professional standards authority

Annual review of performance 2015/16

Pharmaceutical Society of Northern Ireland

About the Professional Standards Authority

The Professional Standards Authority for Health and Social Care[1] 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 www.professionalstandards.org.uk.

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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 http://www.professionalstandards.org.uk/policy-and-research/right-touch-regulation

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About the Pharmaceutical Society of Northern Ireland

The Pharmaceutical Society for Northern Ireland (the PSNI) regulates pharmacists in Northern Ireland. Its work includes:[3]

- 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 for registrants
- Setting standards of 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.

As at 30 September 2016 the PSNI register comprised 2,360 pharmacists. The annual fee for registrants is £398.

[3] The PSNI is also responsible for the registration of pharmacy premises in Northern Ireland and sets standards for pharmacy premises; the responsibility for inspection and enforcement lies with the Department of Health Northern Ireland.

At a glance

Annual review of performance

Regulator reviewed: **Pharmaceutical Society of Northern Ireland**

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.[4] 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.

[4] 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.

1.7 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.

1.8 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.

1.9 This will allow us to assess the reasons for the change(s) and the expected or actual impact of the change(s) before we finalise our performance review report. If the further information provided by the regulator raises concerns, we reserve the right to make a further recommendation to the panel that a 'targeted' or 'detailed' review is necessary.

1.10 We will recommend that a 'targeted' or 'detailed' performance review is undertaken, if we consider that there are one or more aspects of a regulator's performance that we wish to examine in more detail because the information we have (or the absence of relevant information) raises one or more concerns about the regulator's performance against one or more of the Standards:

- A 'targeted' review may be carried out when we consider that the information we have indicates a concern about the regulator's performance in relation to a small number of specific Standards, usually all falling within the same performance review area
- A 'detailed' review may be carried out when we consider that the information we have indicates a concern about the regulator's performance across several Standards, particularly where they span more than one area.

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

2. What we found – our decision

2.1 During September and October 2016 we carried out an initial review of the PSNI's performance from 1 April 2015 to 30 September 2016.[5] Our review included an analysis of the following:

- Council papers, including fitness to practise reports, committee reports and meeting minutes

[5] This year's review covered a longer period than usual due to the change in our performance review process.

- Policy and guidance documents
- Statistical performance dataset (see sections below)
- Third party feedback
- A check of the register
- Information available to us through our review of final fitness to practise decisions under the Section 29 process.[6]

2.2 As a result of this assessment, we undertook a targeted review to look at the PSNI's performance against Standard 3 for Registration. Following careful consideration of the further information that the PSNI provided, we decided that this Standard was met. The reasons for this are set out later in the relevant section of the report.

Summary of the PSNI's performance

2.3 For 2015/16 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.

2.4 This is the first time that the PSNI has met all of the *Standards of Good Regulation*.

The PSNI's legislative framework

2.5 Prior to 2012/13, the PSNI was unable to demonstrate it met all of the *Standards of Good Regulation* for Fitness to Practise and Education and Training due to constraints within its legislative framework; in fitness to practise cases the PSNI was unable to impose a range of sanctions, impose interim orders or restrict the practice of registrants whose fitness to practise was impaired on health grounds and the legislation did not require registrants to undertake continuing professional development. Amendments to the legislation[7] in 2012 ('the 2012 legislation') enabled the PSNI to address these issues. However, in our last performance review, the PSNI did not meet Standard 5 for Fitness to Practise due to an unintended consequence of the 2012 legislation which resulted in the PSNI losing the power to investigate the fitness to practise of pre-registration trainees.[8]

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[6] 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 and Care Professions Act 2002 (as amended).

[7] The Pharmacy (Northern Ireland) Order 1976 was amended by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012.

[8] Students who complete a pharmacy degree must successfully complete a one-year practice placement and a registration examination before applying for registration as a pharmacist. Students must register

2.6 We are pleased to be able to report that the PSNI has met all of the Standards this year; however, during our review we became aware of a number of other issues relating to the PSNI's legislative framework. Many of these have been identified by the PSNI's own review of its legislation. Some of these issues have the potential to impact on the PSNI's ability to protect the public and we have therefore considered them under the relevant Standards; others do not appear to pose any such risk, but collectively they may undermine the PSNI's ability to take a contemporary and flexible approach in response to emerging and future regulatory challenges. The issues of which we are aware are summarised below.

Independent prescribers

2.7 Regulations were required to allow the PSNI to annotate the register entries of registrants who had achieved accreditation as independent prescribers; these regulations were not put in place, which called into question the lawfulness of prescribing acts by these registrants. We discuss this issue under Standard 3 for Registration (see paragraph 5.12 onwards).

Registration appeals

2.8 The PSNI's legislation allows for appeals against registration decisions to be made to its Council. The PSNI sought legislative change to create a statutory Appeals Committee, but the Department of Health Northern Ireland ('the Department of Health') did not share the PSNI's views that this was necessary and directed that the Council could delegate its appeals function to a sub-committee. We discuss this issue under Standard 2 for Registration (see paragraph 5.9 onwards).

