

Annual review of performance 2017/18

# General Pharmaceutical Council



## About the Professional Standards Authority

The Professional Standards Authority for Health and Social Care<sup>1</sup> 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 nine 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.<sup>2</sup> 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.

We are committed to being independent, impartial, fair, accessible and consistent. More information about our work and the approach we take is available at [www.professionalstandards.org.uk](http://www.professionalstandards.org.uk).

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<sup>1</sup> The Professional Standards Authority for Health and Social Care was previously known as the Council for Healthcare Regulatory Excellence

<sup>2</sup> *Right-touch regulation revised*. (October 2015). Available at [www.professionalstandards.org.uk/policy-and-research/right-touch-regulation](http://www.professionalstandards.org.uk/policy-and-research/right-touch-regulation)

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## About the General Pharmaceutical Council

The General Pharmaceutical Council (the GPhC) regulates the pharmacy profession in Great Britain. 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 2018, the GPhC was responsible for a register comprising:

- 55,258 pharmacists
- 23,367 pharmacy technicians
- 14,348 pharmacy premises.

The annual retention fee is currently:

- £250 for pharmacists
- £118 for pharmacy technicians.



# At a glance

Annual review of performance

Regulator reviewed: **General Pharmaceutical Council**

## Standards of good regulation

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### Core functions

**Met**

Guidance and Standards

**4/4**

Education and Training

**4/4**

Registration

**6/6**

Fitness to Practise

**10/10**

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# 1. The annual performance review

- 1.1 We oversee the nine health and care professional regulatory organisations in the UK, including the GPhC.<sup>3</sup> 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.

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<sup>3</sup> These are the General Chiropractic Council, the General Dental Council, the General Medical Council, the General Optical Council, the General Osteopathic Council, the Health and Care Professions Council, the Nursing and Midwifery Council, and the Pharmaceutical Society of Northern Ireland.

- 1.7 When considering information relating to the 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](http://www.professionalstandards.org.uk)

## 2. What we found – our judgement

2.1 During March 2018 we carried out an initial review of the GPhC's performance from 1 March 2017 to 28 February 2018. Our review included an analysis of the following:

- Council papers, including fitness to practise reports, Audit Committee reports and business plan monitoring reports
- Policy and guidance documents
- Statistical performance dataset
- Third party feedback
- A check of the GPhC register
- Information available to us through our review of final fitness to practise decisions under the Section 29 process.<sup>4</sup>

2.2 Following this assessment, we decided to carry out a targeted review of Standards 3 and 6 of the *Standards of Good Regulation for Fitness to Practise*.

2.3 We obtained further information from the GPhC relating to these Standards. As a result of a detailed consideration of this further information we decided that the GPhC had met all of these Standards. The reasons for this are set out in the following sections of the report.

### Summary of the GPhC's performance

2.4 For 2017/18 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 all of the *Standards of Good Regulation for Fitness to Practise*

2.5 The GPhC has maintained its performance since last year,<sup>5</sup> and this is the third consecutive year it has met all of the Standards of Good Regulation.

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<sup>4</sup> 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 \(as amended\)](#).

<sup>5</sup> The 2016/17 GPhC performance review report is available at: [www.professionalstandards.org.uk/docs/default-source/publications/performance-review-gphc---2016-17.pdf?sfvrsn=61fc7320\\_0](http://www.professionalstandards.org.uk/docs/default-source/publications/performance-review-gphc---2016-17.pdf?sfvrsn=61fc7320_0)

## 3. Guidance and Standards

- 3.1 The GPhC has met all of the *Standards of Good Regulation* for Guidance and Standards during 2017/18. 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 The *Standards for pharmacy professionals*,<sup>6</sup> which we reported on in our last report, came into effect in May 2017. Since that time, we have seen nothing to suggest these standards do not reflect up to date practice or fail to adequately prioritise patient and service user safety and patient and service user centred care.

**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 the period under review, the GPhC made some minor amendments to its suite of additional guidance to ensure they were aligned to the *Standards for pharmacy professionals*.
- 3.4 In August 2017, along with the other health and care regulators overseen by the Authority, the GPhC issued a joint statement about managing conflicts of interest. Alongside this statement it published a case study with the Pharmaceutical Society of Northern Ireland and the General Medical Council. The case study, which concerned a doctor with commercial interests in a pharmacy, was developed to help registrants understand and apply the requirements of the standards of competence and conduct in place at each regulator.

**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**

- 3.5 The GPhC continues to consider the views and experiences of key stakeholders' in the development and revision of guidance and standards. Under Standard 2 above we have referred to the joint statement and case study on conflicts of interest which it developed with other health and care regulators overseen by the Authority.

