professional standards authority

Annual review of performance 2018/19

General Pharmaceutical Council

About the Professional Standards Authority

The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and voluntary registration of people working in health and care. We are an independent body, accountable to the UK Parliament.

We oversee the work of 10 statutory bodies that regulate health professionals in the UK and social workers in England. We review the regulators' performance and audit and scrutinise their decisions about whether people on their registers are fit to practise.

We also set standards for organisations holding voluntary registers for people in unregulated health and care occupations and accredit those organisations that meet our standards.

To encourage improvement we share good practice and knowledge, conduct research and introduce new ideas including our concept of right-touch regulation.[1] We monitor policy developments in the UK and internationally and provide advice to governments and others on matters relating to people working in health and care. We also undertake some international commissions to extend our understanding of regulation and to promote safety in the mobility of the health and care workforce.

Our organisational values are: integrity, transparency, respect, fairness and teamwork. We strive to ensure that our values are at the core of our work. More information about our work and the approach we take is available at **www.professionalstandards.org.uk**

---

1 *Right-touch regulation revised* (October 2015). Available at www.professionalstandards.org.uk/policy-and-research/right-touch-regulation.

Contents

About the General Pharmaceutical Council

The General Pharmaceutical Council (the GPhC) regulates the pharmacy profession in the United Kingdom. Its 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.

As at 31 March 2019, the GPhC was responsible for a register comprising:

- 56,288 pharmacists
- 23,387 pharmacy technicians
- 14,314 pharmacy premises.

The annual retention fee is currently:

- £257 for pharmacists
- £121 for pharmacy technicians.

At a glance

Annual review of performance

Regulator reviewed: **General Pharmaceutical Council**

Standards of good regulation

Core functions	Met
Guidance and Standards	4/4
Education and Training	4/4
Registration	6/6
Fitness to Practise	6/10

1. The annual performance review

1.1 We oversee the 10 health and care professional regulatory organisations in the UK, including the GPhC[2] More information about the range of activities we undertake as part of this oversight, as well as more information about these regulators, can be found on our website.

1.2 An important part of our oversight of the regulators is our annual performance review, in which we report on the delivery of their key statutory functions. These reviews are part of our legal responsibility. We review each regulator on a rolling 12-month basis and vary the scope of our review depending on how well we see the regulator is performing. We report the outcome of reviews annually to the UK Parliament and the governments in Scotland, Wales and Northern Ireland.

1.3 These performance reviews are our check on how well the regulators have met our *Standards of Good Regulation* (the Standards) so that they protect the public and promote confidence in health and care professionals and themselves. Our performance review is important because:

- it tells everyone how well the regulators are doing
- it helps the regulators improve, as we identify strengths and weaknesses and recommend possible changes.

The Standards of Good Regulation

1.4 We assess the regulators' performance against the Standards. They cover the regulators' four core functions:

- Setting and promoting guidance and standards for the profession
- Setting standards for and quality assuring the provision of education and training
- Maintaining a register of professionals
- Taking action where a professional's fitness to practise may be impaired.

1.5 The Standards describe the outcomes we expect regulators to achieve in each of the four functions. Over 12 months, we gather evidence for each regulator to help us see if they have been met.

1.6 We gather this evidence from the regulator, from other interested parties, and from the information that we collect about them in other work we do. Once a year, we collate all of this information and analyse it to make a recommendation to our internal panel of decision-makers about how we believe the regulator has performed against the Standards in the previous 12 months. We use this to decide the type of performance review we should carry out.

[2] These are the General Chiropractic Council, the General Dental Council, the General Medical Council, the General Optical Council, the General Osteopathic Council, the General Pharmaceutical Council, the Health and Care Professions Council, the Nursing and Midwifery Council, the Pharmaceutical Society of Northern Ireland, and Social Work England.

1.7 When considering information relating to a regulator's timeliness, we consider carefully the data we see, and what it tells us about the regulator's performance over time. In addition to taking a judgement on the data itself, we look at:

- any trends that we can identify suggesting whether performance is improving or deteriorating
- how the performance compares with other regulators, bearing in mind the different environments and caseloads affecting the work of those regulators
- the regulator's own key performance indicators or service standards which they set for themselves.

1.8 We will recommend that additional review of their performance is unnecessary if:

- we identify no significant changes to the regulator's practices, processes or policies during the performance review period; and
- none of the information available to us indicates any concerns about the regulator's performance that we wish to explore in more detail.

1.9 We will recommend that we ask the regulator for more information if:

- there have been one or more significant changes to a regulator's practices, processes or policies during the performance review period (but none of the information we have indicates any concerns or raises any queries about the regulator's performance that we wish to explore in more detail) or;
- we consider that the information we have indicates a concern about the regulator's performance in relation to one or more Standards.

1.10 This targeted review will allow us to assess the reasons for the change(s) or concern(s) and the expected or actual impact of the change(s) or concern(s) before we finalise our performance review report.

1.11 We have written a guide to our performance review process, which can be found on our website www.professionalstandards.org.uk

2. What we found – our judgement

2.1 During March 2019 we carried out an initial review of the GPhC's performance from 1 March 2018 to 28 February 2019. Our review included an analysis of the following:

- Council papers, including fitness to practise reports, Audit Committee reports, business plan monitoring reports and performance monitoring reports
- Policy and guidance documents
- Statistical performance dataset (see sections below)
- Third party feedback
- Register check
- Information available to us through our review of final fitness to practise decisions under the Section 29 process.[3]

2.2 As a result of this assessment, we decided to carry out a targeted review of:

- Standard 3 of the *Standards of Good Regulation* for Registration
- Standards 3, 5, 6, 7 and 8 of the *Standards of Good Regulation* for Fitness to Practise.

2.3 We obtained further information from the GPhC relating to these Standards. We also carried out an audit of 63 fitness to practise cases closed by the GPhC between 1 March 2018 and 28 February 2019. The cases we audited were divided into the following categories:

- Cases closed at the triage[4] stage
- Cases closed at the investigation stage as not meeting the Threshold Criteria[5]
- Cases closed by the Investigating Committee (IC)[6]

[3] 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).

[4] Stage one of the GPhC's fitness to practise process looks at whether the information received is about an individual or pharmacy on the GPhC's register, and whether the GPhC has the power to look into the issues raised. The GPhC calls this process 'triage'.

[5] Where a case passes triage, the second stage of the fitness to practise process requires the GPhC to investigate if the information received raises concerns that a pharmacy professional might not be fit to practise. At the end of the investigation the case is assessed against the Threshold Criteria to decide whether it should be closed or referred to the IC. If a case does not meet the Threshold Criteria, it will be closed. If it does, it will be referred to the IC.

[6] In cases where the GPhC considers that the Threshold Criteria are met, all the case information is referred to the IC. The IC meets in private to review the case information and decides whether or not there is a case to answer. If there is no case to answer, the case is closed.

2.4 As a result of a detailed consideration of this further information and our audit findings, we determined that the GPhC had not met Standards 5, 6, 7 and 8 for Fitness to Practise. The reasons for this are set out in the following sections of the report.

Summary of the GPhC's performance

2.5 For 2018/19 we have concluded that the GPhC:

- Met all of the *Standards of Good Regulation* for Guidance and Standards
- Met all of the *Standards of Good Regulation* for Education and Training
- Met all of the *Standards of Good Regulation* for Registration.
- Met six of the 10 *Standards of Good Regulation* for Fitness to Practise. The GPhC did not meet Standards 5, 6, 7 and 8.

3. Guidance and Standards

3.1 The GPhC has met all of the *Standards of Good Regulation* for Guidance and Standards during 2018/19. Examples of how it has demonstrated this are indicated below each individual Standard.

Standard 1: Standards of competence and conduct reflect up-to-date practice and legislation. They prioritise patient and service user safety and patient and service user centred care

3.2 We have not seen any evidence that the GPhC's *Standards for pharmacy professionals* have become outdated since their introduction in May 2017. Nor have we seen any evidence that they do not prioritise patient and service user safety and patient and service user centred care. The GPhC has an ongoing programme of cyclical reviews which are generally carried out on a five-year cycle, so the *Standards for pharmacy professionals* are not yet due for review. We are satisfied that this Standard is met.

Standard 2: Additional guidance helps registrants apply the regulator's standards of competence and conduct to specialist or specific issues including addressing diverse needs arising from patient and service user centred care

3.3 In April 2018, the GPhC introduced a new revalidation framework which is discussed in more detail under Standard 6 for Registration. As part of the launch, the GPhC produced a number of guidance documents designed to help registrants understand and meet its new revalidation requirements. These included:

- Guidance on planned and unplanned continuing professional development (CPD)
- Guidance on peer discussions, with separate guidance for pharmacy professionals, peers and employers
- Guidance on reflective accounts.

3.4 Last year we reported that in June 2018 the GPhC published *Guidance to ensure a safe and effective pharmacy team* which is aimed at pharmacy owners and 'explains what the pharmacy owner should do to ensure a safe and effective pharmacy team and meet the standards set out under Principle 2 of the standards of registered pharmacies'. The guidance includes a section on staffing levels, the detail of which was enhanced following feedback received by the GPhC through a public consultation on the draft version of the guidance.

