

Annual review of performance 2017/18

Pharmaceutical Society of Northern Ireland



About the Professional Standards Authority

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

We oversee the work of 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.¹ We monitor policy developments in the UK and internationally and provide advice to governments and others on matters relating to people working in health and care. We also undertake some international commissions to extend our understanding of regulation and to promote safety in the mobility of the health and care workforce.

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.

¹ *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 2018, the PSNI was responsible for a register of 2,563 pharmacists and 550 registered pharmacies. Its annual retention fee for pharmacists is £398 and for registered pharmacies is £155.



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.² More information about the range of activities we undertake as part of this oversight, as well as more information about these regulators, can be found on our website.
- 1.2 An important part of our oversight of the regulators is our annual performance review, in which we report on the delivery of their key statutory functions. These reviews are part of our legal responsibility. We review each regulator on a rolling 12-month basis and vary the scope of our review depending on how well we see the regulator is performing. We report the outcome of reviews annually to the UK Parliament and the governments in Scotland, Wales and Northern Ireland.
- 1.3 These performance reviews are our check on how well the regulators have met our *Standards of Good Regulation* (the Standards) so that they protect the public and promote confidence in health and care professionals and themselves. Our performance review is important because:
- it tells everyone how well the regulators are doing
 - it helps the regulators improve, as we identify strengths and weaknesses and recommend possible changes.

The Standards of Good Regulation

- 1.4 We assess the regulators' performance against the Standards. They cover the regulators' four core functions:
- Setting and promoting guidance and standards for the profession
 - Setting standards for and quality assuring the provision of education and training
 - Maintaining a register of professionals
 - Taking action where a professional's fitness to practise may be impaired.
- 1.5 The Standards describe the outcomes we expect regulators to achieve in each of the four functions. Over 12 months, we gather evidence for each regulator to help us see if they have been met.
- 1.6 We gather this evidence from the regulator, from other interested parties, and from the information that we collect about them in other work we do. Once a year, we collate all of this information and analyse it to make a recommendation to our internal panel of decision-makers about how we believe the regulator has performed against the Standards in the previous 12

² These are the General Chiropractic Council, the General Dental Council, the General Medical Council, the General Optical Council, the General Osteopathic Council, the General Pharmaceutical Council, the Health and Care Professions Council, the Nursing and Midwifery Council, 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 www.professionalstandards.org.uk

2. What we found – our judgement

- 2.1 During November 2018 we carried out an initial review of the PSNI's performance from 1 November 2017 to 31 October 2018. Our review included an analysis of the following:
- Council papers, including committee reports and meeting minutes
 - Policy and guidance documents
 - Statistical performance dataset
 - Third party feedback
 - Register check
 - Information available to us through our review of final fitness to practise decisions under the Section 29 process.³

2.2 As a result of this assessment, we carried out a targeted review of Standard 6 of the *Standards of Good Regulation* for Registration and Standard 6 of the *Standards of Good Regulation* for Fitness to Practise.

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 determined that the PSNI has met all of the Standards. The reasons for this are set out in the following sections of the report.

Summary of the PSNI's performance

- 2.4 For 2017/18 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 This is the third consecutive year that the PSNI has met all of the *Standards of Good Regulation*.

The PSNI's legislative framework

2.6 In our performance report of 2015/16⁴ we set out a number of issues which had resulted from amendments made to the PSNI's legislation in 2012.

2.7 One of the issues noted was that the changes had removed the PSNI's powers to refuse registration to applicants who meet its education and

³ Each regulator we oversee has a 'fitness to practise' process for handling complaints about health and care professionals. The most serious cases are referred to formal hearings in front of fitness to practise panels. We review every final decision made by the regulators' fitness to practise panels. If we consider that a decision is insufficient to protect the public properly we can refer them to Court to be considered by a judge. Our power to do this comes from Section 29 of the [NHS Reform and Health Care Professions Act 2002 \(as amended\)](#).

⁴ The 2015/16 PSNI performance report is available at: www.professionalstandards.org.uk/docs/default-source/publications/performance-review---psni-2016-17.pdf?sfvrsn=90897220_0

indemnity cover requirements, regardless of whether an adverse health and/or character declaration is made.