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<sup>6</sup> The *Standards for pharmacy professionals* is the GPhC's standards of competence and conduct which pharmacy professionals must meet. They describe how safe and effective care is delivered through 'person centred' professionalism. It is available here: [www.pharmacyregulation.org/sites/default/files/standards\\_for\\_pharmacy\\_professionals\\_may\\_2017\\_0.pdf](http://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf)

- 3.6 Last year we referred to the extensive consultation the GPhC undertook when developing the revised guidance on religion, personal values and beliefs. This guidance was published in June 2017. The GPhC also used focus groups comprising stakeholders from the three<sup>7</sup> UK countries to review the new standards. We are satisfied that this Standard continues to be 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**

- 3.7 Guidance and standards documents are available on the website, and there is also a video which features stakeholders discussing what the standards mean to them, and how they can be applied. These materials can also be accessed on smartphones and tablets through the GPhC standards' app, which can be downloaded for free. These documents have been translated into Welsh and continue to appear alongside the English language versions on the website. Other formats are available on request.
- 3.8 Information on how to make a complaint if the standards are not followed is also available, and in May 2017 the GPhC published a revised version of its guidance for whistleblowers<sup>8</sup> who wish to raise a concern about someone or something at their place of work. As a result of this activity we have concluded that this Standard continues to be met.

## 4. Education and Training

- 4.1 The GPhC has met all of the *Standards of Good Regulation* for Guidance and Standards during 2017/18. 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**

- 4.2 We noted in last year's report that the GPhC expected to complete its review of the standards of education and training for the whole pharmacy team in 2017. This review was completed in the period under review, and a series of distinct pieces of work is being taken forward by the GPhC. Through this review and a range of other initiatives and consultation exercises it has conducted in recent years, the GPhC identified the need to look at the

<sup>7</sup> A focus group was not held in Northern Ireland as the GPhC regulates Great Britain. However, the consultation was open to all stakeholders.

<sup>8</sup> A whistleblower is a person who reports certain types of wrongdoing within an organisation that is either private or public. A whistleblower is protected by the law.

education and training requirements of staff who work in pharmacies but are not registered. It decided to review the current arrangements because:

- Independent investigations by *Which?*<sup>9</sup> in 2004, 2008 and 2013 identified variability in the advice provided to patients by some high street pharmacies
- The consultation on the standards for pharmacy professionals identified the need to develop guidance for organisations and pharmacy owners about the tasks and activities completed by unregulated groups such as non-pharmacist managers and pharmacy support staff
- In response to the feedback it heard at its 'Professionalism under pressure' event in October 2016, the GPhC agreed to produce guidance for pharmacy owners about unregistered pharmacy staff
- The current policy framework was out of date and did not reflect the diversity of roles within pharmacy. The GPhC considered it was time to review and update the approach to make sure it is sufficiently flexible and focussed on outcomes, to reflect the needs of patients and the public both now and in the future.

### Background

4.3 In 2010, the GPhC adopted the Royal Pharmaceutical Society for Great Britain's (RPSGB) policy for unregistered pharmacy staff. That policy, which was introduced in January 2005, states that pharmacists have a professional obligation to ensure that dispensing/pharmacy assistants and medicines counter assistants are competent in the areas they are working in, to a minimum standard which is equivalent to the relevant units delivered in the vocational qualification in Pharmacy Service Skills. The policy also provided for the accreditation of dispensing assistant and medicines counter assistant courses.

4.4 In practice, this means that unregistered pharmacy staff can be required to complete courses that are accredited by the GPhC, even though the Pharmacy Order 2010 does not explicitly provide powers for the GPhC to accredit courses for unregistered pharmacy staff. However, we note that Pharmacy Order states 'the Council may from time to time publish or provide in such manner as it sees fit guidance to registrants, employers and such other persons as it considers appropriate in respect of the standards for education, training, supervision and performance of persons who are not registrants but provide services in connection with those provided by registran'.<sup>10</sup>

### Unregistered pharmacy staff

4.5 In March 2017, the GPhC considered its role in the education and training of unregistered pharmacy staff and made the following distinction between

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<sup>9</sup> *Which?* is a not-for-profit charitable organisation that has been championing causes for consumers since it was established in 1957.

<sup>10</sup> Extract taken from Schedule 1, Article 6 (2) of the Pharmacy Order 2010 which is available here: [/www.pharmacyregulation.org/sites/default/files/document/pharmacy-order-2010-updated-may-2018.pdf](http://www.pharmacyregulation.org/sites/default/files/document/pharmacy-order-2010-updated-may-2018.pdf)

registered and unregistered pharmacy staff, in recognition of the need to distinguish between the expectations of the two groups:

- ‘Registered pharmacy professionals – pharmacist and pharmacy technicians have wider obligations and responsibilities as regulated professionals and are bound by the requirements of professional regulation. This involves meeting all of the standards we set for education and training, continuing professional development and professional conduct
- Unregistered pharmacy staff – are primarily accountable to their employer. It is their employer who has responsibility for the impact their work has on patients and the public’.<sup>11</sup>

4.6 During July-October 2017, the GPhC consulted on its proposals to develop guidance to ensure a safe and effective pharmacy team, which would replace the minimum training policy. This consultation also included proposals that:

- The pharmacy owner should be accountable for making sure unregistered staff working in their pharmacy are competent to carry out their roles, instead of the individual pharmacist, as is currently the case
- A new minimum level of competence for staff who are involved in dispensing and supplying medicines should be introduced that unregistered pharmacy staff who are involved in the dispensing and supply of medicines must have the knowledge and skills of relevant units of a nationally recognised Level 2 qualification<sup>12</sup>, or are training towards this
- The GPhC should stop approving individual training programmes and qualifications for unregistered staff.