3.5 In September 2018 the GPhC published an article in *Regulate*[7] which reminded registrants about the requirements of the *Standards for pharmacy professionals* and encouraged registrants to re-familiarise themselves with the specialist guidance which offers practical information on the use of social media.

3.6 We are satisfied that this Standard is met.

Standard 3: In development and revision of guidance and standards, the regulator takes account of stakeholders' views and experiences, external events, developments in the four UK countries, European and international regulation and learning from other areas of the regulator's work

3.7 The GPhC has been carrying out research over recent years to better understand the issues faced by pharmacist prescribers when they are carrying out their prescribing role. This work has included consideration of:

- information received through a prescribers' survey conducted by the GPhC in 2016
- enquiries received by the GPhC through its education and standards team and its inspectors
- fitness to practise cases
- a discussion paper on making sure patients and the public obtain medicines and other pharmacy services safely online, which was published by the GPhC in June 2018
- reports, consultations and guidance produced by other regulators and professional bodies, including *A Competency Framework for all Prescribers* which was produced by the Royal Pharmaceutical Society and has been adopted by a number of the other health and social care regulators.

3.8 Through this research the GPhC identified changes and developments taking place in pharmacist prescribing, such as increasing numbers of pharmacist independent prescribers and the range of work settings becoming more diverse, expanding to GP practices, care homes and online pharmacies.

[7] Regulate is the GPhC's online magazine which it uses to disseminate up to date regulatory news and information.

3.9 Following consideration of the information available, the GPhC identified eight areas it considered important for pharmacist prescribers to reflect on, when prescribing, to ensure safe and effective care is delivered.

3.10 During the period under review the GPhC developed draft guidance and in March 2019 the GPhC launched a consultation to seek the views of its stakeholders on the draft guidance. In November 2019, outside of the review period, the GPhC published the finalised guidance, *In practice: Guidance for pharmacist prescribers*, which took account of the views expressed by stakeholders and sets out the five key areas that pharmacist prescribers must consider in order to prescribe safely and effectively.

3.11 Based on the evidence we assessed we are satisfied that this Standard is met.

Standard 4: The standards and guidance are published in accessible formats. Registrants, potential registrants, employers, patients, service users and members of the public are able to find the standards and guidance published by the regulator and can find out about the action that can be taken if the standards and guidance are not followed

3.12 There has been no change in the way the GPhC publishes its standards and guidance materials. They remain easily accessible on the GPhC's website and there are additional resources available, such as a mobile application, a presentation, video and social media posts.

3.13 The standards and guidance documents are published in Welsh on the GPhC's website and can be requested in other formats. All of the standards and guidance documents are Plain English approved.

3.14 The Raising concerns section of the GPhC's website sets out the action that can be taken if standards and guidance are not followed.

4. Education and Training

The GPhC has met all of the Standards of Good Regulation for Education and Training during 2018/19. Examples of how it has demonstrated this are indicated below each individual Standard.

Standard 1: Standards for education and training are linked to standards for registrants. They prioritise patient and service user safety and patient and service user centred care. The process for reviewing or developing standards for education and training should incorporate the views and experiences of key stakeholders, external events and the learning from the quality assurance process

4.1 Last year we reported on the GPhC's review of its standards of education and training for the whole pharmacy team, including unregistered pharmacy staff.

Criteria for registration as a pharmacy technician

4.2 In August 2018 the GPhC introduced new *Criteria for registration as a pharmacy technician in Great Britain*.

4.3 The new criteria proposed three main changes, the first of which related to the training requirements for pharmacy technicians. This change was introduced and allows applicants training in the UK and non-European Economic Area (EEA) countries to undertake their work-based experience under the direction, supervision or guidance of a pharmacist or a pharmacy technician. Previously this could only be done by a pharmacist.

4.4 The second proposed change was to alter the two-year minimum work experience requirement. The GPhC decided not to introduce this change because the consultation feedback was largely supportive of retaining the existing work experience requirement as it was felt that:

- two years is needed to acquire sufficient depth of knowledge and a range of practical experience
- from a patient safety perspective, two years was considered to be a necessary minimum for the trainee pharmacy technician to demonstrate their competence as an accuracy checker
- anything less than two years was not regarded as appropriate or adequate for hospital pharmacy because of the need to complete rotations through the different areas of specialist practice.

4.5 The third proposed change meant that individuals registered as pharmacists were no longer entitled to automatically register as pharmacy technicians. This change was introduced following the consultation.

4.6 The criteria were updated again in September 2019 in order to incorporate changes necessary to reflect the introduction of integrated knowledge and competence-based courses.[8]

Standards for the education and training of pharmacist independent prescribers

4.7 In January 2019, the GPhC published new *Standards for the education and training of pharmacist independent prescribers*.

4.8 Pharmacists were first able to become independent prescribers in 2006. Since that time, information gathered by the GPhC shows that the demand and opportunities for pharmacist independent prescribers have increased quickly and the nature of the role and practitioners have changed with a broadening of specialisms and practice settings.

4.9 In light of these changes and developments, the GPhC undertook a review of the standards and conducted a consultation on proposed changes to ensure the standards remain fit for purpose.

[8] Integrated courses have been included in the GPhC's *Standards for the initial education and training of pharmacy technicians* since October 2017 but providers have only recently begun developing and submitting integrated courses for accreditation/recognition.

4.10 The new standards have revised learning outcomes and have introduced a new role of Designated Prescribing Practitioners (DPPs). The introduction of DPPs broadens the types of professionals that can provide supervision and training, in contrast to the previous standards which only allowed doctors who were Designated Medical Practitioners (DMPs) to undertake this role.

4.11 The revised learning outcomes are set out under four domains which are linked to some of the *Standards for pharmacy professionals*. The four domains are:

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

Standards for the initial education and training of pharmacists

4.12 For prospective pharmacists training in Great Britain, the current route to registration as a pharmacist involves completing a UK Master's degree in pharmacy (MPharm) approved by the GPhC followed by 52 weeks of pre-registration training signed off as satisfactory by a tutor and passing a national examination, which is set and administered by the GPhC. The GPhC sets standards and learning outcomes for the MPharm degree as well as separate performance standards and learning outcomes for the pre-registration training year.

4.13 Between January and April 2019, the GPhC consulted on proposed changes to its existing *Standards for the initial education and training of pharmacists*, which were introduced in 2011. The changes are being proposed to respond to current developments and to anticipate future changes in pharmacy, including the increasing use of technology and the continued development of the pharmacist's role as a front-line healthcare professional.[9]

4.14 As part of pre-consultation work which began in 2017, the GPhC met with stakeholders, including all schools of pharmacy, Health Education England and professional bodies. The GPhC also established an Education Advisory Group. The feedback the GPhC obtained through this initial work informed the proposals set out in the public consultation.

4.15 The proposals included plans to introduce one set of standards and learning outcomes that cover the full period of education and training before initial registration as a pharmacist. The proposals also included:

- closer integration between academic study and practical experience
- strengthening experiential learning and inter-professional learning

[9] *Revising standards for the initial education and training of pharmacists* paper presented to GPhC Council in November 2018 www.pharmacyregulation.org/sites/default/files/document/20181108-gph-council-meeting-papers-combined.pdf.

- revising the learning outcomes so that they are more focused on developing clinical skills and communication skills, while still retaining the critical importance of science
- strengthening requirements in relation to selection and admission, including a requirement for course providers to assess the values of prospective students in addition to their academic qualification through interactive activities such as multiple mini interviews or group work
- strengthening requirements in relation to equality, diversity and inclusion, including by requiring course providers to conduct an annual review of student performance and admissions by protected characteristic as defined by the Equality Act 2010.

4.16 The GPhC's report on the feedback it received showed that there was broad support for a number of the proposed changes but respondents sought clarification on certain aspects, including further detail about the learning outcomes and how the integration of education and training would be funded. In light of the consultation feedback received, the GPhC will be undertaking further work and engagement with stakeholders before finalising its proposed changes, although it has highlighted that its statutory role does not cover the funding of education and training programmes.

Education and training requirements for pharmacy support staff

4.17 Last year we reported that the GPhC consulted on its proposals to develop guidance to ensure a safe and effective pharmacy team, which included a proposal that the GPhC should stop approving individual training programmes and qualifications for unregistered staff. The feedback received indicated that stakeholders valued the GPhC's involvement in approving training requirements for unregistered pharmacy staff because of the GPhC's independence.

4.18 Consequently, in the current period under review, the GPhC continued developing its education and training requirements for pharmacy support staff, holding focus groups with patients, the public and unregistered staff in October 2018. Revised requirements were agreed in December 2019.

Conclusion against this Standard

4.19 We have seen evidence of the GPhC consulting with its stakeholders and incorporating their views when reviewing and developing its standards for education and training for pharmacy professionals.