Fitness to practise of applicants for registration and of pre-registration trainees

2.9 We have previously reported that an unintended consequence of the 2012 legislation was that the PSNI lost the ability to investigate fitness to practise concerns about pre-registration trainees. The PSNI has also lost the ability to refuse registration on the basis of an adverse declaration of health or character. We discuss this issue under Standard 1 for Registration (see paragraph 5.3 onwards).

English language requirements

2.10 In April 2015 the Department of Health and the PSNI jointly consulted on proposed amendments to the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (NI) (2008) in order to implement the Health Care and Associated Professions (Knowledge of English) Order 2015, which requires that all health care professionals have the necessary knowledge of the English language to practise safely and effectively (see paragraph 5.8). Subsequently the PSNI drafted language regulations and guidance and sent these to the Department of Health in February 2016 and the expected date

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with the PSNI as a pre-registration trainee in order to undertake the practice placement and registration examination.

for implementation was November 2016. We saw correspondence between the Department of Health and the PSNI in May 2016 regarding the draft regulations, and have been told that the Department of Health continues to work with PSNI to progress these regulations.

Fees charged to registrants

2.11 In early 2015 the Department of Health established that the fees charged to registrants by the PSNI were in excess of that provided for by its fees regulations. A review established that, as a result, the PSNI had over-charged fees to a number of applicants and registrants between 1995 and 2015; however, the PSNI had used the fees in proper discharge of its functions and therefore took the view that it was not necessary to refund any overpayments made by applicants or registrants. Revised fee regulations were drafted, consulted upon and came into effect in June 2016. This regularised the position.

Deputising arrangements for the Registrar

2.12 There is no provision in the PSNI's legislation for the Registrar to appoint a deputy to act in any matter on their behalf. The PSNI considers this poses an operational risk. We noted correspondence in 2015 between the PSNI and the Department of Health, which agreed to progress an amendment to the legislation, and have been told by the Department of Health that this is recognised as a priority.

Registration of pharmacy technicians

2.13 We have previously reported (in our performance reviews since 2012/13) on the PSNI's work in seeking to establish if there is an evidence base for compulsory registration of pharmacy technicians, to bring Northern Ireland in line with the rest of the UK. We noted correspondence between the Department of Health and the PSNI in 2015 on this issue, with the Department of Health appearing to accept the merits of registration but noting this would require significant legislative change. It suggested the PSNI carry out a scoping exercise; work which the PSNI had already done and was able to provide. We will continue to monitor any progress in this area.

Future of pharmacy regulation in Northern Ireland

2.14 The PSNI is different to the other regulators we oversee, in that it is responsible for both the regulation of pharmacists and professional leadership of the pharmacy profession in Northern Ireland. The PSNI has delegated its leadership functions to the Pharmacy Forum; however, the PSNI's Council still have overall responsibility for professional leadership. This model goes against best practice in regulation. In October 2015 the Department of Health decided, in principle, to separate the regulatory and leadership functions of the PSNI and in March 2016 the Department of Health consulted on the issue. The consultation also sought views on whether the regulation of pharmacists in Northern Ireland should be delivered through a UK wide model.

2.15 In its response[9] to the consultation, the PSNI agreed that its regulatory and professional leadership roles should be separated. It did not agree with the proposal in the consultation that there should be a UK wide model of regulation. The Pharmacy Forum responded[10] that it agreed that the public and the profession would be better served through separation of the regulatory and professional leadership roles, but this was not viable without proper funding and support. In the Authority's response, we supported both proposals in the consultation. The Department of Health has not yet published the outcome of the consultation.

2.16 During this performance review we were concerned that we were unable to identify evidence of the profession's view being represented to the PSNI in relation to two areas in which we would have expected to have seen it, namely: the fees issue described at paragraph 2.11 and the independent prescribers issue described at paragraph 2.7 and under Standard 3 for Registration (paragraph 5.12 onwards).

Key comparators

2.17 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.

2.18 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.

2.19 Set out below is the comparator data provided by the PSNI for the period under review.

		April 2015 – March 2016	April – June 2016	July – September 2016
1	The number of registration appeals concluded, where no new information was presented, that were upheld	0	0	0
2	Median time (in working days) taken to process initial registration applications for • UK graduates	1	1	1

[9] www.psni.org.uk/wp-content/uploads/2012/10/PSNI-Council-Review-of-Pharmacy-Regulation-in-Northern-Ireland-consu....pdf
[10] http://forum.psni.org.uk/wp-content/uploads/2016/06/Pharmacy-Forum-response-to-DH-Future-of-Pharmacy-Consultation-.pdf