- 2.8 The way the PSNI currently addresses this shortfall is to register any applicant making an adverse declaration (but who otherwise meets the education and indemnity cover requirements) and then immediately refer them to the Registrar to open a fitness to practise enquiry.
- 2.9 Since identifying this issue, the PSNI has been working on addressing it through the introduction of a fit and proper person test as part of its registration process. The PSNI has assured us that work in this area has progressed but its completion is subject to approval from the Department of Health in Northern Ireland.
- 2.10 Previously, any legislative changes were led and drafted by the Department, however that practice has ceased and it is now the PSNI that is responsible for drafting regulations and putting them forward to the Department for approval. The PSNI has told us that it has appointed specialist legal advisors who are working with the PSNI on drafting the legislation.
- 2.11 Due to the current political situation in Northern Ireland and the absence of a Health Minister, the PSNI is at this time unable to publicly consult on draft regulations or present any draft regulations for approval. There has been progress on some aspects, such as the introduction of regulations on 9 October 2017 to regularise the registration status of registrants with Independent Prescriber accreditation. However, the legislation around registration requirements remains in place.

3. Guidance and Standards

- 3.1 The PSNI has met all of the *Standards of Good Regulation* for Guidance and Standards during 2017/18. Examples of how it has demonstrated this are indicated below each individual Standard.

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

- 3.2 This Standard was met last year following a targeted review to understand the extent to which *The Code*⁵ prioritised patient and service user safety and put the needs of the patient first within the context of issues relating to religion, personal values and beliefs.
- 3.3 We were satisfied from our targeted review that there were no significant problems arising out of the practical interpretation of *The Code*.

⁵ *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.psn.org.uk/wp-content/uploads/2012/09/22504-PSNI-Code-of-Practice-Book-final.pdf.

- 3.4 There have been no changes to *The Code* since last year and we have seen no evidence which suggests that it has become outdated since its introduction in March 2016.
- 3.5 We are satisfied that this Standard continues to be met.

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

- 3.6 This Standard was met last year following a targeted review which looked at 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. We were satisfied that the Standard was met as, in its response to our questions, the PSNI told us about its processes for reviewing the need for guidance and said it was in the process of conducting planned and prompted reviews of its guidance and standards documents.
- 3.7 During the period under review, the PSNI has undertaken an extensive review of its existing standards and guidance documents. Due to the number of documents to be reviewed, this work is expected to remain ongoing until late 2019.

Review of Standards and Guidance

- 3.8 At the initial stage of its review process, the PSNI developed a Decision Making Framework with the objective of ensuring the review of its standards and guidance is systematic and produces consistent outcomes. The Framework:
- includes reference to the PSNI's legislative requirements
 - defines the purpose of guidance and standards
 - highlights the principles of right-touch regulation (as identified by the Authority) and
 - provides an overview of the approaches taken by other regulators.
- 3.9 The Framework makes a distinction between Core Standards, Additional Standards and Additional Guidance. It states: '*When an aspect of the proposed Standard is of a complex and multifaceted nature, which may preclude full understanding by registrants or the proposed Standard relates to a uniquely complex aspect of pharmacy practice, which causes increased risk, then guidance related to this Standard and/or related aspect of practice should be considered. In this regards all additional Guidance should be directly related to an aspect of a Core or Additional Standard/s*'.⁶
- 3.10 The PSNI's review resulted in the discontinuance of some guidance documents, such as the *Supplementary Professional Guidance for*

⁶ Extract from *Initial Paper: Purpose of Standards and Guidance – a Decision Making Framework* which the PSNI presented to its Council in April 2018.

Pharmacists in Northern Ireland on the provision of homeopathic products within pharmacy – November 2010 and the Practice Update 03 September 2009 Codeine Containing Products. It resulted in minor changes being proposed in other guidance documents, such as *Supplementary Guidance on Professional Boundaries*.