4.7 After considering the analysis of the consultation feedback it received, the GPhC decided that further work was needed to develop its future approach to the accreditation of courses and its proposals on the minimum training requirement for unregistered staff. Consequently, the GPhC will continue to approve courses for unregistered pharmacy staff, and the training requirements for unregistered members of the pharmacy team remain unchanged. Respondents also suggested that more information was needed on staffing levels, and we note that the guidance the GPhC published in June 2018 included a section on what pharmacy owners should consider when deciding the number of staff and skill mix required to provide safe and effective pharmacy services.

### **Initial education and training requirements for pharmacy technicians**

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<sup>11</sup> Extract taken from March 2017 Council report entitled *Developing an updated regulatory framework from unregistered pharmacy staff*. Available from here: [www.pharmacyregulation.org/sites/default/files/developing\\_an\\_updated\\_regulatory\\_framework\\_for\\_unregistered\\_pharmacy\\_staff\\_march\\_2017.pdf](http://www.pharmacyregulation.org/sites/default/files/developing_an_updated_regulatory_framework_for_unregistered_pharmacy_staff_march_2017.pdf)

<sup>12</sup> A Level 2 qualification is equivalent to 4 – 5 GCSE grades 9,8,7,6,5,4 or grades A\* - C

- 4.8 We noted in our report last year that the GPhC agreed to introduce new Initial Education and Training (IET) standards for pharmacy technicians and that it would develop guidance to help course providers create programmes that meet its new requirements. These new standards have been aligned to meet the requirements of the *Standards for pharmacy professionals*. We have seen that the GPhC Council discussed potential concerns and risks arising from some course providers failing to identify and plan for the level of change required to deliver courses that provide these new learning outcomes from August 2018. The GPhC has said it is actively engaging with course providers and is continuing to provide operational guidance in this area.
- 4.9 The GPhC is reviewing the standards for the initial education and training of pharmacists and is working towards presenting its proposals later in 2018.
- 4.10 Based on the evidence and information we have assessed in this area, we are satisfied that this Standard remains 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**

- 4.11 The GPhC continues to publish information on candidate performance and has used this information to quality assure education programmes. Its analysis of candidate performance in the September 2017 pre-registration examination identified that performance from one pharmacy school was significantly lower than other pharmacy schools. Because of this, the GPhC contacted this institution and met with it to discuss the reasons for the variation. The GPhC has committed to report the outcome of this meeting at a future meeting of its Council.
- 4.12 The GPhC published its updated guidance on the independent prescribing programme for the academic year 2018/19. The guidance sets out the procedures it uses to accredit programmes that train pharmacists to become independent prescribers. We note that for all new providers of accredited programmes, accreditation is provisional and subject to a monitoring event which takes place after the first cohort of students. The guidance states that these monitoring events consider student feedback and evaluation. We saw no evidence of concerns or changes to processes in this area. Accordingly, we have concluded that this Standard remains met in 2017/18.

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

- 4.13 As we have reported in previous years, the GPhC's website includes information on how to raise a concern about pharmacy education and training. This includes information on how it quality assures courses that lead to registration as a pharmacy professional, the details of how these complaints are investigated and what action it can take if concerns are substantiated. We saw no evidence that the GPhC failed to take action in

response to concerns about education and training establishments, and this Standard therefore remains met.

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

- 4.14 The GPhC accredits the following courses that lead to registration and/or annotation as a pharmacy professional:
- Master of Pharmacy (MPharm) degrees leading to pre-registration and registration as a pharmacist
  - Overseas Pharmacists' Assessment Programmes (OSPAPs) leading to pre-registration and registration as a pharmacist
  - Prescribing programmes leading to pharmacist annotation
  - Competency and knowledge-based qualifications leading to registration as a pharmacy technician

As we mentioned in paragraph 4.3 above, the GPhC also accredits pharmacy, dispensing and medicines counter assistant courses which allow individuals working in pharmacies to complete work that supports the safe supply of medicines. The list of providers accredited to deliver these programmes remains available on its website. We therefore consider that this Standard remains met.

## **5. Registration**

The GPhC has met all of the *Standards of Good Regulation* for Registration during 2017/18. Examples of how it has demonstrated this are indicated below each individual Standard.

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

- 5.1 We have not seen any evidence to suggest that the GPhC has added to its register anyone who has not met its requirements for registration.
- 5.2 Registrants are required to renew their registration at least two months before it is due to expire. Those who fail to meet this requirement are removed from the register on the day following the expiry of registration and will not be able to practise as a pharmacy professional.
- 5.3 In March 2018, the GPhC introduced revalidation for pharmacy professionals. The previous framework which remained in place throughout the period under review required registrants to make and keep a record of nine Continuing Professional Development (CPD) entries as a requirement of their continuing registration with the GPhC. Those who fail to submit their CPD records when invited to do so are removed from its register. The performance monitoring report which the GPhC presented to its Council in June 2018, showed that 21 registrants were removed from the register for failing to comply with this requirement in the period under review.