4.20 The revised learning outcomes introduced for pharmacist independent prescribers include a focus on person-centred care and are linked to the GPhC's *Standards for pharmacy professionals.*

4.21 We will monitor the work being undertaken on the *Standards for the initial education and training of pharmacists* and will consider the final proposals put forward by the GPhC when they are published, but we have not identified any concerns about the work completed in the current period under review.

4.22 We are satisfied that this Standard is met.

Standard 2: The process for quality assuring education programmes is proportionate and takes account of the views of patients, service users, students and trainees. It is also focused on ensuring the education providers can develop students and trainees so that they meet the regulator's standards for registration

4.23 There has been no change to the GPhC's process for quality assuring education programmes during the period under review.

4.24 The accreditation process involves the submission of a self-assessment document with supporting evidence and an accreditation event. Accreditation events may include one or more of the following:

- a site visit
- meeting with academic, research, teaching and practice staff
- meeting with senior management
- meeting with students
- viewing of teaching facilities.

4.25 Once a programme is fully accredited, it is subject to a reaccreditation visit every six years, with an interim visit every three years.

4.26 The GPhC publishes accreditation, reaccreditation and interim visit reports. Reaccreditation reports published in the period under review took account of the views of students and reported the steps providers took to ensure that students meet the requirements for registration.

4.27 In addition, any individual can raise a concern about an education programme and information about how to do so is available on the GPhC's website. We are satisfied that this Standard is met.

Standard 3: Action is taken if the quality assurance process identifies concerns about education and training establishments

4.28 In April 2018, the GPhC undertook a reaccreditation visit of an approved programme[10] which found that good character checks were not being undertaken until year two of the MPharm, after students had interacted with patients and the public. It also found that the applications and interviewing of students were being applied inconsistently across the provider's programmes.

4.29 In response to these concerns, the GPhC reaccredited the programme with conditions requiring the provider to:

- undertake good character and health checks as part of the initial admissions process
- review its selection processes to ensure they are fair and equitable.

[10] The visit was to assess Kingston University's Master of Pharmacy degree and Foundation Degree in Pharmaceutical and Chemical Sciences. The report of the visit was published on the GPhC's website: www.pharmacyregulation.org/sites/default/files/document/kingston_-mpharm_reaccreditation_report-_april_2018-final.pdf

4.30 The provider was required to implement the necessary changes before the admission of the next cohort of students. We are satisfied that this is evidence of the GPhC taking action when its quality assurance process identifies concerns about education and training programmes. Accordingly, we are satisfied that this Standard is met.

Standard 4: Information on approved programmes and the approval process is publicly available

4.31 The GPhC continues to publish information about approved programmes and the approval process in a clear and accessible format on the Education section of its website. The website also provides access to guidance and templates for the approval process for education and training providers.

4.32 Reports from accreditation, reaccreditation and interim visits are published on the GPhC's website under each education provider.

4.33 We are satisfied that this Standard is met.

5. Registration

5.1 As we set out in section 2, we considered that more information was required in relation to the GPhC's performance against Standard 3 for Registration and carried out a targeted review. The reasons for this, and what we found as a result, are set out under the relevant Standard below. Following the review, we concluded that this Standard was met and therefore the GPhC has met all of the Standards of Good Regulation for Registration in 2018/19.

Standard 1: Only those who meet the regulator's requirements are registered

5.2 Last year we reported that the GPhC removed 21 registrants from its register for failing to comply with its CPD requirements. In April 2018, the GPhC introduced revalidation,[11] replacing its CPD process. The GPhC began including data about revalidation in its quarterly performance reports[12] from quarter three of the 2018/19 financial year. According to the data presented, the GPhC removed 71 registrants from its register in 2018/19 for failing to meet its revalidation requirements. We have noted the increase in the number of registrants removed from the register but at this time there is limited evidence available about the reasons for this increase. The GPhC is undertaking activities to evaluate the impact of revalidation and these are discussed in further detail below under Standard 6 for Registration.

[11] The GPhC defines revalidation as 'a process which helps to show that the trust members of the public have in pharmacy professionals is well placed. It helps pharmacists and pharmacy technicians to: keep their professional skills and knowledge up to date; reflect on how to improve; show how they provide the safe and effective care patients and the public expect, as set out in the standards for pharmacy professionals'.

[12] The GPhC presents quarterly performance monitoring reports to its Council which include data about different areas of its work, including registrations, fitness to practise, inspections, complaints, education and human resources.

5.3 We are satisfied that this Standard is met.

Standard 2: The registration process, including the management of appeals, is fair, based on the regulator's standards, efficient, transparent, secure, and continuously improving

5.4 The GPhC did not report any changes to how it processes applications to join its register. Its timeframe for processing applications by pharmacists and pharmacy technicians was less than a week in 2018/19.

5.5 The GPhC continues to receive low numbers of registration appeals. In 2018/19, the GPhC received two registration appeals, the same number received in each of the two previous financial years.

5.6 The information we reviewed did not give rise to concerns about the GPhC's performance in this area. We are therefore satisfied that this Standard is met.

Standard 3: Through the regulator's registers, everyone can easily access information about registrants, except in relation to their health, including whether there are restrictions of their practice

5.7 We decided to carry out a targeted review of the GPhC's performance against this Standard to better understand the work that the GPhC had reported during the period under review in relation to the integrity of its register.

5.8 As part of our performance review for 2016/17 we asked the GPhC about an internal audit it had conducted which made some recommendations about the integrity of its register. The audit had made recommendations about the manual processes used by the GPhC to maintain the register. It also reported that the GPhC did not have a policy on how it used the data it acquired from the Royal Pharmaceutical Society for Great Britain (RPSGB).[13] Last year, the GPhC told us that it had implemented the recommendations made by the internal audit.

5.9 During the current period under review, we noticed that the GPhC reported that it had completed a further internal audit as well as an interim assurance review on the integrity of its register. We asked the GPhC to provide further information about this work so that we could establish whether it related to the same issues identified in the internal audit it told us about in 2016/17. We also wanted to check that the issues raised in the period under review did not affect or have the potential to affect how information about registrants is provided.

5.10 The GPhC told us that the work was part of its routine annual internal audit work programme which focuses on different areas from year to year. The findings and recommendations from the audits, and progress against accepted recommendations, are reported on a quarterly and annual basis to the GPhC's Audit and Risk Committee and Council.

[13] The Pharmacy Order 2010 established the GPhC and transferred the regulation of pharmacists in Great Britain from the RPSGB to the GPhC in September 2010.

5.11 The findings reported by the GPhC during the period under review did not raise concerns about the GPhC's procedures or compliance with them. Nor did they identify any concerns about the accuracy of the public facing register or the ease of the public's access to information about registrants.

5.12 We conducted a check of a random sample of 28 entries on the GPhC's register. We did not identify any significant concerns about the information on the GPhC's register or its accessibility.

Conclusion against this Standard

5.13 The evidence we have reviewed suggests that the GPhC has appropriate mechanisms to maintain accurate registration information and to identify and address any concerns that arise. As a result, we are satisfied that this Standard is met.

Standard 4: Employers are aware of the importance of checking a health professional's registration. Patients, service users and members of the public can find and check a health professional's registration

5.14 The Registration section of the GPhC's website has a separate section aimed at employers which states 'If you employ a pharmacist (or a pharmacy technician), you must first check that they are registered as a pharmacist or pharmacy technician with the GPhC'.

5.15 The online registers are prominently linked from the home page of the website. The search function for pharmacists and pharmacy technicians allows the user to search by registration number, forename or surname and also has a 'sounds like' tool which can be used if the spelling of the professional's surname is not known. We are satisfied that this Standard is met.

Standard 5: 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

5.16 The GPhC has not changed its approach to how it manages the risks associated with non-registrants using protected titles during the period under review.

5.17 The GPhC did not report any prosecutions against people who practised as a pharmacy professional whilst not on its registers in 2018/19.

5.18 We have not identified evidence of any concerns about the GPhC's approach in this area. As a result, we are satisfied that this Standard is met.

Standard 6: Through the regulator's continuing professional development/revalidation systems, registrants maintain the standards required to stay fit to practise

5.19 Last year we reported that in April 2018, the GPhC introduced revalidation for pharmacy professionals, replacing its sample-based approach to CPD. Under

the new revalidation framework, every year as part of the renewal of registration, all registrants must carry out, record and submit:

- four CPD entries, at least two of which must be planned learning activities
- one peer discussion
- one reflective account.

5.20 The GPhC reviews a sample of entries, using a partly random and partly targeted selection process.[14] The entries are assessed against criteria which are set out in the revalidation framework. If some of the criteria are not met, the registrant may be entered into a period of remediation to provide a further opportunity to meet them. If the criteria remain unmet following remediation, the GPhC may remove the registrant from the register or remove an annotation on the register entry relating to a speciality.

5.21 Registrants whose submissions have been reviewed receive personalised feedback. Registrants whose records are not reviewed will receive summary feedback based on the reviews the GPhC has undertaken.

