

Annual review of performance 2016/17

Pharmaceutical Society of Northern Ireland



About the Professional Standards Authority

The Professional Standards Authority for Health and Social Care¹ 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.² 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 <u>www.professionalstandards.org.uk</u>.

¹ The Professional Standards Authority for Health and Social Care was previously known as the Council for Healthcare Regulatory Excellence.

² Right-touch regulation revised (October 2015). Available at www.professionalstandards.org.uk/policy-and-research/right-touch-regulation

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About the Pharmaceutical Society of Northern Ireland

The Pharmaceutical Society of Northern Ireland (the PSNI) is the regulator for pharmacists and registered pharmacies in Northern Ireland. Its work includes:

- Ensuring high standards of education and training for pharmacists
- Maintaining a register of pharmacists ('registrants') and a register of students in pre-registration training
- Setting standards of conduct, ethics and performance that registrants must meet
- Setting standards for continuing professional development to ensure registrants maintain their ability to practise safely and effectively
- Taking action to restrict or remove from practice registrants who are not considered fit to practise
- Maintaining a register of registered pharmacies and setting standards they must meet.

As at 30 September 2017, the PSNI was responsible for a register of 2,470 pharmacists and 548 pharmacies. Its annual retention fee for registrants is £398.



Standards of good regulation

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

1. The annual performance review

- 1.1 We oversee the nine health and care professional regulatory organisations in the UK, including the PSNI.³ 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

³ 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, and the Pharmaceutical Society of Northern Ireland.

months. We use this to decide the type of performance review we should carry out.

- 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 <u>www.professionalstandards.org.uk</u>

2. What we found – our judgement

2.1 During October 2017, we carried out an initial review of the PSNI's performance from 1 October 2016 to 30 September 2017. Our review included an analysis of the following:

- Council papers, including committee reports and meeting minutes
- Policy and guidance documents
- Statistical performance dataset (see paragraphs 2.6 to 2.8 below)
- Third party feedback
- Register check
- Information available to us through our review of final fitness to practise decisions under the Section 29 process.⁴
- 2.2 As a result of this assessment, we carried out a targeted review of Standards 1, 2 and 3 of the *Standards of Good Regulation* for Guidance and Standards.
- 2.3 We obtained further information from the PSNI relating to these Standards. As a result of a detailed consideration of this further information, we have decided that the PSNI has met all of the Standards this year. The reasons for this are set out in the following sections of the report.

Summary of the PSNI's performance

- 2.4 For 2016/17 we have concluded that the PSNI:
 - 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 PSNI has maintained its performance since last year⁵ when it met all the *Standards of Good Regulation* for the first time.

Key comparators

2.6 We have identified with all of the regulators the numerical data that they should collate, calculate and provide to us, and what data we think provides helpful context about each regulator's performance. Below are the items of data identified as being key comparators across the Standards.

⁴ 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 <u>NHS Reform and Health Care Professions</u> <u>Act 2002 (as amended)</u>

⁵ The 2015/16 PSNI performance report is available at: <u>www.professionalstandards.org.uk/docs/default-source/publications/performance-review---psni-2015-16.pdf?sfvrsn=0</u>

- 2.7 We expect to report on these comparators both in each regulator's performance review report and in our overarching reports on performance across the sector. We will compare the regulators' performance against these comparators where we consider it appropriate to do so.
- 2.8 Set out below is the comparator data provided by the PSNI for the year from April 2016 to March 2017, the last full year for which comparator data is available. The annual data covers the period 1 April 2016 to 31 March 2017, some of which falls into our previous review period.

1	The number of registration appeals concluded, where no new information was presented, that were upheld	0
2	Median time (in working days) taken to process initial registration applications for	
	UK graduates	1
	 EU (non-UK) graduates 	0
	 International (non-EU) graduates 	0
3	Time from receipt of initial complaint to the final Investigating Committee/Case Examiner decision	
	Median	15 weeks
	Longest case	22 weeks
	Shortest case	12 weeks
4	Time from receipt of initial complaint to final fitness to practise hearing	
	Median	34 weeks ⁶
	Longest case	34 weeks
	Shortest case	34 weeks
5	Time to an interim order decision from receipt of complaint	3 weeks
6	Outcomes of the Authority's appeals against final fitness to practise decisions	
	Dismissed	0
	Upheld and outcome substituted	0
	• Upheld and case remitted to regulator for re-hearing	0
	Settled by consent	0
	Withdrawn	0

⁶ The PSNI reported that this figure relates to one case.