- 3.11 The review also resulted in the identification of the potential need for further guidance in certain areas, such as on the refusal of services on the basis of religion, personal values and beliefs and violence/potential violence or criminal conduct. We note that this guidance is not yet available.
- 3.12 The PSNI has identified that significant changes or new documents may require public consultation. This has impacted on the timeframe for completion of this piece of work.
- 3.13 There is ongoing work in this area, however the evidence we have assessed during the period under review has not raised any concerns about the PSNI's performance against this Standard.
- 3.14 We are satisfied that this Standard continues to be met.

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

- 3.15 This Standard was met last year following a targeted review which considered the extent to which the PSNI took account of the experiences of stakeholders when considering whether to develop additional guidance to assist registrants in understanding the requirements of *The Code*.
- 3.16 As we have reported under Standard 2 above, this year the PSNI has continued its review of its guidance and standards documents and agreed to develop new in practice guidance in the area of religion, personal values and beliefs. This decision was informed by an assessment of the position of other regulators and the results of a registrant survey which was circulated to all registrants in Northern Ireland and received 391 responses.
- 3.17 The Decision Making Framework developed by the PSNI for reviewing its guidance and standards includes an overview of the approach taken by other regulators towards guidance and standards.
- 3.18 In addition, we note that the PSNI has indicated that certain changes to its guidance and standards may require public consultation.
- 3.19 We are therefore satisfied that this Standard continues to be met.

Standard 4: The standards and guidance are published in accessible formats. Registrants, potential registrants, employers, patients, service users and members of the public are able to find the standards and

guidance published by the regulator and can find out about the action that can be taken if the standards and guidance are not followed

- 3.20 This Standard was met last year as we did not identify any changes to how standards and guidance documents were published and made accessible by the PSNI.
- 3.21 This year, some users were unable to open PDF documents on the PSNI's website due to using outdated PDF readers which were not compatible with the PSNI's more modern platform. The PSNI addressed this with a message on its website directing any users experiencing difficulties to contact them directly for the materials required. We are satisfied that the issue is not compromising the accessibility of the standards and guidance, and are satisfied that this Standard continues to be met.

4. Education and Training

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

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

- 4.1 We have previously noted 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*.
- 4.2 In our last two performance reports, we noted that these standards were subject to an ongoing review by the GPhC which was expected to conclude in 2017. The GPhC reported in its annual plan progress report for 2017/18⁷ that there is a possibility that developments in this area might be impacted by government reform of the structure and funding of higher education across Great Britain. As a result, the GPhC said it will continue the development work on these standards and will be consulting on changes this year. The consultation on the *Standards for the initial education and training for pharmacists* was launched in January 2019 and will be open for 12 weeks.
- 4.3 The PSNI sits on the GPhC's external advisory group. In the period under review we have seen that the PSNI is involved in and routinely considers the development work completed by the GPhC in this area. We noted that the PSNI formally considered the GPhC consultation on the education and training standards for Independent Prescribers which closed in June 2018. These standards are explicitly linked to the GPhC's *Standards for pharmacy*

⁷ *Annual Plan Progress Report 2017/18 Quarter 3: October-December 2017* presented by the GPhC to its Council at the meeting of 8 February 2018.

professionals. The PSNI has identified the actions it might need to take for itself depending on the outcome of the consultation.

4.4 We are satisfied that this Standard continues to be met.

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

4.5 This Standard was met with no concerns last year.

4.6 The PSNI works in conjunction with the GPhC to accredit pharmacy courses in two universities in Northern Ireland. In addition, the PSNI accepts the GPhC accreditation of universities in Great Britain.

Accreditation of degrees

4.7 During the period under review, the Master of Pharmacy Degree at Queen's University Belfast was reaccredited until 2023/24.

4.8 In March 2018, through its operational Memorandum of Understanding (MoU) with the GPhC, representatives from the PSNI took part in an interim visit of the Master of Pharmacy Degree at the University of Ulster. The purpose of an interim visit is to monitor the progress made with delivering the degree since accreditation and to observe a range of educational activities to provide assurance that they continue to meet the GPhC's *Standards for the initial education and training for pharmacists*.