5.22 From quarter three of 2018/19,[15] the GPhC began routinely reporting to its Council on its revalidation activities including the number of:

- renewals
- voluntary removals[16]
- lapsed registrants[17]
- complete revalidation submissions
- registrants entered into revalidation remediation
- registrants removed from the register.

5.23 The data presented by the GPhC to its Council for quarter three of 2018/19 showed that the number of voluntary removals for the quarter was higher than for the same quarter in the previous year; 1,500 compared to 1,066. The GPhC confirmed that it would be examining the reasons for voluntary removal as part of its revalidation evaluation activities. A subsequent report showed that registrants who left the register in quarter one of 2019/20 cited a range of reasons for voluntary removal, including moving abroad, profession change, career break and retirement. Only 0.6 per cent of registrants who provided a reason cited revalidation as the reason for their voluntary removal.

[14] According to the GPhC's website, the targeted entries are chosen from three groups of registrants: those who have submitted records late without good reason; those who have previously been asked to carry out remedial measures following a submission review; and those who have a history of poor compliance with the GPhC's standards.
[15] Data about revalidation activities was not available immediately after the introduction of revalidation because the GPhC's rolling registration, where renewal dates are not fixed across the professions but are based on an individual's date of registration, meant that there was a phased introduction for the new revalidation framework.
[16] Registrants that have requested to be removed from the register on a voluntary basis.
[17] Registrants that did not renew their registration by the necessary deadline, resulting in their name lapsing from the register.

5.24 The GPhC also intends to evaluate revalidation through surveys of registrants' perceptions over the first two years and then, once the new system has embedded, the GPhC will evaluate the impact that revalidation has had on the quality of records. In 2020/21, the GPhC will be producing a short piece of feedback for pharmacy professionals highlighting examples of good practice in terms of how records are completed. A more detailed evaluation of how revalidation has worked and how it has impacted on pharmacy professionals and the public will be undertaken by the GPhC in 2021/22.

5.25 The introduction of revalidation for pharmacy professionals is consistent with the recommendation of the Bristol inquiry[18] that all health professionals be subject to regulatory scrutiny and revalidation.

5.26 We have not identified any concerns about the revalidation process introduced by the GPhC and we will continue to monitor the data and analysis reported by the GPhC about its revalidation activities. We are satisfied that this Standard is met.

6. Fitness to Practise

As we set out in Section 2, we considered that more information was required in relation to the GPhC's performance against Standards 3, 5, 6, 7 and 8 for Fitness to Practise and carried out a targeted review. The reasons for this, and what we found as a result, are set out under the relevant Standards below. Following the review, we concluded that Standard 3 was met but that Standards 5, 6, 7 and 8 of the *Standards of Good Regulation* for fitness to Practise were not met in 2018/19.

Standard 1: Anybody can raise a concern, including the regulator, about the fitness to practise of a registrant

6.1 The table below sets out the data the GPhC has published on the source of the complaints received in the last three financial years.

Source of complaints	Annual 2016/17	Annual 2017/18	Annual 2018/19
Member of the public	1,056 (56%)	1,340 (57%)	1,439 (54%)
Other healthcare professional	201 (11%)	265 (11%)	360 (13%)
GPhC Inspector / Internal referral	177 (9%)	200 (9%)	264 (10%)
Self-declaration	148 (8%)	151 (6%)	138 (5%)
Employer	107 (6%)	122 (5%)	167 (6%)
Police and other enforcement organisations	98 (5%)	62 (3%)	76 (3%)

[18] In 2001, a report was published on the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 https://webarchive.nationalarchives.gov.uk/20090811143822/http:/www.bristol-inquiry.org.uk/final_report/the_report.pdf.

Other (including those who want to be anonymous or did not choose a category)	102 (5%)	193 (8%)	230 (9%)
Total	**1,889**	**2,333**	**2,674**

6.2 The data shows that the proportion of complaints received from the different sources has remained broadly consistent. It does not suggest that individuals face barriers to raising a concern with the GPhC about the fitness to practise of a pharmacy professional.

6.3 The targeted review we carried out in relation to Standards 3, 5, 6, 7 and 8 included an audit of 63 cases that were closed by the GPhC during the period under review. We considered whether our audit findings impacted our assessment of the GPhC's performance against this Standard as at the start of our audit, we observed that the GPhC closed 63 per cent of cases at the triage stage of the fitness to practise process. We regarded this to be a high proportion of cases as:

- the GPhC's triage guidance states that it only considers whether a complaint is within its jurisdiction at the initial stages; and
- the proportion of cases closed by the GPhC at this initial stage was significantly higher than the proportion closed at the same stage by the other regulators overseen by the Authority.

6.4 Under Standard 5 below, we have reported that our audit of closed cases established that the GPhC is departing from its internal triage guidance as it is considering factors beyond whether a complaint is within its jurisdiction when triaging cases. We considered whether this departure from guidance could pose a barrier to people raising a concern about the fitness to practise of a pharmacy or pharmacy professional. Our audit identified a small number of cases where we disagreed with a decision to close the case at triage but this was not sufficient to suggest that the GPhC's process in fact poses a barrier to concerns being raised.

6.5 In response to our audit findings the GPhC told us that the data it provided to us about the proportion of cases closed at the initial stages of the fitness to practise process had excluded the complaints which it decided to refer to its inspectors for further investigation. These cases were not included in the information provided to us as the issues raised related to pharmacies rather than fitness to practise issues. When the data on the cases referred to the GPhC's pharmacy inspectors was fully reflected in the number of cases reviewed by the GPhC, we established that 39 per cent of the concerns received were closed at the triage stage. We decided that closing this proportion of cases at the initial stages did not give rise to concerns that the GPhC's processes may be acting as a barrier to concerns being raised about pharmacy professionals or pharmacies. Consequently, we are satisfied that this Standard is met.

Standard 2: Information about fitness to practise concerns is shared by the regulator with employers/local arbitrators, system and other professional regulators within the relevant legal frameworks

6.6 Last year we reported that the GPhC would be carrying out further examinations of online pharmacies after a Care Quality Commission (CQC) investigation of companies providing primary care services over the internet found significant concerns about patient safety.

6.7 During the period under review, the GPhC published a discussion paper to seek views on proposed changes to its *Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet*. The discussion paper and proposals to strengthen the guidance were prompted by feedback the GPhC received through fitness to practise concerns, from patients or their families, as well as through the GPhC's inspections of registered pharmacies. The new guidance was published in April 2019 and in September 2019 the GPhC published a joint statement with other system and health professional regulators about the provision of online primary care services. This outlined the work undertaken and planned to address regulatory gaps, help improve the quality and safety of services for people in the UK, and encourage the use of evidence-based best practice.

6.8 In the current review period, the GPhC also:

- shared information with the Medicines and Healthcare products Regulatory Agency (MHRA) for an investigation into the diversion of medicines from the legal supply chain into the criminal market involving numerous registrants
- signed a Joint Emerging Concerns Protocol with eight other health and social care and systems regulators[19] which sets out the mechanisms the organisations will use to share information about emerging concerns
- signed a Memorandum of Understanding with the Joint Council for Cosmetic Practitioners (JCCP) agreeing areas of cooperation and information-sharing between the two organisations, in particular around fitness to practise concerns and any enforcement action taken.

6.9 We are satisfied that this Standard is met.

Standard 3: Where necessary, the regulator will determine if there is a case to answer and if so, whether the registrant's fitness to practise is impaired or, where appropriate, direct the person to another relevant organisation

New threshold criteria

6.10 In our previous two performance reviews we reported that the GPhC was introducing revised threshold criteria to use when deciding if a case should

[19] The protocol was also signed by: Care Quality Commission, General Dental Council, General Medical Council, Health and Care Professions Council, Health Education England, Local Government and Social Care Ombudsman, Nursing and Midwifery Council, Parliamentary and Health Service Ombudsman.

be referred to its IC.[20] The new criteria were introduced in February 2018 and we indicated that our performance review this year would include a more detailed assessment of the changes and their impact.

6.11 The GPhC also indicated it would be conducting its own assessment of the impact of the new criteria through its internal quality assurance process and through a review of cases closed at the triage and investigation stages of its fitness to practise process.

6.12 We conducted a targeted review this year in order to obtain further information about the impact of the introduction of the new threshold criteria. The review included an audit of 63 closed fitness to practise cases. We also asked the GPhC to share with us its own assessment of the impact of the new criteria.

6.13 The GPhC told us that 507 cases were closed for not meeting the new threshold criteria in the year directly after the new criteria were introduced.[21] In the year directly prior to the introduction of the new threshold criteria,[22] 474 cases were closed. The GPhC has been receiving an increasing number of referrals in recent years; 1,889 referrals were received in 2016/17, 2,333 referrals were received in 2017/18 and 2,674 referrals were received in 2018/19. In this context, we consider that the number of cases closed before and after the introduction of the new threshold criteria appear to be similar and do not suggest that the criteria have had a significant impact on the number of cases being closed.