7	Number of data breaches reported to the Information Commissioner	0
8	Number of successful judicial review applications	0

3. Guidance and Standards

3.1 As we set out in Section 2, we carried out a targeted review of the PSNI's performance against Standards 1, 2 and 3 for Guidance and Standards. 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 these Standards were met and therefore the PSNI has met all of the *Standards of Good Regulation* for Guidance and Standards in 2016/17.

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 This Standard was considered as part of a targeted review this year.
- 3.3 We decided to carry out a further review of performance against this Standard because we wanted to understand the requirements of *The Code*⁷ and the registrant's responsibilities to the patient in circumstances when they do not wish to, or are unable to provide the professional services requested and / or make a professional decision to refer the patient to an alternative provider.
- 3.4 Our interest in this area was prompted by the approach taken by the General Pharmaceutical Council (the GPhC) when it published the *Standards for pharmacy professionals*⁸ in 2017.
- 3.5 In our 2016/17 report of the GPhC's performance, we set out against this Standard the consultation work it had completed on its *Standards for pharmacy professionals*. We were interested in the feedback it received to its proposals which suggested pharmacy professionals could continue to refer service users to other providers '*if their own values or beliefs prevent them from providing care*'. The GPhC received over 1,295 responses⁹ to this consultation. Its analysis of the feedback and a further review of the framework of equalities and human rights legislation led it to agree with respondents who expressed the view that the example used to illustrate how

⁸ Standards for pharmacy professionals is the GPhC's standards of competence and conduct for its registrants. It explains how registrants should deliver safe and effective care, and contains nine standards which set out what is expected of pharmacy professionals. It is available from here:
 www.pharmacyregulation.org/sites/default/files/standards for pharmacy professionals may 2017_0.pdf

⁷ The Code: Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland. It sets out the standards of professional conduct that pharmacists in Northern Ireland are expected to meet and adhere to at all times. It is available from here: www.psni.org.uk/wp-content/uploads/2012/09/22504-PSNI-Code-of-Practice-Book-final.pdf

⁹ The number of responses has been extracted from the *Standards for pharmacy professionals*: *consultation report* considered by the GPhC council in September 2016.

registrants might demonstrate patient centred care did not reflect a focus on putting the needs of the patient first. This is because the example suggested registrants could refuse to deliver services if their personal values and beliefs prevented them from providing the care required. The GPhC altered its approach and held a second consultation on the *Standards for pharmacy professionals*.

- 3.6 As a result of this work the GPhC revised its guidance to indicate that redirecting patients to an alternative provider might not always be sufficient to demonstrate that patient centred care is not being compromised. This was a significant change in its expectations as the standards of conduct, ethics and performance¹⁰ allowed pharmacy professionals to refer service users to other providers if their religious or moral beliefs prevented them from providing a service. Whilst referral to an alternative provider remains an option that pharmacy professionals are able to exercise under the *Standards for pharmacy professionals*, there is an awareness through the expectations set and articulated by the GPhC that referral to another provider might not always be sufficient to demonstrate that the rights and needs of the patient are being put first, and that such action could be regarded as a breach of its standards.
- 3.7 Following our consideration of the outcomes of the work undertaken by the GPhC, we wanted to understand the way in which the PSNI's *Code* dealt with issues relating to religion, personal values and belief. We also wanted to understand what, if any, consideration the PSNI may have given to the question in light of the experience of the GPhC.
- 3.8 We noted that *The Code* directs registrants under principle one to 'always put the patient first'. It also states 'if, for any reason, you are unable to provide a professional service, you have a professional responsibility to take reasonable steps to refer the patient or service user to an appropriate alternative provider for the service they require'. We decided we needed further information to understand the requirements of *The Code* and the PSNI's expectations of registrants in circumstances when they do not wish to, or are unable to provide the professional services requested and/or make a professional decision to refer the patient to an alternative provider.
- 3.9 The PSNI told us it started a programme of work to review standards and guidance in June 2016, and that as part of this review it will look at the potential issues arising from the publication of the GPhC's *Standards for pharmacy professionals*.
- 3.10 The PSNI explained to us that it expects all registrants to use their professional judgement, based on all aspects of The Code and their legal obligations, when making a decision to refer patients to an alternative provider if they are not able to provide a particular service. It cited services such as the provision of the influenza vaccination and certain tests for sexually transmitted infections (which are not universally provided by all pharmacies) as examples of the circumstances where registrants would not