4.9 The report template provides a facility for concerns to be considered as part of the decision-making process and there are opportunities for those participating to raise concerns about education and training establishments. The interim visit did not identify any concerns. The report of the accreditation team recommended that the degree should continue to be accredited for the remainder of the accreditation period until the academic year 2021.

Pre-registration training programme

4.10 The PSNI is responsible for overseeing the quality assurance of the pre-registration training year. During the period under review, the PSNI's Education, Standards and Registration (ESR) Committee maintained oversight of activities in this area. The Committee also received the annual report of the independent external examiner.⁸ The report provided feedback on the pre-registration programme and referred to both tutors and trainees reporting high satisfaction rates on the training received during the last pre-registration training year.

4.11 We have not identified any concerns relating to the processes used for quality assuring the pre-registration education programme and have seen

⁸ *Report of the External Examiner for the PSNI, 2018* presented to the PSNI's Council at its meeting on 31 July 2018.

through the external examiner report that consideration is given to the views of tutors and trainees.

4.12 We are satisfied that this Standard continues to be met.

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

4.13 In last year's report we noted that the PSNI had taken action to investigate and address concerns about an organisation that did not appear to be meeting the standards.

4.14 The information we have reviewed this year indicates the PSNI has addressed the issues we reported on last year and that there are no current concerns about education and training establishments delivering pre-registration training in Northern Ireland.

4.15 We are satisfied that this Standard continues to be met.

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

4.16 This Standard was met with no concerns last year.

4.17 There have been no reported changes in the way the PSNI publishes information on approved programmes and the approval process. This information continues to be easily accessible on the PSNI's website.

4.18 We are satisfied that this Standard continues to be met.

5. Registration

5.1 As we set out in Section 2, we considered that more information was required in relation to the PSNI's performance against Standard 6 and carried out a targeted review. The reasons for this, and what we found as a result, are set out under the relevant Standard below. Following the review, we concluded that this Standard was met and therefore the PSNI has met all of the *Standards of Good Regulation* for Registration in 2017/18.

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

5.2 Last year we noted that the PSNI had failed to remove from its register a number of individuals who had not paid their registration fee. The PSNI rectified the error immediately and established that it had occurred due to a single administrative oversight.

5.3 As part of our review of this Standard this year, we conducted a check of the register entries that related to:

- appealable fitness to practise decisions
- individuals removed from the register for non-compliance with the PSNI's requirements for Continuing Professional Development (CPD)

- individuals removed from the register for non-payment of registration fees.

- 5.4 Our checks did not identify any concerns or anomalies.
- 5.5 As noted in Section 2 above, the PSNI’s legislation does not enable it to refuse registration to applicants who meet its education and indemnity cover requirements. Where an applicant meets those requirements but also makes an adverse health and/or character declaration, the PSNI registers the individual then refers them to the Registrar to open a fitness to practise enquiry.
- 5.6 In the period under review, the PSNI adopted the GPhC’s guidance on student fitness to practise matters operated by UK schools of Pharmacy. The guidance was first introduced by the GPhC in 2011 and was amended in July 2018. It includes explicit reference to the PSNI’s conduct requirements for registration. This should help to ensure that those with adverse health or character declarations are aware of the PSNI’s full requirements before they start their training. This should reduce the likelihood of the PSNI having to register and immediately refer those with an adverse character and/or health declaration directly to the Registrar to open a fitness to practise enquiry.
- 5.7 We have not seen any evidence that individuals who did not meet the PSNI’s requirements have been registered.
- 5.8 We are satisfied that this Standard continues to be met.

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

- 5.9 In last year’s report we noted that the PSNI developed and published a procedure to consider appeals against registration decisions.
- 5.10 The PSNI did not receive any registration appeals last year, nor did it receive any during the current period under review.
- 5.11 Last year there was a slight increase in the time the PSNI took to process applications to join its register, however we considered the processing times remained appropriate.
- 5.12 The table below shows the median timeframe in working days from receipt of completed application to approval decision. The data received to date for 2018/19 shows that the processing times continue to be appropriate, with an improvement in the timeframes from 2017/18.