6.14 The GPhC told us that work on its internal assessment of the impact of the new threshold criteria had begun but was not yet complete. A report on the findings from the internal assessment is expected to be presented to the GPhC's Council in February 2020.

Initial stages of the fitness to practise process

6.15 As we reported under Standard 1, the information available to us before we commenced our audit indicated that the proportion of cases closed by the GPhC at the initial stages of its fitness to practise process was high, and this gave rise to a concern that the GPhC may be closing cases prematurely or inappropriately. As a result, we sought further information to establish the factors that were contributing to the high percentage of cases closed at the initial stages.

6.16 There are three main decision-making stages at the initial stages of the GPhC's fitness to practise process:

- Triage – where the GPhC reviews the information available and decides whether further investigation is needed
- Investigation – at the conclusion of the investigation the GPhC considers whether a case meets the criteria for referral to the IC (with a

[20] The IC decides whether there is a case to answer by applying the 'real prospect' test and considering whether the allegation ought to be considered by the Fitness to Practise Committee.
[21] 1 February 2018 to 31 January 2019.
[22] 1 February 2017 to 31 January 2018.

recommendation for disposal)[23] or can be closed with no further action or with informal advice to the registrant

- IC.

6.17 The IC decides whether there is a case to answer in respect of an allegation referred to it. To make this decision, the IC considers whether the real prospect test is met in relation to the facts and impairment and then considers whether the case ought to be considered by the Fitness to Practise Committee (FtPC) or whether another outcome is appropriate. The IC can decide to:

- close a case with no further action
- issue advice to the registrant or to another person or body involved in the allegation
- issue a warning to the registrant
- agree undertakings with the registrant
- refer the allegation to the FtPC.

Audit findings

6.18 Our audit sample of 63 cases comprised:

- 25 cases closed by the GPhC at triage
- 24 cases closed by the GPhC at investigation for not meeting the threshold criteria
- 14 cases closed by the IC.

6.19 We saw a small number of cases where we disagreed with the triage decision that had been made.

6.20 We also saw some cases where we considered that the triage or investigation decision had been made prematurely because in our view there were further reasonable enquiries that could have been undertaken by the GPhC to enable a more informed decision to be made. In these cases, we could not say whether further investigation would have resulted in a different outcome.

6.21 We did not identify any cases where we disagreed with the IC decision in terms of whether or not the case was referred to the FtPC.

6.22 Our audit identified concerns about other aspects of all three decision-making stages where we thought that reasoning was flawed, lacking or unclear or the outcome appeared contrary to the GPhC's current guidance. However, we did not consider that these concerns had resulted in incorrect decisions being made. These concerns are discussed in further detail under Standard 8.

[23] Rule 7(2)(b) of The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010 provides a discretionary power for the GPhC to make a recommendation to the IC for the disposal of the case. The GPhC exercises this discretionary power in all cases referred to the IC.

6.23 In response to our audit findings about decision-making, the GPhC accepted that on a minority of the cases that we reviewed, the investigation process was truncated or the decision was made prematurely. The GPhC told us that it was confident that the correct outcome was nonetheless reached in those cases.

Conclusion against this Standard

6.24 We did not see any evidence to suggest that the introduction of new threshold criteria has had an adverse impact on the GPhC's decision-making at the initial stages of its fitness to practise process.

6.25 The evidence that we gathered in our audit of closed cases saw only a small number of cases where we disagreed with the triage decision made by the GPhC and we did not identify any cases where we disagreed with the IC decision to close a case. These findings did not give rise to concerns about the GPhC's performance against this Standard in the period under review and we concluded that the GPhC does generally refer cases to the IC and FtPC where necessary. We saw no evidence that the GPhC is failing to signpost people appropriately.

6.26 We are satisfied that this Standard is met.

Standard 4: All fitness to practise complaints are reviewed on receipt and serious cases are prioritised and where appropriate referred to an interim orders panel

6.27 This Standard was met last year when we concluded that the evidence available to us indicated that the GPhC has effective processes in place and it takes immediate action to protect the public from risk of harm as soon as it receives information indicating that an Interim Order (IO) might be required.

Interim Orders

6.28 The table below shows that in recent years the annual median time taken to make an IO decision from the receipt of the information indicating that an interim order might be required has remained consistent at around two weeks. We note that there has been an increase in the time taken to an IO in 2018/19 to 2.9 weeks.

6.29 The time taken for the GPhC to obtain an IO from receipt of a complaint has also increased, however we accept that fluctuations can arise from the particular circumstances in a small number of cases. We will continue to monitor this in our next performance review.

Median time (in weeks) to make Interim Order decisions:	Annual 2016/17	Annual 2017/18	Annual 2018/19
From receipt of complaint	13.3	16.6	19.9
From receipt of information indicating the need for an interim order	2	2.1	2.9

6.30 This year the GPhC has reported an increase in the number of applications made to the High Court for IOs to be extended. The GPhC has previously reported that some of the cases where an extension was required for an IO are subject to a complex investigation being undertaken by the MHRA.[24] We note that all of the applications were granted by the court. This provides us with some assurance that the investigations in these cases are not being delayed unnecessarily by the GPhC.

Number of High Court extensions to interim orders:	Annual 2016/17	Annual 2017/18	Annual 2018/19
Applied for	16	17[25]	24
Granted	15	16	24
Rejected	1	0	0

Risk Assessments

6.31 This year, we conducted a targeted review which included an audit of 63 closed fitness to practise cases.

6.32 Our audit found that there were no documented risk assessments at the triage stage of the process. If cases progress to the investigation stage, risk assessments are completed using a 'checklist' which contains a list of risk factors and questions which staff are required to respond to by ticking yes or no. We identified instances where staff provided further reasoning in the risk assessment document to explain the reasons why particular responses had been provided but this was not present in the majority of the cases we audited. This meant that we could not always identify the reasons why a particular risk was identified or considered to be adequately mitigated in some of the cases we audited. We also observed that in linked cases,[26] staff completed one document which did not always differentiate between the registrants involved, meaning the risk, if any, presented by each registrant was not separately assessed.

6.33 Our audit also found that:

- In 23 cases, risk assessments were not conducted on receipt of new information or in compliance with the timeframes set out in the GPhC's Fitness to Practise manual[27]
- In 12 cases, not all risk factors were identified.

6.34 We identified one case where we disagreed with the reasons the GPhC had provided for not seeking an IO but we did not consider that this had resulted

[24] In 2017, the MHRA began an investigation into the diversion of Prescription-Only Medicines onto the criminal market. The investigation involved a number of pharmacies and pharmacists on the GPhC's register. The investigation remained ongoing during the current period under review.
[25] 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.
[26] Cases against different registrants are sometimes linked and investigated together or in parallel when they relate to the same incident(s).
[27] This is one of the GPhC's internal guidance documents which sets out the processes to be followed at each stage of the fitness to practise process.

in a risk to public protection. We did not identify any cases where we thought the GPhC should have taken action but failed to do so.

6.35 The GPhC told us that although risk assessments are not documented at the triage stage, the triage decision itself is a form of risk assessment where if a potential risk of harm is identified, the case passes the triage stage and is referred for investigation. The GPhC also told us that case review meetings[28] are conducted every two to four weeks and these meetings include a check on whether risk assessments have been completed on the case.

6.36 We advised the GPhC of our concern that its approach to completing risk assessments made it difficult for us to establish if a full and proper assessment of the relevant factors had been made. While we do not prescribe how risk assessments should be undertaken, we consider that they should be documented, to promote a consistent approach and to provide assurance that the relevant issues have been considered. The GPhC agreed that it would be helpful to have documented reasons to explain its assessments of risk, particularly where the level of risk identified had changed from one risk assessment to the next one on the same case. The GPhC told us that it will be reviewing its approach to completing risk assessments and that it has in the meantime reminded its staff of the importance of including further information in the risk assessment so that the issues considered can be identified. The GPhC has also instructed staff to complete separate risk assessments for each registrant in linked cases. We will continue to monitor the GPhC's approach to risk assessments in the next performance review.

Conclusion against this Standard

6.37 The statistical dataset shows that the GPhC continues to take prompt action when it identifies the need for an IO. Although our audit of closed cases identified concerns about the GPhC's approach to documenting the risks that arise in cases, we did not identify any instances in our audit where the GPhC failed to identify serious cases or should have considered an IO but failed to do so. We also did not identify serious cases which the GPhC did not prioritise adequately. We are satisfied that this Standard is met.

Standard 5: The fitness to practise process is transparent, fair, and proportionate and focused on public protection

6.38 When we responded to the GPhC's consultation on its new threshold criteria, we had concerns about:

- The clarity of the revised criteria and how transparently they would be applied
- A risk that cases which may meet the realistic prospect test are closed prematurely, potentially resulting in risks to the protection of the public
- A lack of scrutiny and transparent oversight of decisions being made.

[28] Senior oversight of cases is maintained through meetings between the Case Officer and Senior Case Officer where case progression is reviewed and discussed.