¹⁰ Standards of conduct, ethics and performance set out the standards of conduct, ethics and performance pharmacy professions were required to follow between September 2010-April 2016, before *Standards of pharmacy professionals* was introduced in May 2017.

be able to provide the services required. These appeared to us to be examples of situations where there is a physical bar to the services being provided rather than where a registrant for reasons of their belief might not feel able to provide a service.

- 3.11 The PSNI told us that when it consulted on the draft version of *The Code*, it received only one direct comment which questioned the feasibility of pharmacists referring patients and/or service users to another service provider in all instances when a service could not be provided by a registrant. It also said its ongoing review of its standards and guidance associated with *The Code* will consider the GPhC's guidance on religion, personal values and beliefs.
- 3.12 It shared with us that it has not received a complaint or concerns which suggested a registrant had incorrectly applied the requirements of *The Code* in circumstances when he or she had made the decision not to provide the services requested. This has provided some assurance that the likelihood of registrants redirecting patients/service users elsewhere and not prioritising patient and service user safety, and patient and service user centred care is likely to be low.

Conclusion on performance against this Standard

3.13 Since the PSNI has started a programme of work to review standards and guidance there does not appear to be a significant problem arising out of the practical interpretation of its *Code*, we are satisfied it continues to meet the requirements of this Standard.

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

- 3.14 We carried out a targeted review of this Standard because we wanted to know how registrants are supported to understand the requirements of *The Code* in circumstances where they do not wish to, or are unable to provide the professional services required by a patient/service user.
- 3.15 The PSNI told us it holds no evidence that there is any misunderstanding of how *The Code* must be applied in these circumstances, and that there is no record of registrants seeking its advice on these matters. As we have said, however, it is reviewing the question to assess whether there is evidence to suggest that guidance is needed in this area.
- 3.16 Whilst it has not produced specific guidance in this area, the PSNI directed us to the supplementary guidance it published on the sale and supply of medicines in March 2016. This includes information on how registrants are expected to interact with patients/service users when they are not able to provide the medicine(s) requested. It could be considered that the approach outlined in this publication applies to a wide variety of situations which include the circumstances described above.
- 3.17 In August 2017, the PSNI issued a joint statement (along with the eight other regulators we oversee) containing advice for its registrants on how to deal

with conflicts of interest. The advice includes a case study (developed jointly with the GPhC and the General Medical Council) which illustrates how conflicts can arise and the action that registrants should consider.

3.18 Based on the evidence we assessed and the additional information the PSNI provided to us, we are satisfied that this Standard is met this year.

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

- 3.19 We completed a targeted review of performance against this Standard because we wanted to understand in more detail how the PSNI:
 - Considers if specialist guidance is needed to assist registrants in understanding the requirements of *The Code* in matters relating to religion, personal values and beliefs
 - Takes account of the views and experiences of stakeholders when it develops and/or revises its guidance and standards.
- 3.20 The PSNI told us that when it consulted on the draft standards of competence in 2015, some respondents had suggested supplementary guidance would be useful to help registrants understand its requirements in the following areas:
 - Using social media and electronic communication appropriately
 - The duty of candour
 - Effective working relationships between General Practitioners and community pharmacists; and
 - Selling and advising of products of limited clinical value
- 3.21 Since it published *The Code* in March 2016, the PSNI has issued or revised guidance and supporting materials to assist registrants in understanding its requirements in these areas.
- 3.22 Additionally, the PSNI told us *The Code* is reviewed at least once every five years and that all guidance documents which are linked to it are reviewed within two years of any such review, as part of a rolling programme. In parallel to this, it regularly reviews information to assess if there are forthcoming changes that may impact its work. When there is evidence that emerging trends and developments in policy, pharmacy practice, healthcare regulation, notable media stories and government publications might potentially impact its work, the Registrar will recommend that a prompted review (which is the detailed consideration of the information and evidence obtained) is conducted.
- 3.23 The PSNI explained to us that in order to launch a prompted review, the Registrar must satisfy the Education, Standards and Registration (ESR) committee that the evidence suggests there is the potential for aspects of its standards and guidance to become unfit for purpose and/or there is a gap in