	• EU (non-UK) graduates • International (non-EU) graduates	2 0[11]	0[11] 0[11]	0[11] 0[11]
3	Time from receipt of initial complaint to the final Investigating Committee/Case Examiner decision • Median • Longest case • Shortest case	 28 weeks 86 weeks 5 weeks	 12 weeks 17 weeks 4 weeks	 12 weeks 12 weeks 12 weeks
4	Time from receipt of initial complaint to final fitness to practise hearing • Median • Longest case • Shortest case	 108 weeks 249 weeks 62 weeks	Data not available[12]	
5	Time to an interim order decision from receipt of complaint	8 weeks	2 weeks	0[13]
6	Outcomes of the Authority's appeals against final fitness to practise decisions • Dismissed • Upheld and outcome substituted • Upheld and case remitted to regulator for re-hearing • Settled by consent • Withdrawn	No decisions were appealed during the period under review		
7	Number of data breaches reported to the Information	0	0	0

[11] No such applications were received during the period.
[12] We collect this data annually rather than quarterly.
[13] The PSNI did not make any interim order applications or decisions in this period.

	Commissioner			
8	Number of successful judicial review applications	0	Data not available[12]	

3. Guidance and Standards

3.1 The PSNI has met all of the *Standards of Good Regulation* for Guidance and Standards during 2015/16. Examples of how it has demonstrated this are indicated below each individual Standard.

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

3.2 We reported in the last performance review that the PSNI was progressing a review of its *Code of Ethics* for registrants and had conducted a consultation which ended in May 2015. The revised standards – *The Code: Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland (the Code)* – came into effect on 1 March 2016. This sets out the specific standards expected of registrants under five principles: always put the patient first; provide a safe and quality service; act with professionalism and integrity at all times; communicate effectively and work properly with colleagues; and maintain and develop knowledge, skills and competence.

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 Alongside the review of its standards for registrants and publication of *the Code*, the PSNI reviewed and updated its additional guidance for registrants, including guidance on patient confidentiality and maintaining clear professional boundaries with patients and carers.

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

3.4 In our last performance review we reported that the PSNI conducted a number of pre-consultation communications with stakeholders when reviewing its standards for registrants prior to carrying out a formal consultation. The PSNI considered the responses it received to the consultation when finalising *the Code*.

3.5 *The Code* was launched in February 2016 at an event at which the Chief Pharmaceutical Officer for Northern Ireland delivered the keynote speech.

This was supplemented by two information events for registrants, taking attendees through the requirements of *the Code.*

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

3.6 The PSNI continues to publish standards and guidance on its website, together with information about how to make a complaint if these are not followed and what action the PSNI can take. We were unable to identify from the PSNI's website that its standards, guidance and complaints information can be made available in alternative formats or languages. The websites of the other regulators we oversee all have sections targeted at patients and service users, and we would encourage the PSNI to consider how it might make information for users of pharmacists and pharmacy services more clearly available.

4. Education and Training

4.1 The PSNI has met all of the *Standards of Good Regulation* for Education and Training during 2015/16. 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 The PSNI has adopted the GPhC's *Standards for the initial education and training for pharmacists* and *Education and training requirements for pharmacist independent prescribers*. We reported in the GPhC's performance review for 2015/16 that it was continuing work to review its standards for education and training for pharmacists and pharmacy technicians. We have not identified evidence of the PSNI's involvement with this ongoing review, although we note that the GPhC has yet to consult on revised standards for pharmacist education. We noted that the PSNI's Education, Standards and Registration Committee had input into the PSNI's review of *the Code*. As the GPhC review progresses we will expect to see evidence of the PSNI assuring itself that the GPhC's *Standards for the initial education and training for pharmacists* continue to link to the PSNI's standards for registrants.

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

4.3 The PSNI and the GPhC work together to quality assure undergraduate and education programmes for pharmacists in Northern Ireland, and the PSNI has adopted the GPhC's accreditation methodology into its own procedures. We reported in the GPhC's performance review for 2015/16 that there had been no changes to its procedures for quality assuring education programmes, and similarly the PSNI has not made any changes to its procedures in 2015/16.

4.4 Two pharmacy degree courses are accredited in Northern Ireland. During the period under review, one was subject to reaccreditation and the other was subject to an interim accreditation visit. An independent prescribing course was also reaccredited.

4.5 Following graduation, students must complete a year of pre-registration training in a pharmacy and pass a registration examination before they can register as a pharmacist with the PSNI. The PSNI oversees pre-registration training. It sets standards for pre-registration training, approves pharmacy premises for training purposes, accredits tutors, and sets the syllabus for the registration examination, and sets the examination. It has an independent Examination Committee which reviews the training syllabus, quality assures the examination papers and ratifies the examination results. We have not identified any changes or concerns this year relating to this aspect of the PSNI's work.

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

4.6 As set out above, two courses were reaccredited and one course was subject to an interim accreditation visit in 2015/6. No concerns arose.

4.7 In the 2014/15 performance review report we said that the PSNI considered that there were appropriate mechanisms in place for undergraduate students and pre-registration trainees to raise concerns about their education and training. We expressed the view that it would be preferable for the PSNI to introduce a dedicated mechanism to allow students and trainees to raise concerns directly with the PSNI. In August 2016 the GPhC published new guidance for students, trainees and others about how to raise a concern about pharmacy education and training with the GPhC. This would allow an undergraduate student in Northern Ireland to raise a concern with the GPhC about a course accredited jointly by the PSNI and the GPhC, but does not apply to pre-registration trainees in Northern Ireland. The PSNI may wish to consider whether there is value in adopting the GPhC's guidance, or signposting undergraduate students to it.