**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 its registration processes this year. The criteria to register as a pharmacy professional requires applicants to successfully complete a qualification accredited by the GPhC; complete a specified period of pre-registration training or a qualified period of work experience; pass a pre-registration examination set by the GPhC, and demonstrate they have the necessary knowledge of English to practise safely in Great Britain. In order to sit the pre-registration examination or meet its work experience requirements, applicants must be signed off as being 'satisfactory or better' (in the case of pharmacists) or endorsed by a supervising pharmacy professional of good standing with the GPhC (in the case of pharmacy technicians).
- 5.5 The number of registration appeals received continues to be low, with the GPhC reporting it received two appeals in the period under review. The criteria for registering as a pharmacy professional means it is unlikely that those who do not meet its requirements can be considered eligible to apply for registration. The information we reviewed does not suggest that its management of its processes in this area is not fair or inefficient.
- 5.6 Article 39 of the Pharmacy Order 2010 outlines the registration appeals process. In order for an appeal to be considered it must be received in writing and within 28 days from receipt of notification of the decision. The appellant bears the burden of proof in establishing that the decision should be overturned.

**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 The checks we completed on a sample of entries on the GPhC's registers did not identify any anomalies in the information provided. We did not find any other evidence to suggest its registers are not accurate or accessible and therefore this Standard continues to be 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**

- 5.8 The GPhC has a data subscription service which allows organisations to download information from its registers, excluding personal information such as home addresses. The service provides information for permitted purposes in return for a fee, and allows users to:
- Extract data for all registered pharmacists, pharmacy technicians and/or registered pharmacies; and
  - Download the list of changes (additions to and removals/suspensions) to the register.

- 5.9 The registration section of the website clearly states that ‘anyone who is not registered with the GPhC but practices as a pharmacist or pharmacy technician, or refers to themselves as such, is breaking the law and can be prosecuted’. The register features prominently on the website and there is a separate section for employers which includes a reminder of their duty to check the registration status of pharmacy professionals they employ.

**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**

- 5.10 The GPhC reviewed and published its criminal prosecution policy in the period under review. In July 2017, it published *Working in pharmacy when not on the register*, an information sheet for former registrants, staff and employers which outlines the roles and activities that can only be carried out by a registered pharmacist. It also specifies activities which can be completed by, or under, the supervision of a registered pharmacist.
- 5.11 The GPhC’s website continues to include information about the action it can take to prevent the improper use of its protected titles. In its annual fitness to practise report to the year ending 31 March 2018, the GPhC reported it brought forward three successful criminal prosecutions against people who practised as a pharmacy professional whilst not on its registers.

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

- 5.12 We have previously reported that the GPhC uses a sample-based approach to reviewing CPD records. In the period under review, it selected the records of 1,544 registrants. This included those randomly selected alongside the records of two registrants who had required a second attempt at meeting its CPD requirements in the last two years, and the records of registrants who have been restored to its registers in the last two years but have not previously had their CPD records reviewed. Twenty-one registrants were removed from its registers for failing to comply with its requirements to submit CPD records, but the sample suggested an overall compliance rate of 97%.
- 5.13 We noted in our report last year that the GPhC was proposing to change its arrangements for the continuing professional development of its registrants. In October 2017, it agreed to introduce revalidation for pharmacy professionals. The new arrangements, which came into effect in April 2018, are designed to help registrants demonstrate how they provide safe and effective care to the public. With the introduction of revalidation, the GPhC decided it would not request to review CPD records related to previous periods. However, it reminded registrants of their duty to continue meeting its requirements for CPD until revalidation was introduced in April 2018.
- 5.14 As a result of revalidation, registrants are now required to carry out, record and submit four CPD entries, at least two of which must be planned learning activities; one peer discussion; and one reflective account as part of the

annual renewal of their registration with the GPhC. Renewals are completed online through myGPhC, a password protected self-service website designed for registrants to renew their registration, update their personal details and submit their CPD records directly to the GPhC.

## 6. Fitness to Practise

- 6.1 We considered that more information was required in relation to the GPhC's performance against Standards 3 and 6 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 both these Standards were met and therefore the GPhC has met all of the *Standards of Good Regulation* for Fitness to Practise in 2017/18.

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

- 6.2 The GPhC website provides information on how to raise a concern about pharmacy professionals. Its annual report and accounts to the year ending 31 May 2018 records that the GPhC continues to receive and open cases from a variety of sources.
- 6.3 Its annual fitness to practise report to the year ending March 2018 records that the number of concerns it received increased to 2,333. This represented an increase of approximately 23 per cent on the number of complaints it received in 2016/17.