the current provisions that require review. Irrespective of how the review of standards and guidance is commissioned, the process includes stakeholder engagement which is not restricted to patient groups, pharmacists, pharmacy representative bodies and other regulators. This has provided further assurance that the views and experiences of stakeholders form an integral part of the development and review of its standards and guidance.

3.24 For these reasons, 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

3.25 In previous years we have been satisfied with the arrangements made by the PSNI to publish its standards and guidance. We have not identified any changes to how standards and guidance documents are published and made accessible by the PSNI, and are therefore satisfied that this Standard remains met.

4. Education and Training

The PSNI has met all of the Standards of Good Regulation for Education and Training during 2016/17. 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 that the PSNI adopted the GPhC's *Standards for the initial education and training for pharmacists* and *Education and training requirements for pharmacist independent prescribers,* and that these were subject to an ongoing review which was expected to conclude in 2017. We did not identify evidence of the PSNI's involvement in the GPhC review and we commented that as the review progressed, we would expect to see evidence of the PSNI assuring itself that the GPhC's *Standards for the initial education and training for pharmacists* continued to link to the PSNI's standards for registrants.
- 4.2 This year, we have seen evidence of the PSNI's involvement in the GPhC review of its standards, education and training for the whole pharmacy team. It attends meetings of the GPhC external advisory group which was established to ensure input from the full range of key stakeholders in the development of the standards for pharmacist education and training.

4.3 From the information we have reviewed, we are satisfied that the PSNI has input into the relevant forum and so continues to meet this Standard.

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

4.4 The PSNI's works with the GPhC to quality assure undergraduate and education programmes for pharmacists in Northern Ireland. Together, they did not approve or reaccredit any courses in Northern Ireland during the period under review, as the relevant programmes remain accredited until the academic years 2017/18 and 2020/21.

Pre-registration training programme

- 4.5 The PSNI is responsible for quality assuring its pre-registration programme, which comprises a 52-week placement and pre-registration examinations that trainees must complete and pass before they can be admitted onto its register.
- 4.6 During the period under review the PSNI's ESR committee considered a report outlining the findings of its annual review of the training syllabus and the pre-registration examinations completed in 2017. No concerns were reported by the independent external examiner who completed the report. However, we noted that in February 2017, the ESR committee decided that some aspects of the pre-registration programme could benefit from review in the short, medium and longer term. Some of the areas that could potentially benefit from review were identified as:
 - The format of the pre-registration examination it was noted that the GPhC introduced a new approach in 2016
 - Performance standards for trainees
 - Arrangements for quality assuring the programme
 - Tutor and trainee absences when completing the pre-registration programme
 - The training, competence and continuing professional development requirements for tutors.
- 4.7 The ESR committee agreed that a programme of work looking at the standards that trainees are required to meet, as well as those standards that training providers are required to adhere to should be carried out. This review is now underway. We will follow up on the progress and outcomes of this review over future years, and have concluded that this Standard is met this year.