6.39 We said we would consider the impact of the new threshold criteria in our next performance review.

6.40 This year, we carried out a targeted review of this Standard to obtain further information about the impact of the new threshold criteria. We also sought further information about a fitness to practise hearing decision which was not published online when we expected it to be.

6.41 Our targeted review and audit of closed cases did not identify any concerns about the impact of the new threshold criteria or how they are being applied in practice by the GPhC.

Fitness to practise hearing decision

6.42 Our check of the GPhC register identified a fitness to practise hearing decision that was not published on the website. The GPhC told us that it had identified an error with the decision which, in its view, meant that the decision to restrict the registrant's practice could not be given effect. The GPhC decided to manage the resulting risk through an agreement with the registrant. We were satisfied from the GPhC's response that this was an exceptional case where the GPhC took action to mitigate potential risk to the public. The GPhC has taken steps to prevent a recurrence of the factors that led to the error. We have concluded that the circumstances of this isolated case do not adversely impact our overall assessment of performance against this Standard.

Audit findings

6.43 Whilst our audit did not identify any concerns about the new threshold criteria or with their application by the GPhC, we did identify concerns about other aspects of the GPhC's fitness to practise process which are relevant to our assessment of performance against this Standard.

Triage

6.44 The GPhC's internal triage guidance to staff which applied to the cases we reviewed states that the triage decision is simply about whether or not a matter falls within the GPhC's jurisdiction. Cases that do not fall within the GPhC's jurisdiction are closed and, if appropriate, the complainant may be signposted to another organisation. Cases that fall within the GPhC's jurisdiction are referred for investigation.

6.45 Through our audit of closed cases we established that the GPhC is not complying with its own guidance. In practice, when the GPhC makes a triage decision it considers a number of other factors apart from whether or not a concern is within its jurisdiction. We saw cases where the triage decision took account of the proportionality of the GPhC taking further action, the sufficiency of grounds/information/evidence, or the registrant's level of insight where the concerns were not related to health matters.[29] The GPhC confirmed to us that its triage process requires staff to consider factors beyond whether or not a case is within its jurisdiction and that this deviates

[29] The GPhC's guidance allows for consideration of insight in health cases.

from the process described in its current guidance for staff. We understand that the GPhC intends to review its guidance materials in 2020.

Health cases and pre-IC undertakings

6.46 The GPhC's internal triage guidance refers to three different outcomes for cases where the matters raised relate to the health of a registrant:

- if there are no concerns about the registrant's fitness to practise, then 'close the matter and remind registrant to only practise if fit to do so/inform us if there is a change in their health'
- if there are concerns about the registrant's fitness to practise, then refer to Stream 2
- pre-IC undertakings.[30]

6.47 We noticed that the triage guidance does not explain the circumstances in which pre-IC undertakings should be offered to a registrant. The absence of guidance in this area could lead to inconsistent decisions.

6.48 In the sample of health cases that we audited, we saw occasions where the GPhC closed the case but asked the registrant to provide further information about their health. We note that this outcome is not described in the GPhC's guidance and that the correspondence we saw in these cases, and in the pre-IC undertakings case that we audited, did not explain to registrants:

- the basis on which the GPhC was requesting further information or inviting the registrant to agree to pre-IC undertakings when a decision had been made that there was no evidence of current fitness to practise concerns
- that they were under no obligation to comply with the GPhC's request.

6.49 We consider that telling a registrant their case is closed whilst simultaneously asking them to provide further information or to agree to undertakings is potentially confusing as it is not clear whether the case is in effect closed or what consequences there may be, if any, if the registrant does or does not provide the further information requested by the GPhC.

6.50 The GPhC told us that it tailors its approach to the individual circumstances of each registrant and that this will result in a variety of outcomes. The GPhC indicated that this tailored approach is a proportionate way of supporting registrants with health conditions. The GPhC accepted that the information provided to registrants about undertakings could be improved and told us that it had already begun work on reviewing the information with a view to producing revised guidance by the end of 2019.

Informal guidance issued by the GPhC

6.51 Where a case does not meet the threshold criteria for referral to the IC, the GPhC may decide to close the case and issue informal guidance to the

[30] A mechanism used by the GPhC where a registrant can agree to comply with specified undertakings on a voluntary basis. The undertakings can include providing further information to the GPhC at specified intervals. Unlike undertakings issued by the IC or the FtPC, there is no statutory basis for pre-IC undertakings.

registrant. In the cases we reviewed where guidance of this type was issued, the GPhC's correspondence to the registrant did not explain that the letter constituted guidance or what the future consequences of being issued with guidance might be.

6.52 In response to our audit findings, the GPhC acknowledged that it needs to review and update some of its guidance and documentation, including those related to informal guidance issued. We understand that the GPhC has included this work in its plans for 2019/20, some of which has already begun.

Warnings issued by the IC

6.53 The IC has the power to issue warnings to registrants. The GPhC uses its discretionary power to make a recommendation to the IC for the disposal of a case in all cases that it refers to the IC. The GPhC is required to provide registrants with the opportunity to comment on the recommendation it makes to the IC.

6.54 Where the GPhC has not recommended a warning but the IC is minded to issue a warning, the GPhC's guidance[31] states that the IC must adjourn its consideration of the case to provide the registrant with an opportunity to comment on the warning. The IC can decide to impose a warning even if the registrant does not agree to it.

6.55 The GPhC's legislation[32] enables registrants to request that their case is referred to the FtPC. The legislation does not set out any qualifying circumstances which must be met in order for a registrant to request a referral to the FtPC.

6.56 Our audit found that:

- registrants were invited to comment on a warning without being told the proposed wording of the warning
- registrants were invited to complete a form that asks whether they agree to the warning or whether they request their case be referred to the FtPC, suggesting these are the only two options available to the registrant.

6.57 The GPhC told us that the work it has planned for 2019/20 includes a review of the notices and letters issued to registrants.

6.58 In July 2018 the GPhC updated its publication and disclosure policy to reflect its approach to publishing information about warnings issued by the IC. The GPhC policy is to publish the fact of the warning, rather than the determination or a summary. Our audit provided an opportunity to consider how this policy was being applied.

6.59 We noticed that publishing the fact of the warning meant that no information was included about the reasons for the warning being issued. This approach did not appear to us to be fully transparent as members of the public are not able to see why regulatory action was considered necessary.

[31] Paragraph 5.5 of *Good decision making: Investigating committee meetings and outcomes guidance*
[32] Article 53(3) of the Pharmacy Order 2010.

Conclusion against this Standard

6.60 We consider that when a process departs from the guidance in place, as we observed in the triage and health cases that we audited, this has the potential to impact on the transparency of the process being followed for both registrants and the public. This is because the parties involved will not have full and accurate information about how their case will be considered, how decisions about their case will be made and what the possible outcomes will be. It also risks outcomes that may be unfair or which do not protect the public.

6.61 We were also concerned about the transparency of the information provided by the GPhC to registrants about pre-IC undertakings, guidance and warnings.

6.62 The concerns we have summarised above relate to the approach being followed by the GPhC in a number of different areas rather than being isolated instances that were contrary to its usual approach. They involved a number of areas within the GPhC's fitness to practise process: triage; health cases; and the issuing of informal guidance and of warnings.

6.63 Our findings about the transparency of these processes meant that we could not be assured that the processes in place were fair, particularly in circumstances where a registrant is invited by the GPhC to agree to undertakings or to a warning on the basis of incomplete information.

6.64 We understand that the GPhC will update its triage guidance in the first quarter of 2020. We were encouraged that, prior to our audit of closed cases, the GPhC had begun reviewing its guidance relating to undertakings. It has told us that it will also be reviewing the information that is provided to registrants about informal guidance and warnings. We will monitor the progress of this work. However, this improvement work is still in its early stages. Consequently, we have concluded that this Standard is not met for the period under review.

Standard 6: Fitness to practise cases are dealt with as quickly as possible taking into account the complexity and type of case and the conduct of both sides. Delays do not result in harm or potential harm to patients and service users. Where necessary the regulator protects the public by means of interim orders

6.65 All of the regulators overseen by the Authority are required to provide statistical information on the handling of fitness to practise cases. The information we receive includes the median timeframes taken to reach the following key decision points:

- from receipt of a complaint to the final decision of the IC
- from the final decision of the IC to the final decision of the FtPC
- from initial receipt of the complaint to the final decision of the FtPC.

6.66 We have in recent years commented on the GPhC's performance against the timeliness measure which looks at the overall time taken by the GPhC to obtain a final hearing decision from the initial receipt of the complaint:

- In our 2015/16 performance review report we reported an increase in the median timeframe from receipt of complaint to the final FtPC decision but accepted the GPhC's explanation that this was a short-term consequence of its focus on the disposal of its oldest cases. We noted that we would expect to see the overall timeframe to show improvement as the number of aged cases continued to decline, although it may take some time for this to become apparent in the dataset. The Standard was met.
- In our performance review for 2016/17 we saw evidence of a reduction in the number of older cases in the GPhC's caseload and we reported that the median time taken from receipt of complaint to a final FtPC determination had remained stable. The Standard was met.
- Last year we reported that the data continued to show sustained, rather than improving, performance in the overall end to end timeframe for concluding cases. The Standard was met.