	2015/16 ⁹				2016/17				2017/18				2018/19	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
UK graduate	1	1	1	1	1	1	1	1	3	3	3	3	1	2
EU/EEA graduate	2	2	2	2	0	0	0	0	6	5	5	5	1	2
Non-EU/EEA graduate	0	0	0	0	0	0	0	0	0	0	0	0	0	0

⁹ Quarters are aligned to the financial year, not the performance review year. As a result, some of the figures for 2017/18 fall outside the period under review (1 November 2017-31 October 2018).

5.13 We are satisfied that this Standard continues to be 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

5.14 This Standard was met with no concerns last year when we noted that the PSNI uses its website to publish a list of individuals removed from the register as well as information on registrants with restrictions on their practice.

5.15 The PSNI continues to publish this information on its website in the same way and we have not identified any concerns about this process.

5.16 The register remains highly visible on its website and information relating to restrictions on practice are disclosed by an annotation and a link to the full committee determination, except where this relates to health matters.

5.17 We are satisfied that this Standard continues to be met.

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

5.18 The following text is featured on the PSNI's website on the question mark icon on the registration search page: 'If a pharmacist is not on our register they are not eligible to practise in Northern Ireland. It is incumbent on all pharmacist employers, pharmacy superintendents and contractors to ensure that all pharmacists employed are registered in Northern Ireland'.

5.19 In addition, standard 4.4.5 of *The Code* states that registrants must 'take all reasonable steps to ensure that those persons you employ, or supervise, comply with all legal and professional requirements and best practice guidance'.

5.20 We are satisfied that this Standard continues to be met.

Standard 5: Risk of harm to the public and of damage to public confidence in the profession related to non-registrants using a protected title or undertaking a protected act is managed in a proportionate and risk-based manner

5.21 The PSNI does not have the power to take enforcement action against the misuse of the title of pharmacist in Northern Ireland. The responsibility for this lies with the Department of Health in Northern Ireland under the Medicines Act 1968.

5.22 In previous reports we have noted that the PSNI is a member of the Pharmacy Networking Group¹⁰ (PNG). We understand from information previously provided to us that material relevant to instances of non-

¹⁰ The Pharmacy Networking Group comprises the PSNI, 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.

registrants using a protected title or undertaking a protected act is shared through this group. The PSNI continues to be a member of the PNG and we have not seen any evidence to suggest that there have been any changes in this information-sharing process.

5.23 We are satisfied that this Standard continues to be met.

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

5.24 This Standard was subject to a targeted review so that we could better understand how the PSNI implements and enforces its current system for CPD.

5.25 Last year we noted that the PSNI continued to develop its model for CPD. As part of this ongoing work, this year the PSNI commissioned external auditors to conduct a review of the current framework.

5.26 The current CPD framework sets out requirements for pharmacists who are applying to re-join the register after a break in registration. The PSNI presented a paper to its Council in September 2018¹¹ which suggested that the PSNI was not enforcing its CPD requirements for these types of applications.

5.27 The PSNI explained that it can, and does, enforce the requirements that apply to pharmacists who were previously removed from the register for non-compliance with CPD. However, its legislation does not enable it to enforce the requirements that apply to pharmacists who previously withdrew from the register on a voluntary basis.

5.28 In the long term, the PSNI told us that the changes it is proposing to its legislation to enable it to introduce a fit and proper person test (discussed at Section 2.9 above) would also allow it to apply and enforce further requirements on anyone applying to return to its register after a period of 12 months' absence or more. The legislative changes will be subject to approval from the Department of Health in Northern Ireland.

5.29 The PSNI told us about the processes it has in place to manage the potential risks until its legislation is changed. It seeks to obtain CPD evidence on a voluntary basis but, if this is not received, it undertakes targeted sampling of the registrant during the next annual CPD submission cycle. This enables the PSNI to eventually assess the CPD evidence of all registrants that are restored to the register after previously having withdrawn voluntarily.

5.30 The PSNI can remove registrants for non-compliance with CPD and has done so in the past, as evidenced by its published lists of registrants removed from the register. According to the PSNI's annual report for 2017/18,¹² in 2015/16 six individuals were removed for non-compliance with

¹¹ *Review of the draft CPD framework 2018* paper presented by the PSNI to its Council at the meeting on 18 September 2018.