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

- 4.8 We have seen evidence that the PSNI takes action if concerns are discovered about education and training establishments.
- 4.9 In February 2017, the ESR committee considered evidence that a small number of organisations may not have complied with its standards for the pre-registration training programme. These concerns were investigated and it established that one corporate body did not appear to be meeting the standards. The PSNI explained to us that it acted to address and resolve these concerns with the organisation concerned, and any potential risks arising from not fully complying with its standards have been further investigated and resolved by the Registrar. It told us it has no concerns that its standards for pre-registration training are not being met.
- 4.10 The July 2017 edition of the PSNI's quarterly newsletter included an article on complying with the standards for pre-registration training. It also included information on how to raise concerns about pre-registration training.
- 4.11 From the information we reviewed, we are satisfied that appropriate action is being taken when the quality assurance process identifies concerns about education and training establishments.

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

4.12 The PSNI continues to publish information about approved education and training programmes for pharmacists. Its website includes details of the institutions offering these programmes alongside information on the approval process. The accreditation reports, which are completed in conjunction with the GPhC, are also available on its website.

5. Registration

5.1 The PSNI has met all of the Standards of Good Regulation for Registration during 2016/17. 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

5.2 As part of the performance review we carry out a check of a small number of entries on the regulator's website. We select a random sample of registration entries from the final fitness to practise decisions which we review under our Section 29 powers. We use this information to help us assess the accuracy of the regulator's register. Due to the small number of fitness to practise cases concluded by the PSNI's Statutory Committee in the period under review, we broadened our register check to incorporate the registration entries of:

- Individuals removed from the register for failing to comply with its requirements for Continuing Professional Development (CPD)
- Individuals removed from the register for non-payment of the registration fee.
- 5.3 The accuracy checks we completed on the register entries of the eight individuals removed from the register for failing to comply with CPD requirements did not identify any anomalies.
- 5.4 In September 2017, the PSNI published a list containing the names of individuals removed from its register for non-payment of the registration fee for 2017/18. Through our checks against this list, we found the PSNI had failed to update its register and the six individuals on the published list were still listed on the register. We notified the PSNI of our findings and asked it to:
 - Review the registration entries and rectify the errors identified
 - Tell us the reasons why the information we expected to find was not displayed on the register; and
 - Outline the actions it will take to minimise the likelihood of the error reoccurring.
- 5.5 The errors we reported were corrected immediately. The PSNI told us that because of the errors we discovered it completed further checks on the registration entries of all the individuals it had removed from the register during 2017. This check did not identify any errors.
- 5.6 The PSNI investigated the reasons why the errors we identified had occurred. It explained to us that although it had completed all the necessary checks and issued the notification paperwork it is legally required to complete to effect removal from the register, the database was not updated because of an administrative oversight which occurred during staff absence. As a result of these errors, it reviewed its written operating procedures and made several changes so that all staff are aware of the processes and action that must be taken to effect removal from the register.

Conclusion on performance against this Standard

5.7 Although we identified several instances where the PSNI failed to remove from its register individuals who had failed to pay its registration fee for 2017/18, we note this arose out of a single administrative oversight and was rectified immediately. As a result of the changes the PSNI told us it has introduced to minimise the likelihood of this error reoccurring, and we are satisfied this administrative oversight does not prevent the PSNI from meeting this Standard this year.

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

5.8 Last year we reported on the limitations to the PSNI's ability to set requirements for registration and noted that it could not refuse registration to applicants who could not be considered fit to practise due to an adverse health or character matter. The PSNI identified it did not have an appeals procedure in place and recognised that it needed to introduce one.

- 5.9 Whilst the PSNI has always informed applicants of right to appeal registration decisions made by the Registrar, during the period under review, it finalised and published on its website the procedure it will use to consider appeals against registration decisions.
- 5.10 We have seen no evidence which would lead us to consider that this Standard is not 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

- 5.11 This Standard was met in 2015/16 after a targeted review into potential concerns about the registration status of Independent Prescribers¹¹ (IP) because the relevant regulations had not been made. Whilst this was unsatisfactory, we decided this Standard was met as we saw no evidence that the PSNI provided incorrect information to the public on this issue.
- 5.12 During the period under review and following the conclusion of the public consultation on its proposals to regularise the registration status of registrants with the IP accreditation, the PSNI submitted draft regulations to the Department of Health in Northern Ireland (the Department) in January 2017. The two organisations worked together to progress the draft regulations which subsequently came into effect on 9 October 2017.
- 5.13 The PSNI continues to publish and feature on its website a list of individuals removed from the register. Information on registrants with restrictions on their practise is also accessible from its website through the list of determinations made by the Statutory Committee.