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

4.8 The PSNI continues to publish on its website information about approved training programmes, the accreditation process and accreditation reports.

5. Registration

5.1 As we set out in Section 2 of this report, we identified concerns about the PSNI's performance against Standard 3 and carried out a targeted review. The reasons for this, and what we found as a result, are set out under the relevant Standard below.

5.2 Following the review, we concluded that this Standard is met and therefore the PSNI has met all of the *Standards of Good Regulation* for Registration in 2015/16.

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

5.3 We did not see any evidence to suggest that the PSNI added to its register anyone who has not meet its registration requirements; however, there are limitations to the PSNI's ability to set requirements for registration. The PSNI has identified that the 2012 legislation took away its ability to refuse registration to applicants who could not be considered fit to practise as a pharmacist due to a declared adverse health or character matter. This means that the PSNI is required to accept every application for registration where the applicant meets its educational and (in the case of applicants for registration as pharmacist) indemnity cover requirements. This creates a risk to patient safety as individuals who are not fit to practise must be registered by the PSNI and, accordingly, are able to practise as pharmacist trainees and pharmacists.

5.4 Under the original 1976 legislation, the Registrar could refer any application which included such a declaration to the Statutory Committee, which was able to refuse registration if the applicant had been convicted of a criminal offence or 'been guilty of such misconduct' that, in the opinion of the Committee, meant the applicant would not be fit to remain on the register if they were registered. This aspect of the Statutory Committee's role was lost in the 2012 legislation and was not replaced with any corresponding power to refuse registration on the part of the Registrar; instead, the PSNI was given the power to make regulations with respect to health and character requirements but such regulations were not made.

5.5 Having identified this issue and requested from the Department of Health urgent changes to its legislation to resolve it, the PSNI put in place administrative steps to minimise the risks to patients and to confidence in the profession:

- Applicants for registration as a pre-registration trainee or as a pharmacist are required to make a declaration as to their health and character, which requires them to disclose any issues which may raise a concern about their fitness to practise as a pharmacist
- Where an adverse declaration is made by an applicant for registration as a pharmacist, the applicant is registered (in the absence of the PSNI being able to refuse registration) and the Registrar immediately commences a fitness to practise investigation. If the declaration is of a

very serious nature, the Registrar will seek an interim order to restrict the registrant's practice whilst the investigation is conducted

- Where an adverse declaration is made by an applicant for registration as a pre-registration trainee, the applicant is registered and the PSNI has put in place a procedure to ensure closer supervision of their practice during the pre-registration year, pending fitness to practise proceedings being instigated once the student completes the pre-registration year and is registered as a pharmacist.[14]

5.6 We have not seen any evidence of an actual risk to the public or confidence in the profession having arisen, and we note the steps the PSNI has put in place to address the potential risks. However, we agree with the PSNI that changes are needed to its legislation to restore its power to refuse applications for registration and to investigate the fitness to practise of pre-registration trainee registrants. The PSNI has told us that it was agreed with the Department of Health in late 2016 that the practice of the Department drafting regulations would cease and the PSNI would become responsible for putting forward draft regulations to the Department for approval. The PSNI has assured us that it is in the process of drafting regulations to address this issue.

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

5.7 As set out above, the PSNI is unable to refuse applications for registration unless the applicant does not meet its educational or indemnity cover arrangements. These are matters of fact which would not usually allow an applicant for registration to successfully appeal against a decision to refuse registration. The PSNI has, in fact, never received an appeal against a decision to refuse registration; neither has it put in place an appeals procedure.

5.8 During the period under review, the absence of an appeals procedure has become an issue for the PSNI as it has begun to prepare for the implementation for pharmacists in Northern Ireland (planned for 2017) of the Health Care and Associated Professions (Knowledge of English) Order 2015. This legislation sets an expectation that pharmacists in Northern Ireland – together with other health care professionals in Great Britain – have the necessary knowledge of the English language to practise safely and effectively. It enables the PSNI to require applicants for registration to provide evidence that they have the necessary knowledge if, on considering their application, the Registrar is not satisfied that the applicant has demonstrated this. The PSNI will be able to refuse registration if the Registrar is not satisfied that the applicant can meet the requirement. The PSNI will publish guidance as to the evidence an applicant must produce and how the Registrar will reach a decision, but there is the potential for applicants to argue that an incorrect view has been taken of how well they meet the

[14] We reported in the 2014/15 performance review that the PSNI had lost the ability to investigate the fitness to practise of student registrants due as another unintended consequence of the 2012 legislation.

language criteria and appeal a decision to refuse registration. Therefore, the PSNI needs to put in place an appeals procedure.