¹² www.psni.org.uk/wp-content/uploads/2012/10/Pharmaceutical-Society-NI-Annual-Report-and-Accounts-17-18.pdf.

the CPD requirements, in 2016/17 nine individuals were removed and in 2017/18 eight individuals were removed.

- 5.31 We also wanted to know how many applications the PSNI receives from pharmacists seeking to re-join the register after a break in registration so that we could better understand the numbers, and therefore the level of risk, involved. The PSNI told us that in 2015/16 it received 41 applications, in 2016/17 it received 41 applications and in 2017/18 it received 16 applications. The PSNI had over 2,300 pharmacists on its register for each of these years so the number of applications received to re-join the register is relatively low. We are satisfied that the associated risk is therefore low and that the processes the PSNI currently follows are a reasonable and proportionate way of managing that risk.
- 5.32 We are satisfied that this Standard continues to be met.

6. Fitness to Practise

- 6.1 As we set out in Section 2, we considered that more information was required in relation to the PSNI's performance against Standard 6 and carried out a targeted review. The reasons for this, and what we found as a result, are set out under the relevant Standard below. Following the review, we concluded that this Standard was met and therefore the PSNI has met all of the *Standards of Good Regulation* for Fitness to Practise in 2017/18.

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

- 6.2 In last year's report we noted that during the 2016/17 financial year the PSNI did not receive any complaints from employers and there was a significant increase in the number of complaints referred by the Registrar. The PSNI told us that it was an exceptional year as a single investigation had resulted in several registrants being referred by the Registrar.
- 6.3 The table below is recreated from the annual report to the year ending 31 May 2018 and records the source of complaints received by the PSNI in 2015/16, 2016/17 and 2017/18 financial years.

Source	2015/16		2016/17		2017/18	
	No.	%	No.	%	No.	%
Anonymous	0	0%	1	4%	1	4.5%
DoH ¹³	5	23%	1	4%	0	0%
Employer	4	18%	0	0%	1	4.5%
HSCB ¹⁴	1	4.5%	1	4%	0	0%
Other regulator	1	4.5%	0	0%	2	9.1%

¹³ Department of Health in Northern Ireland.

¹⁴ Health and Social Care Board.

Pharmacy	1	4.5%	0	0%	1	4.5%
Public	4	18%	6	23%	6	27.3%
Police service	1	4.5%	0	0%	0	0%
Registrar	0	0%	8	31%	1	4.5%
Self-referral	5	23%	9	34%	10	45.5%
Total	22	100%	26	100%	22	100%

- 6.4 This year, the number of referrals by the Registrar has decreased and is in line with previous years. This supports the PSNI's position that last year was an exception rather than an emerging pattern.
- 6.5 The number of complaints from employers remains low. Having looked at the source of complaints received by other regulators overseen by the Authority, we are satisfied that the low number of referrals received from employers does not give rise to concerns about the PSNI's performance against this Standard.
- 6.6 The PSNI only receives a small number of complaints and so small increases or decreases can result in what appear to be substantial year-on-year variation. We are mindful that the statistical significance of these variations is limited in the context of these small numbers.
- 6.7 The information we have reviewed does not suggest there are difficulties in referring complaints about pharmacists to the PSNI, and we have seen that the PSNI itself refers concerns to the Registrar on receipt of information indicating a potential concern about a registrant's fitness to practise. We are therefore satisfied that this Standard continues to be met.

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

- 6.8 This Standard was met last year with no concerns when we reported that the PSNI updated its MoU with the GPhC and was undertaking a comprehensive review of its information sharing arrangements with the Pharmaceutical Society of Ireland (PSI).
- 6.9 During the period under review, the PSNI has developed and signed a MoU with the PSI. As part of the MoU, the two organisations have regular meetings and attend each other's Council meetings.
- 6.10 As we have noted under Section 5.22, the PSNI continues to be a member of the PNG. We have seen that it continues to contribute to this group and attends monthly meetings to share information and intelligence about complaints as appropriate.
- 6.11 We are satisfied that this Standard continues to be met.