### **Workplace pressures**

- 6.4 In looking at the Standard we also look at how regulators respond to complaints and concerns that they receive to ensure that they are not ignored. In January 2018, the BBC aired *Inside Out: Pharmacists under pressure*, an investigation into Boots the Chemist. The programme looked at concerns raised by a whistleblower who had reported concerns to the GPhC in 2015. In the programme the whistleblower and several other current and former Boots staff said that understaffing in Boots could pose a risk to patients.
- 6.5 The GPhC issued a statement before the programme was aired. This said that the GPhC considers every concern it receives about pharmacy professionals and pharmacies, and that it had previously completed an investigation into the issues the whistleblower had reported to them. Its investigation concluded that there was not 'sufficient objective, independent evidence to suggest a risk to patient safety across the organisation'.<sup>13</sup> Shortly after the programme was aired the GPhC said it would publish new guidance for pharmacy owners which emphasises what they are expected to do to

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<sup>13</sup> Extract taken from the GPhC's response to BBC Inside Out, issued on 9 January 2018 and available here: [www.pharmacyregulation.org/news/gphc-response-bbc-inside-out](http://www.pharmacyregulation.org/news/gphc-response-bbc-inside-out)

make sure they have a safe and effective pharmacy team in every pharmacy. This guidance was published in June 2018.

- 6.6 We considered whether the GPhC's response to, and its management of the concerns raised about workplace pressures, raised a concern about its performance against this Standard. We concluded that it did not. In reaching our decision we noted that the GPhC has been aware of and has responded to this issue over a number of years. In our 2016/17 performance review report we noted that it hosted a 'professionalism under pressure' event in October 2016, and that this event addressed some of the issues raised by the whistleblower and its own subsequent investigation into the large multiple pharmacy. At that time the Registrar issued a statement which reminded pharmacy owners of their responsibilities to make sure pharmacies have enough staff for the safe and effective provision of pharmacy services. It also published a report of the event it held in October 2016. We have seen evidence that the GPhC is mindful of its role and the influence it can bring to support pharmacy professionals and pharmacy owners in meeting their obligations to ensure that pharmacy services are delivered safely and effectively. These responsibilities are outlined in the *Standards for Pharmacy professionals* and the *Standards for registered pharmacies*<sup>14</sup> have most recently been reinforced in the guidance it published to ensure a safe and effective pharmacy team.
- 6.7 From the information we have considered, we are satisfied that anybody can raise a concern about the fitness to practise of a pharmacy professional. Therefore, we have concluded that the GPhC has continued to meet this Standard in the period under review.

**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**

- 6.8 The GPhC continues to have arrangements in place for sharing information about fitness to practise concerns with other regulators. In March 2017, it issued a statement with the General Medical Council, the Care Quality Commission (CQC) and the Medicines and Healthcare Products Regulatory Agency which reiterated its commitment and responsibility to working closely together to 'help make sure that people are receiving safe and effective care'.
- 6.9 Additionally, after the CQC reported that its investigation of companies providing primary care services over the internet found significant concerns about patient safety, the GPhC announced it would carry out further examinations of online pharmacies selling medicines to ensure they were meeting its standards.
- 6.10 From the information we have reviewed we are satisfied that the GPhC has shared and acted on intelligence it has received from system and other professional regulators. Therefore, we decided that the Standard is met in 2017/18.

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<sup>14</sup> *The Standards for registered pharmacies* sets out the requirements for the provision of pharmacy services at or from a registered pharmacy. They apply to all pharmacies registered with the GPhC

**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**

- 6.11 This Standard was met last year when we noted that in July 2017, the GPhC agreed to introduce revised threshold criteria for use when deciding if a case should be referred to its Investigating Committee (IC). Although we outlined our intention to look at the new threshold criteria and review any potential impact in this performance review, the new threshold criteria did not come into effect until February 2018, This meant that the number of cases where the new criteria will have been applied was likely to be low, and as such, we did not complete a detailed review of the changes this year but will do so next year when there will be a larger number of cases for us to review and assess.
- 6.12 This year we carried out a targeted review of performance against this Standard because there appeared to be a discrepancy in the quarterly information which we received from the GPhC. This information showed the IC was only able to conclude between 58 – 65 per cent of the cases it considered in any quarter. Additionally, the number of cases where the GPhC had told us about the decision of the IC was greater than the total number of cases it reported the IC had concluded in each quarter.
- 6.13 We asked the GPhC to explain the discrepancy we identified in the information it provided to us, and to tell us the reasons why the IC was not able to conclude a greater proportion of the cases referred to it. It told us that cases referred to the Fitness to Practise Committee (FtPC) were not included in the performance information it provides to us about the number of cases concluded by the IC. It explained it did not consider such cases to be concluded because a final decision has not yet been made, and under its rules, cases that have been referred to the FtPC for a hearing, but a hearing has not yet started can be referred back for the IC to consider rescinding the referral to the FtPC. The GPhC told us these cases are counted and included in the breakdown it provides to us on the outcome of the cases concluded by the IC. This explained the discrepancy in the information we reviewed about the number of cases concluded by the IC. As a result of this clarification we could see that the IC concluded a high proportion of the cases it considered, as indicated in the table below:

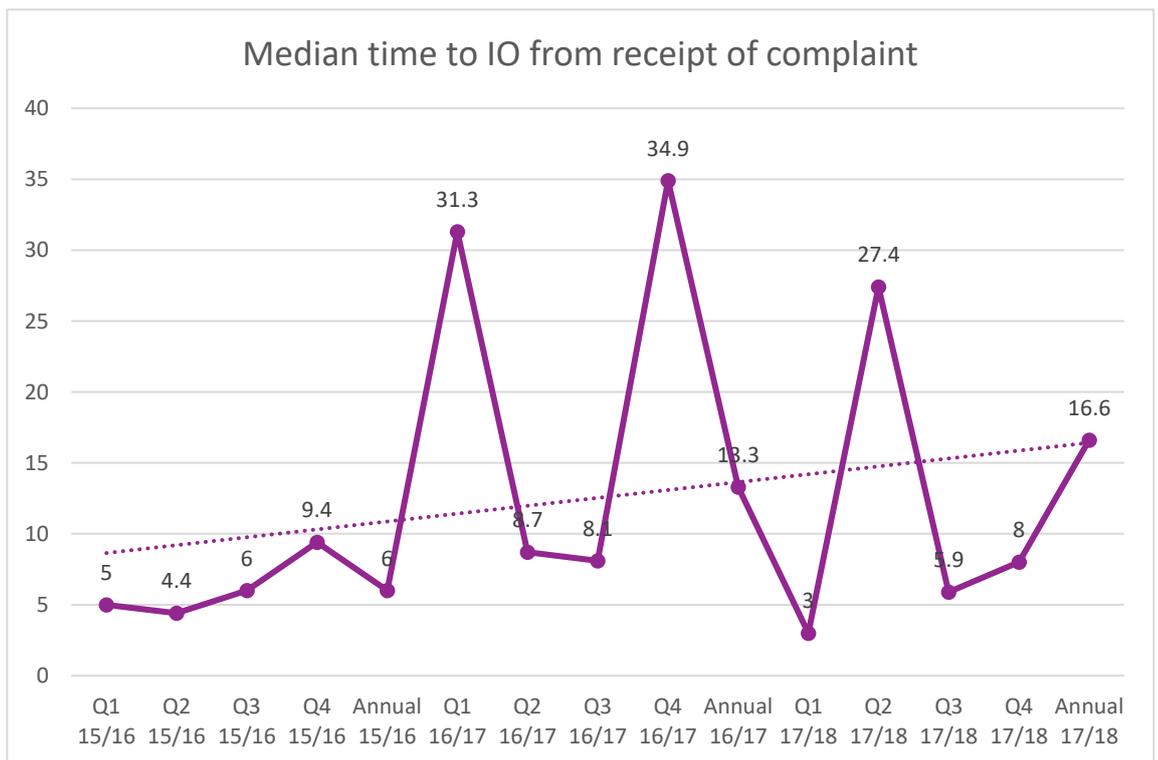
	16/17 annual	Q1 17/18	Q2 17/18	Q3 17/18	Q4 17/18	17/18 annual
No. of cases considered by the IC	181	55	42	20	48	165
No. of cases concluded by the IC	106	27	26	11	29	93
No. of cases referred to the FtPC	71	26	10	7	16	59

Total	177 <b>98%</b>	53 <b>96%</b>	36 <b>86%</b>	18 <b>90%</b>	45 <b>94%</b>	<b>152</b> <b>92%</b>
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6.14 Based on the additional information provided to us in relation to this Standard, we are satisfied that this Standard remains met in 2017/18.

**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**

In 2016/17, the GPhC met this Standard following a targeted review into the reasons for the increase in the median time taken to obtain an Interim Order (IO) from receipt of a complaint. We decided the Standard was met because we accepted the explanations provided by the GPhC that the particular circumstances in a small number of cases had led to fluctuations in the time taken to obtain an IO from receipt of the complaint. This fluctuation has continued in the period under review, as illustrated in the graph below:



6.15 This year, the GPhC reported that the annual median for obtaining an IO from initial receipt of the complaint was 16.6 weeks, an increase of approximately three weeks from the 13.3 weeks it reported to us in 2016/17. The following table compares the GPhC’s performance this year against the performance it has reported to us over the last four years:

Annual median time for IO decision from receipt of complaint:	Year
14 weeks	2013/14
18 weeks	2014/15
6 weeks	2015/16
13.3 weeks	2016/17
16.6 weeks	2017/18

6.16 From this information we can see that except for 2015/16 when the median reported was six weeks, the 16.6 weeks reported in 2017/18 is generally in keeping with that reported in previous years. We can also see that the annual median of six weeks reported in 2015/16 can be regarded as something of an outlier because it is a significantly lower timeframe than that reported to us in previous years, and that level of performance has not been sustained.

6.17 The other key measure we consider in this area is the time taken to obtain an IO from receipt of the information indicating that one is required. The GPhC's performance against this measure has remained consistent throughout the period under review (and indeed since 2015/16), at a median of two weeks. This suggests to us that its processes continue to be effective, with the GPhC taking immediate action to protect the public from risk of harm as soon as it receives information indicating that an IO might be required. On this basis, 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**

6.18 This Standard was met in 2016/17 following a further review which looked at the impact of the revised guidance the GPhC issued to the IC in January 2016. We had previously expressed concerns that the guidance appeared to introduce a new additional test of proportionality which had the potential to result in lenient outcomes. Last year we reviewed anonymised copies of the IC determinations in the previous three years where the realistic prospect test had been met but the IC has decided not to refer the matter to the FtPC. At the end of our review we decided there was no evidence that allowing cases to be closed by the IC where the realistic prospect test was met was resulting in unduly lenient outcomes.

