

Equality Act	The law that protects people from discrimination in the UK.

Equality Impact Assessment (EIA)	A process of considering the likely impact on different groups of people of a project or piece of work, intended to ensure that the work does not discriminate against anyone.

F

Fitness to Practise (FtP)	Regulators have a duty to consider information, such as complaints, which indicates that a **registrant** may not be fit to practise. If a regulator decides that a **registrant'**s fitness to practise is impaired, it may take action to protect the public, to maintain public trust in the profession and/or declare and uphold professional standards.
Fitness to Practise Committee (FtPC)	An independent committee of the GPhC which makes final decisions about whether a registrant's fitness to practise is impaired.

I

Inspection	A visit undertaken by the GPhC to assess whether a pharmacy meets the Standards for registered pharmacies.
Inspectorate team	A team within the GPhC's Insight, intelligence and inspection directorate responsible for carrying out inspections of pharmacies and managing Stream 1 investigations.
Interim Order	A decision by a regulator to restrict the practice of a professional while the regulator investigates a concern about their fitness to practise. Interim orders can only be imposed if they are necessary to address serious risks.
Investigating Committee (IC)	An independent committee of the GPhC which considers fitness to practise complaints to decide whether a professional has a case to answer.

K

Key Performance Indicator (KPI)	Regulators measure and report on their own performance, including to their Council. A regulator may set and report on performance targets in areas of its work it considers particularly important. These are known as KPIs.

M

Median	The middle number in a set of data: for example, the median time it takes a regulator to process registration applications means that half the applications were processed within that time.
Medicines and Healthcare products Regulatory Agency (MHRA)	Medicines and Healthcare products Regulatory Agency (MHRA) The organisation responsible for regulating medicines, medical devices and blood components for transfusion in the UK.
Memorandum of Understanding (MoU)	An agreement between two or more organisations about how they will work together.
Monitoring and Concerns team	A team within the GPhC's fitness to practise directorate which is responsible for triaging cases on receipt and monitoring compliance of registrants subject to conditions, Investigating Committee undertakings or voluntary agreements.
myGPhC portal	An online portal for registrants to electronically manage various aspects of their GPhC registration, including renewal and revalidation.

O

Over-arching objective	The Health and Social Care (Safety and Quality) Act 2015 introduced legislative amendments which set out that the over-arching objective of the regulators and the Authority in exercising their functions is the protection of the public.

P

Performance Review	Our annual review of how well a regulator is performing. You can find more information about our performance review process on our website.
Pharmacist independent prescribers (PIP)	Pharmacists who have undertaken additional training to enable them to independently prescribe, supply and administer medicines and medical devices. Registrants with this additional qualification have their entry on the GPhC register annotated accordingly.

Pre-IC undertakings	See voluntary agreements.
Professionals Regulation Team	A team within the GPhC's fitness to practise directorate which is responsible for managing and investigating fitness to practise concerns about pharmacy professionals.
Protected act	An activity which only a registered professional is allowed by law to carry out. For example, only registered dentists can legally carry out dentistry in the UK.
Protected characteristic	The **Equality Act 2010** makes it illegal to discriminate against someone on the basis of any of the following: age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief; sex; and sexual orientation. These are known as protected characteristics.
Protected title	A title which only a registered professional is allowed by law to use. For example, only a registered osteopath can use the title osteopath in the UK.

R

ReciteMe	Accessibility software which enables users to customise a website to their needs.
Register	Each regulator maintains a register, that is, a list of the people it regulates and who have met its criteria for registration. The GPhC also maintains a register of pharmacy premises that have met its criteria for registration.
Registrant	A professional on a register is known as a **registrant**.
Registration assessment	The examination that prospective registrants must pass after completing their qualifications and training in order to be eligible to register with the GPhC.
Rescission	The process used by the Investigating Committee to cancel a referral to the Fitness to Practise Committee in certain circumstances. The Investigating Committee can rescind all or part of a case against a registrant.

S

Section 29	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).
Stakeholder	A person or organisation who has an interest in a regulator's activities, for example a group that represents patients or professionals.
Standards for Pharmacy Professionals	The standards of conduct, competence and safe practice that registered pharmacy professionals must follow
Standards for Registered Pharmacies	The standards of safe and effective operation that all registered pharmacies must meet.
Statutory functions	The activities a regulator must carry out by law. The regulators we oversee are required to set standards for the professions they regulate, hold a register of professionals who meet those standards, assure the quality of training for entry to the register, and take action if a registrant may not be fit to practise. Some regulators have other statutory functions as well.
Statutory regulators	The regulators we look at in our **performance reviews** are statutory regulators. This means that their powers and responsibilities are set out in law.
Stream 1 investigation	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.
Stream 2 investigation	The second of two investigation routes used by the GPhC for cases which progress past triage. Cases which meet, or are likely to meet, the threshold criteria after further investigation are investigated via Stream 2, which is managed by the GPhC's Professionals regulation team.

T

Targeted review	Part of our **performance review** where we seek more information about how a regulator is performing. You can find more information about our performance review process on our website.
The Pharmacy Order 2010	The Order made under powers in the Health Act 1999, as amended by the Health and Social Care Act 2008, that gives the GPhC its powers and responsibilities. You can find the Pharmacy Order 2010 at www.pharmacyregulation.org/about-us/what-we-do/legislation
The Shaw Trust	A charity which employs people with a wide range of disabilities and accessibility needs and supports organisations in checking the accessibility of their websites. You can find out more about their work at https://www.shaw-trust.org.uk/.
Threshold Criteria	The criteria used by the GPhC to decide whether a fitness to practise concern should be referred to its Investigating Committee for consideration. These criteria are applied to cases that progress past triage to further investigation, after the further investigations have been conducted.
Triage	The initial assessment undertaken by the GPhC when it receives a fitness to practise concern. The GPhC may decide to close the case or to further investigate the concerns raised.

V

Voluntary agreements (previously known as Pre-IC undertakings)	A non-statutory agreement between the GPhC and a registrant setting out specific terms the registrant agrees to comply with for a defined time period.

W

Whistleblowing | Disclosing information about wrongdoing within an organisation.

Useful links

Find out more about:

- the 10 regulators we oversee
- the General Pharmaceutical Council
- 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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