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

6.12 In October 2016 the PSNI introduced updated threshold criteria for the referral of cases to its Scrutiny Committee.¹⁵

6.13 The evidence we assessed last year did not suggest that the changes had had an adverse impact on decision-making, but we indicated that we would review the position again this year.

6.14 The numbers of cases considered by the PSNI’s Scrutiny Committee since the introduction of the updated criteria are consistent with previous years, with the exception of 2015/16, which appears to have been an outlier. This is shown in the table below.

	2014/15	2015/16	2016/17	2017/18
Number of cases considered by an Investigating Committee/ Case Examiner	4	9	4	4

6.15 The numbers do not suggest that the updated criteria have impacted the number of cases being considered by the Scrutiny Committee. We are satisfied that this Standard continues to be 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

6.16 The Registrar of the PSNI reviews all cases on receipt and part of the review involves assessing whether there is a potential need for an interim order.

6.17 The table below shows the data provided by the PSNI on timeframes for obtaining an interim order.

Median time to interim order committee decision (in weeks):	2014/15	2015/16	2016/17	2017/18
From receipt of complaint	4	8	3	18
From decision that there is information indicating the need for an interim order	4	4	3	2

6.18 When compared with the data from 2016/17, the time taken to obtain an interim order from receipt of the referral increased from three weeks to 18 weeks. However, the time taken to obtain an interim order from receipt of the information indicating the need to obtain one decreased from three weeks to two weeks. This timeframe has remained relatively consistent and low. The relatively small size of the PSNI's caseload means that a small number of cases may significantly affect the overall timeframes reported. As noted in

¹⁵ The PSNI’s Scrutiny Committee is the equivalent of Investigating Committees/Case Examiners within other regulators and decides whether a case should be referred to a hearing before the Statutory Committee.

Section 6.6 above, year-on-year fluctuations may therefore appear to be greater than for regulators with larger caseloads and we recognise that the statistical significance of these fluctuations in establishing trends or patterns is limited.

6.19 We are satisfied that this Standard continues to be met.

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

6.20 Last year we reported that the PSNI had increased the visibility of its fitness to practise process by issuing and publishing:

- practice directions setting out the pre-hearing procedures to be followed by its Statutory Committee during fitness to practise proceedings
- 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.

6.21 This year the PSNI continued its work to update its Indicative Sanctions Guidance (ISG) for fitness to practise hearings. It completed its review of the current guidance and drafted an updated version. As part of the work it undertook during the pre-consultation stage of the review, the PSNI invited the Authority to comment on a discussion paper it prepared about the ISG.

6.22 The Authority's responses were incorporated into a revised draft and we are satisfied that the revised guidance is more focused on public protection than the existing ISG.

6.23 The PSNI carried out a public consultation on the revised draft guidance, which ended on 26 October 2018. The PSNI published the final version of the revised guidance in January 2019, and it will take effect from 27 March 2019.

6.24 We are satisfied that this Standard continues to be met.

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

6.25 We completed a targeted review of the PSNI's performance against this Standard because we wanted to understand why there had been a significant increase in the number of older cases within the PSNI's caseload and how the PSNI was managing these cases.

6.26 At the end of the reporting period for 2017/18, the PSNI reported that it had one case that was 104-155 weeks old. In the first quarter of the 2018/19 period, the PSNI reported that it had 10 cases that were 104-155 weeks old.

6.27 From the information available to us it was not clear why the number of older cases had increased. We did, however, note that the PSNI had reported to its Council throughout the year that a number of its cases would not be closed

within its own internal Key Performance Indicator (KPI) timeframes because they either involved third party investigations or complex health matters.

- 6.28 We asked the PSNI for more information about these older cases and how it was managing them.
- 6.29 The PSNI told us that there were errors in the figures it reported to us for the first quarter of 2018/19 and that there was only one case that was 104-155 weeks old, not 10 as initially reported. The corrected figures are shown in the table below.