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 register is clearly visible on the front page of the PSNI website, and its annual report and accounts to the year ending 31 May 2017 highlighted *'it is the duty of every employer to check the current registration status of all employed pharmacists, including locums, before the engagement of, and for the engagement of their services*'. There is also a formal requirement for pharmacy premises to check the registration status of all employees as part of the annual renewal of premises registration.

Standard 5: Risk of harm to the public and of damage to public confidence in the profession related to non-registrants using a

¹¹ An Independent Prescriber (IP) is a pharmacist who, following additional training and accreditation, has obtained the right to prescribe medicines independently. A pharmacist with the IP annotation can autonomously assess patients with diagnosed or undiagnosed conditions and make decisions about the management of those conditions, including prescribing medicines.

protected title or undertaking a protected act is managed in a proportionate and risk-based manner

- 5.15 As we have explained in previous performance review reports, the PSNI's legislation is different from the other regulators we oversee in that it does not refer to protected titles or protected acts. This means the PSNI does not have the power to take enforcement action against the misuse of the title of pharmacist in Northern Ireland. However, it can bring about private prosecutions for the misuse of the title if it is in the public interest to do so.
- 5.16 The Department is responsible for investigating and taking action against instances of illegal practise under the Medicines Act 1968. The PSNI contributes to this work through its membership of the Pharmacy Networking Group¹² (PNG) where information on instances of non-registrants using a protected title or undertaking protected acts is shared. The PNG met on a number of occasions in the period under review.
- 5.17 We are therefore satisfied that this Standard remains met.

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

- 5.18 The PSNI has continued to develop its model for continuing fitness to practise, and CPD expert advisory group which was established to provide informed feedback on the development of its proposals in this area met for the first time in March 2017. We understand the 'straw model' which comprises CPD, peer review and case studies will be risk-based in that it will initially focus on registrants in patient facing roles and those returning to work after an extended period of absence. The PSNI intends to consult on this proposed model.
- 5.19 All registrants are required to submit a CPD portfolio each year as a condition of registration. In 2016/17 99.3 per cent of registrants met this requirement, and eight individuals were removed from the register for failing to submit the information required. We are therefore satisfied that this Standard is met this year.

6. Fitness to Practise

6.1 The PSNI has met all of the Standards of Good Regulation for Fitness to Practise during 2016/17. Examples of how it has demonstrated this are indicated below each individual Standard.

¹² The Pharmacy Networking Group comprises the Department of Health and the Health and Social Care Board in Northern Ireland. Together these organisations are responsible for investigating complaints about pharmacies and pharmacists in Northern Ireland. The PNG meets regularly to share information about concerns and which organisation they should be investigated by.

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

- 6.2 The PSNI continues to receive a small number of complaints each year from a variety of sources. It received 26 complaints during 2016/17, which is a small increase in the number of complaints it received last year.
- 6.3 We noted from its annual report to the year ending 31 May 2017 that it did not receive any complaints from employers and that the Registrar was the source of almost a third of the complaints it investigated in 2016/17. The figures for the source of complaints received by the PSNI since 2014/15 can be seen in the table below:

		014/15	2015/16		2016/17	
Source	No.	%	No.	%	No.	%
Anonymous	0	0%	0	0%	1	4%
DoH ¹³	1	3%	5	23%	1	4%
Employer	3	10%	4	18%	0	0%
HSCB ¹⁴	3	10%	1	4.5%	1	4%
Other regulator	1	3%	1	4.5%	0	0%
Pharmacy	1	3%	1	4.5%	0	0%
Public	15	48%	4	18%	6	23%
Police service	0	0%	1	4.5%	0	0%
Registrar	0	0%	0	0%	8	31%
Self-referral	7	23%	5	23%	9	34%
Total	31	100%	22	100%	26	100%

- 6.4 We asked the PSNI for more information about any reasons for the change in the source of the complaints they had received. In doing this, we were mindful that this was the first time over the last three of its annual reports that the PSNI had received no referrals from employers.
- 6.5 The PSNI told us that due to the relatively small number of complaints it receives each year, the statistical significance that can be drawn from the variation in the number of complaints it investigated in 2016/17 is low. However, it also said that 2016/17 was an exceptional year, with one investigation conducted by the Registrar resulting in seven referrals of individual registrants. The PSNI said it was not aware of barriers to employers. None are obvious to us.
- 6.6 From the information we have received, we are satisfied that the changes in the profile of complaints do not raise concerns about the PSNI's performance against this Standard.