6.19 In 2017/18 the GPhC consulted on and introduced new threshold criteria for the referral of cases to the IC. The Authority responded to the consultation and we outlined concerns about:

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

6.20 The revised criteria were agreed in July 2017 and came into effect on 1 February 2018. As the threshold criteria was only recently introduced and the

number of cases where it will have been applied in the period under review is likely to be low, we will consider the impact of these changes in our next performance review.

- 6.21 We have seen no evidence to suggest the fitness to practise process operated by the GPhC is not transparent, fair, proportionate and focussed on public protection. Therefore, we are satisfied that this Standard is met this year.

**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**

- 6.22 Last year we conducted a targeted review against this Standard because we wanted to assess whether the improvements we noted in the age profile of the GPhC's caseload in our 2015/16 performance review had been sustained. We noticed a reduction in the number of cases aged over 52 weeks and commented that there had been an increase in the time taken for the IC to consider a case from the initial receipt of the complaint. However, we recognised that the GPhC operates a 'frontloading and case ready' system whereby cases are fully investigated before they are presented to the IC. This can increase the time taken to conclude an investigation but can lead to a reduction in the time taken to hear final cases. We concluded that this Standard was met in 2016/17.
- 6.23 This year we completed a targeted review of performance against this Standard because we wanted to understand the available performance information in more detail. We noticed that the further improvements we had expected to see in the overall end to end timeframe for concluding cases had not materialised. We also identified a potential concern about the progression of cases to a final hearing following referral by the IC and the proportion of cases concluding within their original hearing day allocation.

#### **The dataset**

- 6.24 The GPhC's dataset showed a reduction in the total number of cases in the categories<sup>15</sup> we report on, sustained performance in the median time taken from initial receipt of a complaint to final IC decision, sustained performance in the median time taken from final IC decision to the final FtPC determination, but a slight increase in the overall time taken to conclude cases from 93.7 weeks in 2016/17 to 95 weeks this year.
- 6.25 The following table compares the GPhC's performance against these key measures over the last three years:

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<sup>15</sup> As part of the statistical dataset we ask the regulators to tell us the number of open cases in three categories: (1) cases aged up to 52 weeks; (2) cases aged between 53-104 weeks; and (3) cases aged between 105-156 weeks.

Measure	2015/16 annual	2016/17 annual	2017/18				2017/18 annual
			Q1	Q2	Q3	Q4	
Number of open cases older than:							
52 weeks	↓106	↑114	101	100	112	105	↓105
104 weeks	↓37	↓34	38	30	33	28	↓28
156 weeks	↑10	↑12	9	13	8	10	↓10
Median time from receipt of initial complaint to the final FtPC determination	↑96.6	↓93.7					↑95
Median time taken from receipt of an initial complaint to a final decision by the IC	↓48.4	↑52.4	61.1	55.0	38.3	45.9	↔52.0
Median time taken from final IC to the final FtPC determination/or other final disposal of the case	↓34	↔34					↔34.8

6.26 The table shows the GPhC has maintained its performance in the investigation and progression of cases in 2017/18.

### Progression of cases to a final hearing following referral by the IC

6.27 Last year we reported that there had been an increase in the number of hearings which had been postponed or adjourned, which meant that fewer cases had been concluded in the course of the year. We noted that the GPhC had commissioned a review to look at the reasons for the increase, and we accepted it was undertaking work to reduce the number of adjournments and postponements of hearings.

6.28 The annual measures which the GPhC reported to us in May 2018 showed that there has been a significant increase in the number of cases referred by the IC for a substantive hearing, and where that hearing has not yet begun. We are aware that there are several reasons that could explain this. However, given our concerns about the increase in the number of successful postponement applications made in 2016/17, we asked the GPhC to provide us with further information about its performance in this area.

6.29 In its response to our additional questions, the GPhC explained to us there had not been an increase in the number of postponements of final hearings between 2016/17 and 2017/18. Therefore, this was not a contributory factor to the increase we noted in the number of cases referred for a substantive hearing that had not yet started. The GPhC advised us that there were two key reasons for the increase.

- 6.30 The first reason was based on the size and composition of its caseload. The GPhC told us that over the course of the period under review, it had experienced an increase in the number of complaints it received about the individuals on its registers. From Q4 2016/17 to Q4 2017/18, it saw an increase of approximately 23.5 per cent. This resulted in a 10.2 per cent increase in its total caseload. The GPhC managed this increase by holding additional meetings of its IC in March 2018. This then resulted in a higher number of cases being referred to the FtPC in Q4 2017/18, which were then awaiting a final hearing.
- 6.31 The second reason is that the Pharmacy Order 2010 requires that cases assessed as requiring an IO are directly referred to the FtPC, regardless of whether the investigation is yet sufficiently complete to enable a final hearing to be held. The GPhC told us that at the time of its response, there were 33 cases where an IO had been imposed, but a final hearing had not yet commenced, and that this had contributed to an increase in the number of cases at this stage of the process.
- 6.32 Based on the further information provided by the GPhC, and the fact there has not been a significant increase in the overall time taken to conclude cases, we are satisfied that there is no evidence of concerns. We will continue to monitor the GPhC's performance in this area.