Measure	2015/16 annual	2016/17 annual	2017/18 annual	Q1 2018/19	Q2 2018/19
Median time from receipt of initial complaint to the final FTP Committee determination/or other final disposal of the case (weeks)	108	34 ¹⁶	24	40	N/A ¹⁷
Median time taken from receipt of an initial complaint to a final decision by the IC or case examiners on whether there is a case to answer (weeks)	28	15	47	24	12
Median time taken from final IC/case examiner decision to the final FTP Committee determination/or other final disposal of the case (weeks)	15	12	N/A ¹⁸	N/A	N/A
Number of open cases (at the end of the period) which are older than:					
52 weeks – 103 weeks	0	2	9	10	10
104 weeks – 155 weeks	0	0	1	1	3
Above 156 weeks	0	0	0	0	0

- 6.30 The PSNI also told us that it monitors and manages cases that involve third party investigations through regular contact with those third parties and through information-sharing with the PNG. The PSNI confirmed that it undertakes regular risk assessments during the course of its investigations and it applies for interim orders where necessary.
- 6.31 We are therefore satisfied that this Standard continues to be met.

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

- 6.32 This Standard was met last year with no concerns identified.
- 6.33 Like last year, the PSNI has not reported any significant changes to how those involved in fitness to practise proceedings are kept updated or

¹⁶ The PSNI reported that this figure relates to one case.

¹⁷ The PSNI has informed us that no cases were closed by the FTPC in this quarter and so no median timeframes can be recorded.

¹⁸ This data is not available. The PSNI reported to us that this case was a direct referral and as such it is not able to calculate the timeframe from the final decision of the IC to the final FTPC determination.

supported. The evidence we assessed does not suggest the arrangements fail to ensure that all parties are regularly updated on the progress of their case, and we saw no evidence that the PSNI does not support all parties to participate effectively in fitness to practise proceedings.

6.34 We are satisfied that this Standard continues to be met.

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

6.35 This Standard was met last year when we noted that the PSNI had strengthened its internal processes so that decisions made at the initial stages of the fitness to practise process are routinely reviewed to ensure they are appropriate and do not give rise to public protection concerns.

6.36 The PSNI has not reported any changes to its processes this year.

6.37 We have noted under Section 6.21 that the PSNI has continued its work on its ISG for final hearing decisions and that we are satisfied that the proposed new guidance is more focused on public protection than the existing ISG.

6.38 The PSNI reported one appealable decision to the Authority during the period under review and we provided the PSNI with some learning points following our review of that decision. We did not consider the points raised to be sufficiently serious to negatively impact our review of the PSNI's performance against this Standard.

6.39 We are satisfied that this Standard continues to be met.

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

6.40 This Standard was met last year with no concerns.

6.41 This year we have seen no evidence to suggest that the PSNI is failing to follow its processes in this area or that its policies are insufficient.

6.42 We conducted a review of the PSNI's website and are satisfied that decisions from final hearings are published in accordance with the provisions of its publications and disclosure policy.

6.43 There is no record of the PSNI failing to notify the Authority of decisions made by the Statutory Committee during the period under review.

6.44 We are satisfied that this Standard continues to be met.

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

6.45 This Standard was met last year with no concerns.

6.46 This year we noted from our review of the PSNI Council papers that the PSNI's IT applications and services were moved from its on-site IT

infrastructure to a cloud-based service.¹⁹ The PSNI's files were all transferred over to the new service. We have not seen any evidence which suggests this change may have a negative impact on the PSNI's information security.

- 6.47 In May 2018, the PSNI published a revised Privacy Statement in light of the new General Data Protection Regulation (GDPR) which came into effect in the same month.
- 6.48 The PSNI did not report any other changes to how it treats and retains information about fitness to practise cases, nor did it report any data breaches to the Information Commissioner's Office.²⁰
- 6.49 We are therefore satisfied that this Standard continues to be met.

¹⁹ *IT Cloud Project 2018/19* paper presented by the PSNI to its Council at the meeting on 10 April 2018.

²⁰ The Information Commissioner's Office is the UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals.

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for Health and Social Care April 2019