6.67 This year, the data again shows sustained performance in terms of the overall end to end timeframes. We noted that some of the other data reported by the GPhC could indicate declining performance in this area. We decided to conduct a targeted review against this Standard because we wanted to better understand the factors that might be contributing to the data reported by the GPhC.

Timeliness of the key stages of the fitness to practise process

6.68 The data in the table below shows a reduction of just over one week in the overall end to end timeframe for the fitness to practise process. This is only a small improvement and the timeframe is the same as it was in 2016/17, so we consider this continues to show sustained, rather than improved, performance.

Median time (in weeks) from:	Annual 2015/16	Annual 2016/17	Annual 2017/18	Annual 2018/19
Receipt of initial complaint to final IC decision	48.4	52.4	52	49.1
Final IC to final FtPC decision	34	34	34.8	37.7
Receipt of initial complaint to final FtPC decision	96.6	93.7	95	93.7

Number of older cases

6.69 The table below shows an increase in the absolute number of open cases that are older than 52 weeks from 2017/18 to 2018/19.

Measure	Annual 2015/16	Annual 2016/17	Annual 2017/18	Annual 2018/19
Number of referrals received	1,939	1,889	2,333	2,674
Number of cases older than:				

52 weeks	106	114	105	105
104 weeks	37	34	28	34
156 weeks	10	12	10	16
Total	153	160	143	155
Number of cases over 52 weeks as a percentage of referrals received	7.9%	8.5%	6.1%	5.8%

6.70 As part of the targeted review we obtained further information from the GPhC on the reasons for this increase. The GPhC told us that most of the cases aged over 52 weeks old are subject to investigations by third parties. We understand that cases older than 12 months are subject to additional management scrutiny to determine if there are any options for case progression. In December 2018, the GPhC produced guidance on undertaking parallel investigations which aims to ensure that cases subject to third parties are progressed by the GPhC wherever possible and that unnecessary delays are avoided.

6.71 The GPhC also told us that when the number of older cases is considered as a proportion of its overall caseload, rather than as an absolute number, the statistical dataset shows that its performance is consistent with last year. This data is reflected in the table which records the proportion of the GPhC's caseload that is aged over 52 weeks has reduced marginally from the 6.1 per cent recorded for 2017/18 to the 5.8 per cent reported for 2018/19. However, we note that where there is an increase in the number of overall referrals received, we would expect to see an associated decrease in the proportion of older cases if the absolute number of older cases were remaining stable or improving. While outside of this review period, the early data for 2019/20 shows a continued increase in the number of older cases.

Adjournments/postponements of final hearings

6.72 The table below shows that in 2018/19 there was a reduction in the proportion of cases concluded by the GPhC's FtPC in 2018/19.

	Annual 2015/16	Annual 2016/17	Annual 2017/18	Number of decisions made by a final FtPC and with the following outcomes[33]	Annual 2018/19
Number of cases considered by a final FtPC	117	104	120	Total	109

[33] From 2018/19 we started requesting data on concluded and adjourned final hearings in a different format.

Number of cases concluded by a final FtPC	112 (96%)	89 (86%)	99 (83%)	Final	76 (70%)
				Adjourned	33

6.73 In our 2016/17 performance review report we reported that the GPhC was undertaking work to address an increase in the number of successful postponement and adjournment applications made.

6.74 This year, we asked the GPhC if it had identified any reasons for the apparent decline in the proportion of final hearings being concluded. We also asked for an update on the work it had undertaken on postponements and adjournments. The GPhC told us that it has an internal Quality Review Group (QRG) which meets on a regular basis to review the outcomes of statutory committee meetings and hearings and to identify any actions for improvement in the GPhC's management of cases and hearings. The QRG did not identify any patterns or trends in the cases that were postponed or adjourned in the period under review and the GPhC told us that it considered the majority of postponements/adjournments granted were reasonable. The GPhC will continue monitoring any case that has been postponed or adjourned through the QRG.

6.75 While outside of the performance review period, we have noted that the data reported for 2019/20 so far shows an improvement in the proportion of cases concluded by the FtPC.

Triage processing times

6.76 As part of its performance monitoring report to Council, the GPhC provides quarterly reports on its triage processing times according to its internal key performance indicators (KPIs). We noticed that the proportion of cases being triaged within the KPIs was decreasing over the course of 2018/19. The data reported by the GPhC is set out in the table below.

Measure	Q1 2017/18	Q2 2017/18	Q3 2017/18	Q4 2017/18	Q1 2018/19	Q2 2018/19	Q3 2018/19	Q4 2018/19
All concerns received during period[34]	N/A	595	583	691	681	635	702	656
All cases triaged during period	462	563	611	667	704	626	629	700
Of which cases triaged within 3 working days[35]	458 99.1%	540 95.9%	381 62.4%	485 72.7%	479 68.0%	491 78.4%	263 41.8%	170 24.3%

[34] The GPhC began reporting on this item from quarter two of 2017/18.
[35] The GPhC stopped reporting on cases triaged within three working days at the end of 2018/19.

Of which cases triaged within 5 working days[36]	N/A	N/A	532 87.1%	601 90.1%	599 85.1%	546 87.2%	489 77.7%	318 45.4%

6.77 We asked the GPhC if it had identified any reasons for the apparent decline in the triage processing times and what action was being taken to address any reasons identified. The GPhC told us that it had introduced additional senior oversight in triage towards the end of 2018. The GPhC's view of the impact of this additional oversight is that it appears to be improving the GPhC's capability to resolve cases using the right regulatory tools. The GPhC will continue this approach to triage in 2019/20 to produce more data to aid the evaluation of the effectiveness of the additional management oversight at triage.

6.78 We accept the GPhC's explanation of the data and note that, while outside of the performance review period, the triage processing times reported for 2019/20 to date show significantly increased proportions of cases being triaged within the KPIs. We will continue to monitor the data to see whether performance is sustained.

Our audit findings

6.79 Our audit found what we considered to be avoidable or unexplained delays in 35 of the 63 cases we reviewed. This amounts to 56 per cent of the cases we audited. In 26 of those cases, we defined the delays as 'significant' because they were not caused by external factors, so were within the GPhC's control, and they were either over a month long or were multiple delays of more than two weeks. All of the significant delays we noted were on cases that had progressed to the investigation stage of the GPhC's fitness to practise process. This means that we found significant delays on 68 per cent of the investigation cases that we audited. We noticed that where we identified delays on cases, there was limited evidence of the management oversight that had taken place and what effect it had had in ensuring case progression.

6.80 We did not identify any cases where the delays resulted in harm or potential harm to patients or service users.

6.81 The GPhC broadly accepted our audit findings about the timeliness of its case progression and told us that it has an ongoing programme of training and development which is partly aimed at improving timeliness. The GPhC has committed to minimising avoidable delays, managing expectations appropriately and explaining clearly to parties when delays are unavoidable.

Conclusion against this Standard

6.82 The timeframes reported by the GPhC this year show that the median time for cases to be considered by the IC is 49.1 weeks. The median time for cases that are referred to the FtPC to be considered at a final hearing is 93.7 weeks. These timeframes are not significantly different to those reported by the GPhC last year. They are also high in the context of the other regulators

[36] The GPhC began reporting on this item from quarter three of 2017/18.

that we oversee. Our previous reports have indicated concerns with the overall length of time taken but have noted factors which suggest that the timeframes might reduce. The expected improvements in the overall end to end timeframe for concluding cases have still not materialised as we would have expected.

6.83 We also identified avoidable or unexplained delays in a high proportion of the cases we reviewed and we consider that this indicates there is capacity for the GPhC to improve how quickly cases progress through its fitness to practise process. While our audit sample only represents a small proportion of the GPhC's overall caseload, we did not see any evidence to suggest that the delays we identified were limited to the cases in our audit sample, or to a particular process or certain type of case. We therefore consider that these delays are likely to be found across the GPhC's caseload.

6.84 The GPhC has recognised that the timeliness of its fitness to practise cases can be improved and has committed to put measures in place to achieve this. We welcome this commitment and will monitor its work. We have, however, concluded that this Standard is not met.

Standard 7: All parties to a fitness to practise case are kept updated on the progress of their case and supported to participate effectively in the process

6.85 The *Gosport Independent Panel Report*[37] and the Authority's *Lessons Learned Review* of the NMC[38] raised concerns about the experience of patients and service users involved with fitness to practise cases and the support provided to them by healthcare organisations and regulators.

6.86 The GPhC publishes guidance documents about the different stages of its fitness to practise process, which include *I've raised a concern – what happens next?* and *Advice and support for pharmacy professionals involved in the FtP process*. The GPhC says it will update parties regularly during an investigation. We carried out a targeted review of this Standard to obtain further information about how the GPhC's processes for updating and supporting parties operate in practice.