5.9 The PSNI has recognised this and sought legislative change as it did not consider that the provisions of its legislation allowed it to consider appeals against refusals to register. The Department of Health disagreed with the PSNI's interpretation and took the view that there was provision for the Council of the PSNI to consider such appeals. The PSNI did not consider that this was appropriate or consistent with other registration appeal provisions (relating to continuing professional development), whereby the Statutory Committee decided on any appeal. In the absence of support for legislative change from the Department of Health, the PSNI has set up a sub-committee of its Council to deal with appeals to refuse registration.

5.10 We were concerned at the absence of a registration appeals procedure as this is fundamental to meeting this Standard. However, in deciding the Standard is met we took into account:

- There has, to date, been no need in practice for the PSNI to have a procedure in place
- The PSNI provides information to applicants that there is a right of appeal contained within is legislation
- The PSNI identified the need to address this ahead of the implementation of the English language requirements. We therefore expect to see a procedure in place and published at the time of implementation.

5.11 We do not have a view on the interpretation of the legislation in relation to this issue, but we do not disagree with the PSNI's view that there should be consistency within its legislation. We also consider that appeals should not be determined by Council member given the PSNI's statutory remit of overseeing both the regulatory and professional leadership functions of the PSNI (see paragraph 2.14), and note that the PSNI's solution ensures that Council members do not hear appeals

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

5.12 We carried out a targeted review of this Standard as we identified a concern about the status of a particular group of registrants and whether the information provided to the public about the status of these registrants was clear.

5.13 The group of registrants affected were pharmacists who, following additional training and accreditation, had obtained the right to independently prescribe medicines ('IPs').[15] In September 2016 the PSNI issued a public letter to IPs setting out irregularities within the PSNI's legislative framework which affected their status. Whilst we understood the nature of these irregularities, it

[15] These registrants can (within their areas of competence) autonomously assess patients with diagnosed or undiagnosed conditions and make decisions about the management of those conditions, including prescribing medicines.

was not clear to us from this letter whether IPs could – or could not – continue to independently prescribe pending a resolution of the irregularities. With this not being clear, we were unable to assess whether there was any risk to the public arising from this issue, or if the information that the PSNI had made available to registrants and the public (including the information on its register) was accurate. We also received feedback from an educational organisation that the PSNI had not provided guidance on whether IPs could continue to prescribe medicines legitimately.

5.14 Through the targeted review we established the following understanding.

The irregularities with the PSNI's regulations

5.15 The authority for pharmacists in Northern Ireland to prescribe arises from the Medicines Act 1968 (as amended). The provisions of the Medicines Act in this regard were transposed into the Human Medicines Regulations 2012 (HMR 2012) which allow only those registrants '*noted in the relevant register as qualified to order drugs, medicines, and appliances as a pharmacist independent prescriber'* to prescribe independently.

5.16 Regulations were made in 2004[16] to allow the annotation in the register of supplementary prescribers.[17] These regulations set out that, in order to be annotated in the PSNI register as a supplementary prescriber, a pharmacist must have been registered for at least two years, have completed a course accredited by the PSNI, and paid a fee to the PSNI.

5.17 The PSNI's legislation enabled it to make regulations with respect to '*annotation of the register of pharmaceutical chemists to indicate particular qualifications, specialist areas of practice and status'*.

5.18 In 2012 most of the Medicines Act 1968 was transposed into HMR 2012 and a new form of wording was created in relation to pharmacist prescribers. (HMR 2012 introduced the concept of 'noting' IPs on the register rather than annotating, which was retained for some other professions). No comparable power to 'note' in the register was introduced.

5.19 When the PSNI became aware of this through its review of legislation (see paragraph 2.6) and in the absence of a specific power, it used a general power contained in its legislation to note the register for IPs.

5.20 However, the PSNI received legal advice that it was open to legal challenge due to its failure to make specific regulations for IPs in the same way as had been made for supplementary prescribers. An additional complication was that, whilst the PSNI had the power to 'annotate' the register, it did not have the power to 'note' the register as was required by the HMR 2012.

5.21 The Department of Health wrote to advise the PSNI that specific regulations were required and the organisations worked together to quickly produce draft regulations and carry out a public consultation, shortening the period of consultation from the usual 12 weeks to eight weeks. This consultation

[16] The Pharmaceutical Society of Northern Ireland (General) (Amendment) Regulations (Northern Ireland) 2004.
[17] Supplementary prescribers may prescribe medicines, but only within the framework of a patient-specific management plan which has been agreed with an independent prescriber.

closed on 9 January 2017. The PSNI anticipates that the regulations will be in place by August 2017.

The position of independent prescribers

5.22 The PSNI told us that it had received legal advice to the effect that IPs could continue to prescribe legitimately because the solution the PSNI had put in place of using its general powers to annotate the register meant that the requirements of the HMR 2012 were met. However, we understand that the Department of Health disagreed with this view and advised the PSNI that specific Regulations were required to enable the Society to annotate the register.