¹³ Department of Health in Northern Ireland.

¹⁴ Health and Social Care Board.

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

6.7 Last year we reported that the PSNI entered into a Memorandum of Understanding (MoU) with the Disclosure and Barring Service to facilitate the early exchange of information about registrants under investigation. This year, we have seen that it updated its MoU with the GPhC and agreed arrangements to share information with the Pharmaceutical Society of Ireland.

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

- 6.8 This Standard was met last year when we noted the PSNI updated its threshold criteria for the referral of cases from the Registrar to the Scrutiny Committee to ensure it was consistent with the new requirements of *The Code*. The evidence we assessed this year did not indicate that these changes have had an adverse impact on decision making in the fitness to practise process. We note the PSNI is to bring forward further proposals to amend this threshold criteria and that these are to be publicly consulted on later in 2018. We will review the impact of any changes in the next performance review cycle.
- 6.9 As the PSNI has not made any changes to its processes in this area and we saw no evidence of inappropriate decisions or poor practice, we have concluded that this Standard remains 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

- 6.10 We have seen no evidence of concerns about how risk assessments are completed by the PSNI. The Registrar continues to review all cases on receipt, and this review includes whether there is a potential need for an interim order.
- 6.11 We noted through the annual report and accounts to the year ending 31 May 2017 that the PSNI held 10 interim order hearings relating to six registrants. The median time taken to obtain an interim order from receipt of the complaint has improved from the eight weeks reported in 2015/16 to three weeks in 2016/17. The time taken to obtain an interim order from the decision that there is information indicating the need to apply for one improved from four weeks in 2015/16 to three weeks in 2016/17.
- 6.12 We are therefore satisfied that this Standard remains met.

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

- 6.13 This Standard was met last year when we noted that the PSNI's audit of 10 fitness to practise cases which was completed in August 2015 identified instances where it was not following its own procedures. We commented that whilst we did not consider these findings raised concerns about its performance against this Standard, due to the small number of cases it receives and investigates, the PSNI is in a position to ensure its procedures are followed properly in every instance.
- 6.14 During 2017, the PSNI issued practice directions which set out the prehearing procedures to be followed by its Statutory Committee during fitness to practise proceedings. It also published working guidance for the conduct of clinical advisors who are appointed to advise its committees when they are considering issues related to the physical and/or mental health of a registrant subject to fitness to practise proceedings. The publication of these documents has increased the visibility of the fitness to practise process. We did not see any evidence to suggest that there are concerns about the fitness to practise processes operated by the PSNI.

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

- 6.15 This Standard was met in the 2015/16 performance review even though there was an increase in the time taken to conclude cases from initial receipt of the complaint. We decided this Standard was met because:
 - The evidence we assessed demonstrated three of the four cases considered at a final hearing were subject to investigation by third parties and this prevented the PSNI from progressing its own investigations
 - The PSNI had concluded all its older cases which were lengthening its median timescales; and
 - In September 2016, the PSNI told us it had no cases which had been open for longer than one year.
- 6.16 We decided that taken together, we could not conclude that the overall increase in the end to end timescale in 2015/16 was representative of the general timeliness of the PSNI's fitness to practise process.