6.87 Our audit identified concerns about customer service in 47 of the 63 cases we reviewed, which amounts to 75 per cent. The most prevalent or concerning examples were:

- parties not being updated
- processes not being clearly explained
- outcomes not being sent
- avoidable or unexplained delays
- short response deadlines being given.

[37] In June 2018 the Gosport Independent Panel published a report into Gosport War Memorial Hospital which concluded that the lives of over 450 patients were shortened while in the hospital.
[38] In May 2018 we published our *Lessons Learned Review* which looked at the NMC's handling of fitness to practise cases concerning midwives at the Furness General Hospital.

6.88 In Standard 5 we have set out our concerns about the transparency of the information provided by the GPhC to registrants in health cases and warning cases. We were concerned that registrants were being asked to decide whether or not to agree to a certain course of action proposed by the GPhC without being provided with complete information. We consider this may have restricted the registrant's ability to make an informed decision and to participate effectively in some stages of the process.

6.89 The GPhC broadly accepted our findings on customer service and told us that it:

- has an ongoing programme of training and development for staff, which will include elements aimed at addressing the concerns we identified
- will take forward work to improve customer service through its wider fitness to practise strategy
- has established a Customer Service Forum which is developing an action plan to improve customer service in fitness to practise
- has a training plan for this year which includes improving staff's understanding of the needs of vulnerable stakeholders.

6.90 We recognise that the GPhC is taking positive steps to address the concerns we have identified but we cannot yet assess the impact the above work might have or when any improvements may be evidenced. As a result, we have concluded that this Standard is not met.

Standard 8: All fitness to practise decisions made at the initial and final stages of the process are well reasoned, consistent, protect the public and maintain confidence in the profession

6.91 In last year's report we indicated that our next review was likely to look in more detail at changes made by the GPhC to the initial stage of its fitness to practise process and the decisions made under the new arrangements.

6.92 This year, we carried out a targeted review to assess the impact of the introduction of new threshold criteria and also to obtain further information about the GPhC's approach to protected cautions and convictions.

Protected cautions and convictions

6.93 Through our Section 29 work we identified a case where a panel erroneously decided that it could not consider an allegation of dishonestly failing to disclose a caution because the caution was protected[39] at the time of the hearing. The caution was not protected at the time of the alleged failure to disclose so the Panel was entitled to consider the allegation of dishonestly failing to disclose the caution to the GPhC.

[39] The Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 (as amended in 2013) provides for certain spent convictions and cautions to be 'protected', which means they are not subject to disclosure after a specified period of time.

6.94 The same error had previously been made by a panel in early 2017 and had been a cause for concern for both the Authority and the GPhC. We asked the GPhC what action it was taking to prevent further recurrences.

6.95 We were satisfied by the GPhC's response that it has taken reasonable steps to ensure panel members are aware of the correct legal position on protected cautions and convictions. The GPhC's QRG will monitor performance in this area to identify any further recurrences.

Our audit findings

6.96 Our audit sample included cases where decisions had been made at the three early stages of the GPhC's fitness to practise process; triage, investigation and IC. The investigation stage is the point at which a case is assessed against the new threshold criteria.

6.97 Our audit did not identify any concerns about the impact or application of the new threshold criteria, but it did identify other concerns at all three of the initial decision-making stages.

6.98 At triage, we saw cases where:

- we disagreed with the triage decision or considered it was made prematurely because in our view further enquiries could reasonably have been made to enable a more informed decision to be taken
- the triage decision was based on factors that are not set out in the GPhC's current triage guidance, for example the proportionality of taking further action, the sufficiency of grounds/information/evidence or the registrant's level of insight where the concerns were not about their health.

6.99 At investigation, we saw examples of cases where:

- further enquiries could reasonably have been made to enable a more informed decision to be taken
- the reasoning for the threshold criteria decision was inaccurate or inappropriate. In these cases, we did not think that the flawed reasoning had led to an incorrect decision being made
- the reasons for the GPhC's recommendation to the IC for disposal of the case were unclear or flawed. Again, in these cases, we did not think that the flawed reasoning had led to an inappropriate recommendation being made
- the outcomes were contrary to the GPhC's internal guidance.

6.100 At IC, we saw examples of cases where:

- the reasons were limited and did not address all aspects of the case or the decision
- the IC decision heavily reflected the wording contained in the GPhC's recommendation with little or no evidence of independent consideration of the factors in the case

- the IC issued advice or a warning but did not specify the wording of the advice or warning to be issued
- the IC issued undertakings without an admission from the registrant that their fitness to practise was impaired, contrary to Rule 10(1) of the GPhC's Fitness to Practise and Disqualification rules, which requires the registrant to admit their fitness to practise is impaired in order for the IC to agree undertakings with them.

6.101 Our audit identified concerns about the quality of the record-keeping on cases as we saw multiple examples where documents, decisions or the reasons for decisions were not recorded on the case file. This meant that we could not always assess the overall management of the case or establish why a decision had been made. The concerns about the recording of decisions and reasons for decisions were particularly evident at the triage stage of the process where we saw cases where there were no reasons recorded for the decision or the reasons had to be inferred from the correspondence with the parties.

6.102 We also found a number of cases which appeared to us to be factually similar but were managed differently and different recommendations for their disposal were made. From the documented information, we could not establish why differing approaches had been taken so these outcomes appeared to us to be inconsistent.

6.103 The GPhC told us that it quality assures its triage decisions through random and scheduled look back exercises and management dip sampling. In response to our audit findings, the GPhC supplemented this approach by introducing a peer review of decisions made at triage to take no further action on cases.

6.104 The GPhC accepted that on a minority of cases the process was truncated or the decision was made prematurely but it was confident that the correct outcome was nonetheless reached in those cases. The GPhC accepted our audit findings about record-keeping and also acknowledged that the documentation of reasoning at triage and in its IC decisions requires improvement and work on this has been included in its plans for 2019/20. Prior to our audit, the GPhC had already identified that its IC decisions require improvement and had begun implementing measures aimed at achieving this.

6.105 The GPhC did not agree with our audit findings about inconsistent decisions. It told us that cases that appear to be factually similar may have underlying nuances which warrant different decisions being reached, but the GPhC accepted that in some of the cases we highlighted the quality of the record keeping meant that it was difficult to ascertain the reasons for the decisions made.

Conclusion against this Standard

6.106 We considered our audit findings in the context of the evidence available to us about decisions made at the final stage of the GPhC's fitness to practise process. Our review of final hearing decisions did not identify any significant

concerns during the review period. We have not appealed a GPhC final hearing decision using our Section 29 powers since 2014.

6.107 Through our audit we established that the GPhC is following a triage process that is not set out in its current internal guidance and we consider that this exposes a risk of inconsistent decisions being made.

6.108 Our audit found examples of flawed or unclear reasoning at all three of the initial decision-making points. The GPhC had already identified for itself that its IC decisions require improvement. We are encouraged that the GPhC has already begun work to improve its IC decisions and that it has acknowledged the documentation of reasons at triage similarly needs to be improved.

6.109 Based on the evidence that we saw, we could not conclude that decisions made in the period under review at the initial stage of the fitness to practise process were well reasoned and consistent. Consequently, we concluded that this Standard is not met.

Standard 9: All fitness to practise decisions, apart from matters relating to the health of a professional, are published and communicated to relevant stakeholders

6.110 We conducted a check of the GPhC's registers and website using a random sample of 20 per cent of the appealable decisions the GPhC reported to us during the period under review. Four of the decisions we expected to see were not published and so we requested further information from the GPhC. The GPhC told us that three of these decisions were not published due to human error and rectified the errors promptly. The GPhC also told us it would be carrying out additional training with the relevant staff teams to reinforce the procedures and responsibilities associated with publishing determinations on its website. The fourth decision is discussed above at paragraph 6.42 and we decided that the circumstances of this isolated case did not adversely impact our assessment of performance against Standard 5.

6.111 Last year we reported that the GPhC had updated its *Publication and disclosure policy* to ensure compliance with the General Data Protection Regulation (GDPR). The GPhC consulted on the changes to the policy between July and September 2018. An updated version of the policy was published in August 2019.

6.112 The changes made to the policy mean that the GPhC no longer publishes details of cases where the IC issues a warning. We have set out our concerns about this approach at paragraph 6.59.

6.113 We do not consider that the small number of publication errors or the updated approach to the publication of IC warnings are significant enough at this time to adversely impact our assessment of the GPhC's performance against this Standard. As a result, we are satisfied that this Standard is met.

Standard 10: Information about fitness to practise cases is securely retained

6.114 The GPhC has not reported any data breaches to the Information Commissioner's Officer (ICO) in the period under review. We have not seen

any evidence which suggests that information about fitness to practise cases is not being securely retained.

6.115 We are satisfied that this Standard is met.

Professional Standards Authority for Health and Social Care
157-197 Buckingham Palace Road
London SW1W 9SP

Telephone: **020 7389 8030**
Fax: **020 7389 8040**
Email: **info@professionalstandards.org.uk**
Web: **www.professionalstandards.org.uk**

professional standards authority