5.23 The PSNI also told us that it met with the five health trusts in Northern Ireland and the Health and Social Care Board (whom together employ the majority of IPs). These organisations decided to continue with the pharmacist prescribing services that they made available to patients.

5.24 The PSNI shared with us confirmations it had obtained from indemnity insurance providers that the issue would not invalidate IPs' indemnity arrangements.

5.25 At the request of the Department of Health, the PSNI refrained from adding new annotations to the register for those registrants who completed independent prescribing accreditation until such time as the required regulations are in force. The PSNI met with the accredited course provider to explain this and the PSNI told us that no difficulty with this approach was identified.

The risk to patients

5.26 All IPs have completed a qualification accredited by the PSNI and are competent to independently prescribe regardless of the irregularities described above. The risk to patients was that, in the event of making a claim against an IP, the registrant's indemnity insurance provider would refuse to indemnify the claim on the basis that the registrant's actions were not lawful. This risk was addressed as noted above.

Our conclusion

5.27 We consider it is unsatisfactory that regulations were not made at the appropriate time but we are satisfied that once the PSNI identified this it recognised the seriousness of the issue and took action to assure itself of the legal position, to assess and manage the risks, and to take steps to ensure a proper solution was put in place. We consider that the information contained in the letter to IPs in September 2016 could have set out much more clearly that IPs could, in the PSNI's view, continue to prescribe legitimately; however, whilst this information was in the public domain it was directed at IPs and we have seen no evidence that the PSNI provided incorrect or unclear information to patients and the public on this issue. We have therefore concluded that the Standard is met.

5.28 As part of the performance review process, we carry out a check of a small number of entries on the regulator's register. We found no errors in our check of the PSNI's register.

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

5.29 The register remains prominently displayed on the PSNI's website. The PSNI reminds employers of their obligation to regularly check the registration status of employees in newsletters, and requires pharmacy premises on annual renewal to confirm that the registration status of all employees has been checked.

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

5.30 The PSNI's legislation differs from that of the other regulators we oversee in that it does not refer to protected titles or protected acts. The Medicines Act 1968 created the offence of misusing the title of pharmacist in Northern Ireland, and that the responsibility for enforcement of offences within the Act lays with the Department of Health. However, in common with the other regulators we oversee, the PSNI can bring private prosecutions for misuse of title if it is in the public interest to do so. The PSNI has previously told us that very few instances of misuse of title are reported but that occasionally issues arise with pharmacists who are registered in Great Britain or Ireland failing to register with the PSNI before practising in Northern Ireland. Intelligence and information about potential cases is shared through the Pharmacy Networking Group (see paragraph 6.3). As noted above at Standard 4, the PSNI also reminds pharmacy employers to regularly check the registration status of employees and warns employers that their own fitness to practise is likely to be investigated if they are found to have employed an unregistered person as a pharmacist.

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

5.31 Registrants are required to submit a continuing professional development (CPD) portfolio each year as a condition of registration. The PSNI audits a sample of these portfolios to ensure they meet its standards for CPD; registrants whose initial portfolio submission does not meet the standards are allowed an opportunity to remedy deficiencies. In 2015/16 all registrants whose portfolios were sampled ultimately met the PSNI's standards. Six registrants were removed from the register for non-compliance with the CPD requirements.

5.32 In May 2016 the PSNI decided to develop a continuing fitness to practise 'straw model' comprising three elements: CPD, peer review and case

studies. An expert advisory group has been established to support the development work, and the resulting model will be piloted before being introduced.

6. Fitness to Practise

6.1 The PSNI has met all of the *Standards of Good Regulation* for Fitness to Practise during 2015/16. Examples of how it has demonstrated this are indicated below each individual Standard.

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

6.2 The PSNI receives a small number of complaints each year from a variety of sources, including through the Pharmacy Networking Group (see paragraph 6.3). We noted from the PSNI's annual report for the year ending 31 May 2016 that the proportion of complaints received which came from members of the public was only 18 per cent, compared to 48 per cent in 2014/15 and 36 per cent in 2015/16. However, the total number of complaints received had also fallen (from 31 in 2014/15 to 22 in 2015/16) and there had been an increase in the number of referrals from the Department of Health (up from one in 2014/15 to five in 2015/16). We have seen nothing to suggest that there are any barriers to members of the public raising a concern with the PSNI. Given the small number of complaints received, we do not consider the decline in the number of complaints from the public is evidence of cause for concern.

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

6.3 We have previously reported that since 2013 the PSNI has been part of the Pharmacy Networking Group which includes the Department of Health and the Health and Social Care Board. Together these organisations have responsibility for investigating complaints about pharmacies and pharmacists in Northern Ireland and work collaboratively. This enables the sharing of information about concerns and ensures that concerns are dealt with by the appropriate organisation.

6.4 During the period under review, the PSNI entered into a Memorandum of Understanding with the Disclosure and Barring Service (DBS) to facilitate the early exchange of information about registrants under investigation by the DBS.