Progression of cases and timeliness during 2016/17

6.17 Due to the relatively small number of cases investigated by the PSNI, it is not appropriate to look for trends in the quarterly performance dataset it provides to us as the statistical significance in variations is likely to be very low. Because of this, we also consider and take account of patterns in recent years. This table sets out the median time taken to progress cases through the fitness to practise process in recent years, alongside the number of cases it has considered and concluded, and the size of its caseload:

Measure	2014/15	2015/16	2016/17
	annual	annual	annual
Median time from receipt of initial complaint to the final Scrutiny Committee/case examiner decision (weeks)	26	28	15
Median time taken from final IC or case examiner decision to final Statutory Committee decision (weeks)	N/A	15	12
Median time taken from receipt of initial complaint to the final FTP Committee determination or other final disposal of the case (weeks)	91	108	34 ¹⁵
Number of open cases (at the end of the period) which are older than:			
52 weeks	3	0	2
104 weeks	0	0	0
156 weeks	0	0	0

6.18 The table shows that the time from receipt of a complaint to consideration by the Scrutiny Committee and from the Scrutiny Committee to the Statutory Committee has improved during the period under review. However, we are mindful that the data relates to a small number of cases and in one instance a single case, and as such is not necessarily representative of the PSNI's fitness to practise process.

- 6.19 The PSNI's annual report and account to the year ending 31 May 2017 contains information on the composition of its caseload, and from this we noted:
 - 26 new cases were opened in 2016/17, with nine closed in the same period
 - Of the 17 cases that were open on 31 May 2017, the median open timeframe was 26 weeks
 - 10 of the 17 cases open on 31 May 2017 involve separate external investigations that involve the criminal justice or another statutory body
- 6.20 Whilst there was an increase in the number of cases that have been open for longer than one year in 2016/17, the number remains low at two cases. For the second consecutive year the PSNI does not have any cases that have been open for longer than two years.
- 6.21 We therefore consider that this Standard remains met.

¹⁵ The PSNI reported that this figure relates to one case.

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

- 6.22 Last year we reported that an audit commissioned by the PSNI identified a small number of instances where it did not update parties involved in fitness to practise proceedings. We decided that the audit findings were not sufficiently serious to warrant the Standard not being met.
- 6.23 During the period under review, the PSNI did not report any changes to how it manages this aspect of its fitness to practise process. We saw no evidence that parties are not being kept updated on the progress of their case or were inadequately supported in fitness to practise proceedings.

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

- 6.24 Last year we reported the PSNI had made limited progress with its review of the *Indicative Sanctions Guidance* which was introduced for its Statutory Committee in 2012. Whilst it has not yet completed this review, we note it has made a formal public commitment to consulting on these proposals and introducing new guidance in 2018. Although we are not aware of any public protection risks resulting from the delay in completing this work, we would encourage the PSNI to conclude this review and publish its proposals as soon as possible.
- 6.25 The PSNI reported one appealable decision to the Authority in the period under review, and we provided the PSNI with some learning points following our review of the decision.
- 6.26 During the period under review the PSNI has strengthened its internal processes which review decisions made at the initial stages of the fitness to practise process. In order to ensure that these decisions are subject to enhanced scrutiny it introduced a new process whereby:
 - The Scrutiny Committee routinely reviews all decisions made by the Registrar to close a case when it meets
 - The Chair of the Scrutiny Committee routinely reviews decisions to close a case that was considered by a Scrutiny Committee where they were not the Chair presiding.
- 6.27 This means that all fitness to practise decisions are reviewed to assess they are appropriate and do not give rise to concerns about public protection. From the information available to us, we are satisfied that the PSNI has proper measures in place to quality assure decisions made at both the initial and final stages of the fitness to practise process.

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

- 6.28 The PSNI continues to publish decisions of final fitness to practise hearings on its website. These decisions are also referred to on the social media platforms it uses to publicise its work.
- 6.29 As part of our performance review we checked a sample of entries on the PSNI register. This did not identify instances of errors in the publication of fitness to practise information, and we have not seen any other evidence to suggest decisions are not published and communicated to relevant stakeholders.

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

6.30 The PSNI has not made changes to how it treats and retains information about fitness to practise cases, and it did not report any data breaches to the Information Commissioner's Office¹⁶ in the period under review.

¹⁶ The Information Commissioner's Office is the UK's independent authority set up to <u>uphold information</u> rights in the public interest, promoting openness by public bodies and data privacy for individuals.

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