#### **The proportion of cases concluding within their original hearing day allocation**

- 6.33 The annual measures which the GPhC reported to us in May 2018 also showed that there had been a reduction in the percentage of final hearings that concluded within their original hearing day allocation. We asked the GPhC to explain the reasons for this. In its response the GPhC told us it identified an error in the information it provided to us in 2016/17 for this measure. The GPhC corrected the data. This showed that the sharp decline we identified had, in fact, occurred in 2016/17, when the percentage of cases concluded within the original number of hearing days allocated was 77 per cent and not 100 per cent (as was originally reported). We do not regard the corrected percentage reduction for 2017/18, from 77 per cent to 75 per cent, as significant. We note that the significant reduction in this figure which occurred between 2015/16 and 2016/17 did not result in any negative trend in median timescales for case progression in that period.

#### **Conclusion against this Standard**

- 6.34 Following our consideration of the additional information we received, we have reached the view that the GPhC has maintained its performance against this Standard, and we have concluded that this Standard is met in 2017/18.

**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**

- 6.35 This Standard was met last year when we noted the GPhC had not reported any significant changes to how it updates parties in fitness to practise proceedings.
- 6.36 In September 2017 the GPhC introduced *Casetracker*, a new information system for use in its fitness to practise department. *Casetracker* merged information stored across several databases into one system, with the aim of providing staff with access to key pieces of information about a pharmacy professional at a glance. The GPhC anticipates *Casetracker* will help it improve information sharing, case management and customer service in its fitness to practise processes and proceedings.
- 6.37 We saw no evidence that the GPhC is not keeping parties updated on the progress of their case at least once every two months (as required by its own key performance indicator) or that it is generally failing to facilitate effective participation in fitness to practise proceedings. We are satisfied that this Standard continues to be 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**

- 6.38 Although the GPhC has made some changes to how it considers and investigates the concerns it receives at the initial stages of its fitness to practise process, and we have reported on these in our previous reports, the evidence we have assessed this year does not indicate these changes have resulted in decisions that are not well reasoned and/or fail to adequately protect the public. We saw no evidence that decisions fail to maintain public confidence in the profession. It is likely that in our next review we will look at the changes made at the initial stage of the fitness to practise process and the decisions made under these new arrangements in more detail.
- 6.39 Like last year, we did not use our Section 29 powers to appeal a final fitness to practise decision in 2017/18, and we have not identified any significant concerns with the quality of decisions made at the final stages of the fitness to practise process. Indeed, the Authority has not used its powers to appeal a final decision made by the GPhC since 2014.

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

- 6.40 The GPhC did not make any changes to how it publishes and communicates fitness to practise decisions to relevant stakeholders in the period under review.
- 6.41 However, in July 2018, it introduced an updated version of its publication and disclosure policy which covers its approach to publishing and disclosing information about registrants who are subject to fitness to practise

investigations. The policy also sets out the information that is disclosed to third parties and how requests for information are dealt with. Although the updated policy was introduced to ensure the GPhC is fully compliant with the requirements of the General Data Protection Regulations (GDPR),<sup>16</sup> it is consulting on the changes it has made, and is specifically seeking views on its proposals to:

- Set out what it considers when making decisions to publish or disclose information in the public interest
- Revise the length of time sanctions are displayed on a registrant's entry in its online register which includes lowering the period for removal from an indefinite period to 10 years, and introducing a specific timeframe for displaying information about restoration in the online register.

6.42 As the amended policy was not introduced in the period under review, is subject to public consultation, and there is the possibility it will be amended in response to the feedback received, we will consider the impact of these changes in the 2018/19 performance review.

6.43 Like last year, our check of its registers did not identify any errors or anomalies in the information provided and there was no evidence that information was either withheld or disclosed inappropriately. Accordingly, this Standard remains met.

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

6.44 Last year we noted the GPhC had not achieved full alignment with ISO27001, the international standard for information security management it told us it was working towards in the 2015/16 performance review. It has not achieved this in the period under review.

6.45 In December 2017 the GPhC reported a serious data breach to the Information Commissioner's Office (ICO). The breach arose as a result of human error, and the GPhC told us it acted to rectify the breach and minimise its impact as soon as it was able to do so. The GPhC conducted a review of the circumstances of the data breach and it told us about two measures it introduced in response, to reduce the likelihood of a reoccurrence.

6.46 We understand that following its assessment of the breach, the action taken to rectify the error, and the measures introduced to prevent the error from being repeated, the ICO decided that it would not take action against the GPhC. In its response the ICO recognised that the breach had been contained and it stated that the GPhC 'has robust data protection policies and procedures in place'. In this context and because the GPhC has not reported a serious data breach to the ICO in recent years<sup>17</sup>, and we did not identify any other evidence to suggest it is not securely retaining information

<sup>16</sup> The GDPR is a new, European-wide law that replaces the Data Protection Act 1998 in the UK. It came into effect on 25 May 2018.

<sup>17</sup> Our statistical dataset shows that the GPhC has not reported a data breach to the ICO since 2014/15.

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about fitness to practise cases, we are satisfied this Standard is met in 2017/18.

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