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

6.5 This Standard was met at our last review. During 2015/16, following the review of its standards for registrants, the PSNI updated its threshold criteria for the referral of cases from the Registrar to the Scrutiny Committee[18] to ensure it was consistent with *the Code.* We have not identified any other changes to the PSNI's process which alter the tests being applied at the case to answer or impairment stages; nor have we seen evidence that these tests are not being appropriately applied. The PSNI makes information available to the public about other avenues of complaint and, as outlined under Standard 2 above, can direct concerns to relevant organisations through the Pharmacy Networking Group.

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

6.6 We have not identified any changes to the PSNI's procedures for risk assessing cases on receipt and throughout the lifetime of a case. In August 2015, the PSNI asked its auditors to audit ten fitness to practise cases against our casework framework.[19] The audit did not identify any concerns in the area of risk assessment.

6.7 The PSNI reported to us that the median time taken in 2015/16 to obtain an interim order decision from receipt of a complaint was eight weeks, but that there were only two cases during the year where a referral for an interim order was made. This figure compares to a median of four weeks in 2014/15 and 11 weeks in 2013/14. Given the very small number of cases the PSNI refers for interim order hearings, we do not consider these differences are statistically significant. We note that in the first quarter of 2016/17 (April to June) the PSNI reported to us that the median was only two weeks; no referrals were made in the second quarter of 2016/17 (July to September).

6.8 We have seen evidence that the PSNI has put interim orders in place to restrict the practise of registrants where there are ongoing fitness to practise investigations which, for reasons outside of the its control, the PSNI is unable to progress. We refer to this further under Standard 6 below.

[18] The Registrar investigates fitness to practise allegations made against registrants and, if the allegation meets the required criteria, refers it to the Scrutiny Committee which then decides whether to refer the case to the Statutory Committee for a final hearing. The Scrutiny Committee may also: dismiss the allegation, require a registrant to undergo a health assessment, issue advice or a warning, or agree undertakings with a registrant.

[19] From time to time we carry out audits of a sample of cases that the regulators have closed at the initial stages of the fitness to practise process. These are cases that have not proceeded to a final hearing. We assess cases against a 'casework framework' describing the key elements common to the initial stages of an effective fitness to practise process that is focused on protecting the public. We last audited the PSNI in 2014 and a copy of our audit report is available on request.

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

6.9 This Standard was not met in 2014/15 due to the PSNI failing to identify that, as a result of the 2012 legislation, it no longer had the power to investigate concerns about the fitness to practise of student registrants (or those applying for student registration), but had pursued investigations in three such cases. We noted in our 2014/15 report the steps the PSNI had taken to remedy the situation and we have discussed this issue at Standard 1 for Registration (see Section 5 above).

6.10 The PSNI's audit of ten fitness to practise cases carried out in August 2015 identified a number of instances of the PSNI's procedure not being followed, but gave an overall audit rating of 'satisfactory'. The issues identified were of a similar nature to the weaknesses we reported in our initial stages audits in 2013 and 2014.[19] We did not consider that the findings of our audits raised concerns about the PSNI's performance against the *Standards of Good Regulation*. Similarly, we do not consider that the PSNI's own audit findings raise such concerns; however, given the small number of cases dealt with by the PSNI we consider that it is in a position to ensure that its procedure is properly followed in every instance.

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

6.11 In the 2014/15 performance review we expressed some concerns about the PSNI's performance in this area but concluded that the Standard was met. The reasons for this were:

- The median length of time from receipt of a complaint to final disposal was 91 weeks, which was an increase of 17 weeks from 2013/14. However, as the PSNI concluded only four cases at a final hearing – three of which the PSNI had been unable to progress due to police or health investigations – we were unable to conclude that the delays were representative of the general timeliness of the PSNI fitness to practise process
- The PSNI had not met is own key performance indicator (KPI) for timeliness for the same reason. The PSNI had reviewed and revised its KPIs and we recognised it was challenging for the PSNI to set achievable KPIs given the small number of cases it handles.

6.12 This table sets out the time taken to progress cases in recent years, together with the number of cases considered and concluded:

	2013/14	2014/15	2015/16
Number of cases considered by an Investigating Committee[20]/case examiner	5	13	9
Number of cases concluded by an	5	12	9

[20] The Scrutiny Committee of the PSNI.

Investigating Committee/case examiner			
Median time taken from receipt of initial complaint to final Investigating Committee/case examiner decision (weeks)	25	26	28
Number of cases considered by a final Fitness to Practise Committee[21]/case examiner	5	4	3
Number of cases concluded by a final Fitness to Practise Committee/case examiner	5	3	3
Median time taken from final Investigating Committee decision to final Fitness to Practise Committee decision or other final disposal of the case (weeks)	16	N/A	15
Median time taken from receipt of initial complaint to the final Fitness to Practise Committee determination or other final disposal of the case (weeks)	74	91	108

6.13 This demonstrates the small number of cases considered and concluded by the PSNI's committees. It also shows that the time from receipt of complaint to consideration by the Scrutiny Committee, and from Scrutiny Committee to Statutory Committee is constant. However, it also shows that the end-to-end timescale for cases concluded at a final hearing has increased by a further 17 weeks in 2015/16.

6.14 The PSNI's annual report for 2015/16 provided contextual information relating to this timescale. The report states that four cases were closed by the Statutory Committee in the year to 31 May 2016,[22] three of which followed investigations by third parties which had prevented the PSNI from hearing the cases until those investigations had concluded. The fourth was a case which predated changes to the PSNI's fitness to practise powers in 2012 and this limited the PSNI's ability to resolve the case. The annual report also states that, whilst these cases were ongoing, the registrants were subject to interim orders which restricted their practice in order to protect the public.

6.15 We concluded that the PSNI has met this Standard despite the increase in the end-to-end timescale for the same reasons we decided it was met last year: the small number of cases and the impact of third party investigations on the PSNI's ability to progress cases does not allow us to conclude that the increase is representative of the general timeliness of the PSNI's fitness to practise process.

6.16 The PSNI has told us that as at 30 September 2016 it has no cases which have been open for longer than one year. It has therefore closed all of its aged cases, which we anticipate will mean that the data is provides us for 2016/17 will be more representative of the time being taken to progress cases.

[21] The Statutory Committee of the PSNI.
[22] This is not the same period reported in the table above; the table refers to financial years (1 April to 31 March).

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

6.17 The PSNI's audit of ten fitness to practise cases carried out in August 2015 identified a small number of instances of parties not being updated or being provided with incorrect information about timeframes. Despite the small number of cases dealt with by the PSNI, we do not consider this to be evidence of a widespread failure on the part of the PSNI to update and support parties. We have seen no other evidence of concerns about the PSNI's performance in this area.

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

6.18 The 2012 legislation enabled the PSNI to refuse applications for removal from the register ('voluntary removal') from registrants who were subject to a fitness to practise investigation or proceedings. The PSNI put in place regulations which allow the Registrar to grant such an application where '*the public interest would be best served*'. In our initial assessment we noted that, for the first time, the Registrar had granted an application for voluntary removal from a registrant who was subject to an interim order whilst there were ongoing fitness to practise proceedings.

6.19 We have previously said[23] that we would expect to see any regulator that operates a voluntary removal mechanism demonstrating that it has assessed the public interest, that it has properly applied its guidance and that it has produced a thoroughly reasoned decision specifically addressing the public interest. We were unable to find any information about the process followed by the PSNI or any decision-making guidance for the Registrar, and so we asked the PSNI for more information about this case and how the decision to grant voluntary removal had been made.

6.20 The PSNI told us that the case concerned a registrant who had declared a health issue. An interim order restricting the registrant's practise was put in place whilst an investigation was carried out. The registrant applied for voluntary removal from the register 15 months into the investigation, due to their ongoing health issues. The Registrar granted the application and the PSNI shared with us the reasons for this.

6.21 In view of the additional information provided by the PSNI about the process it followed and the reasons for granting voluntary removal, we were satisfied that the PSNI appropriately exercised its power to allow voluntary removal where there were ongoing fitness to practise proceedings. We would encourage the PSNI to make more information available about how it deals with such applications and the factors the Registrar will take into account when deciding whether it is in the public interest to grant voluntary removal.

[23] Our 2013 report on our audit of the NMC's initial stages fitness to practise process. Copy available on request.

6.22 In the 2014/15 performance review we reported that that the PSNI was progressing a review of its *Indicative Sanctions Guidance* for the Statutory Committee and that we were pleased to note that the PSNI would publically consult on any proposed revisions, given that it had not done so when the guidance was introduced in 2012. We have noted that the PSNI has made limited progress during 2015/16 with this review. However, we are not aware of any concerns with the existing guidance, the number of cases considered by the Statutory Committee is small, and in our review of decisions under the Section 29 process[6] we have not identified any decision we considered to be lenient. Therefore we do not consider that the delay in reviewing the guidance creates a significant risk of decisions being made which would call into question the PSNI's performance against this Standard.

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

6.23 Fitness to practise decisions, apart from matters relating to the registrant's health, are published on the PSNI website. Our check of register entries (see paragraph 5.28) did not identify any errors in publication of fitness to practise information, and we have not seen any other evidence to suggest the PSNI is failing to publish and communicate fitness to practise decisions.

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

6.24 This Standard was not met in 2013/14 due to a data breach in 2013 which we considered to be serious. Following this breach, the PSNI commissioned an external audit of its data protection procedures which made a number of recommendations, and in August 2015 a follow-up audit was carried out to assess progress against the recommendations. This found that the recommendations had been largely implemented except that staff and PSNI Council members had not been asked to sign a declaration that they understood their data protection responsibilities. The audit also identified that data protection refresher training for staff was required. The PSNI remedied these issues.

6.25 The PSNI did not report any data breaches to the Information Commissioner's Office in 2015/16 and we have not seen any evidence to suggest that the PSNI is not securely retaining information about fitness to practise cases.

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