professional standards authority
for Health and Social Care

performance review 2020/21

PHARMACEUTICAL SOCIETY OF NORTHERN IRELAND

ABOUT THE PERFORMANCE REVIEW PROCESS

We aim to protect the public by improving the regulation of people who work in health and care. This includes our oversight of 10 organisations that regulate health and care professionals in the UK. As described in our legislation, we have a statutory duty to report annually to Parliament on the performance of each of these 10 regulators.

Our performance reviews look at the regulators' performance against our Standards of Good Regulation, which describe the outcomes we expect regulators to achieve. They cover the key areas of the regulators' work, together with the more general expectations about the way in which we would expect the regulators to act.

In carrying out our reviews, we aim to take a proportionate approach based on the information that is available about the regulator. In doing so, we look at concerns and information available to us from other stakeholders and members of the public. The process is overseen by a panel of the Authority's senior staff. We initially assess the information that we have and which is publicly available about the regulator. We then identify matters on which we might require further information in order to determine whether a Standard is met. This further review might involve an audit of cases considered by the regulator or its processes for carrying out any of its activities. Once we have gathered this further information, we decide whether the individual Standards are met and set out any concerns or areas for improvement. These decisions are published in a report on our website.

Further information about our review process can be found in a short guide, available on our website. We also have a glossary of terms and abbreviations we use as part of our performance review process available on our website.

The regulators we oversee are:

General Chiropractic Council • General Dental Council • General Medical Council • General Optical Council • General Osteopathic Council • General Pharmaceutical Council • Health and Care Professions Council • Nursing and Midwifery Council • Pharmaceutical Society of Northern Ireland • Social Work England

Find out more about our work

www.professionalstandards.org.uk

Pharmaceutical Society of Northern Ireland
performance review report 2020/21

At the heart of everything we do is one simple purpose: protection of the public from harm

Contents

The Pharmaceutical Society of Northern Ireland

key facts & stats

The PSNI regulates pharmacists and registered pharmacies in Northern Ireland.

As at 30 September 2021, the PSNI was responsible for a register of:

2,870 pharmacists,
553 registered pharmacies

Annual registration fee is: £398 for pharmacists; £155 for pharmacy premises

The PSNI's 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; and
- Maintaining a register of registered pharmacies and setting standards they must meet.

Standards of Good Regulation met for 2020/21 performance review

General Standards	5/5
Guidance and Standards	2/2
Education and Training	2/2
Registration	4/4
Fitness to Practise	4/5

Meeting, or not meeting, a Standard is not the full story about how a regulator is performing. You can find out more in the full report.

Social Pharmaceutical Society of Northern Ireland

Executive summary

How the PSNI is protecting the public and meeting the Standards of Good Regulation

This report arises from our annual performance review of the PSNI, which is one of 10 health and care professional regulatory organisations in the UK which we oversee. We assessed the PSNI's performance against the Standards of Good Regulation which describe the outcomes we expect regulators to achieve in each of their four core functions.

Pharmaceutical Society of Northern Ireland's performance during 2020/21

We looked particularly at the PSNI's performance against Standards 3, 15, 16, 17 and 18 and conducted an audit of a sample of closed fitness to practise cases. We concluded that the PSNI had not met Standard 15 because, although it had addressed the concerns we reported in 2018/19, we had serious concerns about the fairness and transparency of some aspects of its process.

To carry out this review, we collated and analysed evidence from the PSNI and other interested parties, including Council papers, performance reports and updates, committee reports and meeting minutes, policy, guidance and consultation documents, our statistical performance dataset and third-party feedback. We also utilised information available through our review of final fitness to practise decisions under the Section 29 process[1] and conducted a check of the accuracy of the PSNI's register. We used this information to decide the type of performance review we should undertake. Further information about our review process can be found in our Performance Review Process guide, which is available on our website.

Key developments and findings

Equality, Diversity and Inclusion (EDI)

The PSNI's Equality Impact Assessments are of a good standard. It holds a reasonable amount of data about the diversity of its registrants, which it uses to inform its policy work. It started collecting data on the diversity of its Associates this year and has identified potential areas for improvement. We continue to disagree with the PSNI about its decision to not collect diversity data about its Council members. However, after considering the

[1] 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).

PSNI's wider work in EDI and recognising that the work of the Northern Ireland Statistics and Research Agency provides a level of assurance that the diversity of Council members is being monitored, we determined Standard 3 is met.

Registration assessment

The first sitting of the PSNI and GPhC joint common registration assessment was due to take place in June 2021 but was deferred because of the pandemic. To avoid delays for candidates, the PSNI proceeded with its own separate registration assessment in June 2021 and this was welcomed by stakeholders. There were no reported issues with the assessment and the pass rate was comparable to previous years.

The fitness to practise process

In 2018/19, we had concerns about the transparency and fairness of the PSNI's fitness to practise process and about the information provided to parties to support them to participate effectively in the process. The PSNI implemented a number of changes to address these concerns and our audit this year found clear evidence that the changes have been effective. The PSNI has addressed our concerns from 2018/19 and we determined that Standard 18 is met as a result.

Despite our concerns from 2018/19 being addressed, we could not conclude that Standard 15 was met because we identified other concerns about the fitness to practise process:

- registrants are not always explicitly told they are the subject of the investigation
- the PSNI's position on investigating serious cases without consent is that it does not consider it appropriate to disclose a complainant's details against their wishes, even in serious cases
- the PSNI did not accept that if a registrant under investigation knows the Registrar, this could be a perceived or actual conflict of interest
- the PSNI has not published information setting out its interpretation of the Statutory Committee's powers when reviewing Conditions of Practice Orders.

We determined that Standard 15 is not met because of these concerns.

How the Pharmaceutical Society of Northern Ireland has performed against the Standards of Good Regulation

General Standards

Standard 1: The regulator provides accurate, fully accessible information about its registrants, regulatory requirements, guidance, processes and decisions.

Concerns from last year

1.1 Last year, this Standard was met but we reported concerns about two areas:

- several fitness to practise determinations were published on the PSNI's website for longer than they should have been[2]
- there was a lack of published information on the powers of the Statutory Committee and the PSNI's interpretation of them.

1.2 This year, we found no further instances of determinations being published beyond the timeframes of the PSNI's policy so there is no evidence this issue is ongoing. However, no new information has been published about the powers of the Statutory Committee and the PSNI's interpretation of them. We remain of the view that this information should be published by the PSNI and we have also considered this issue under Standards 15 and 16.

Activity this year

1.3 There has been no significant change in the way the PSNI provides information about its work. It does so primarily through its website and direct communications to relevant parties, such as emails to registrants notifying them of new or updated guidance.

1.4 This year, the PSNI:

- reintroduced its quarterly newsletter in March 2021
- held several online events, including one on the Future of the Integrated Education and Training for pharmacists
- carried out two surveys[3] that included questions about the information and communications provided by the PSNI. The responses were mostly positive but highlighted some areas for improvement. The PSNI has used the responses to inform its Communications Strategy and identify areas for

[2] The PSNI's *Policy on the disclosure and publication of fitness to practise information* sets out the publication timeframes.
[3] One survey asked temporary registrants primarily about their employment but also asked whether the information provided by the PSNI was useful. The other survey sought registrants' views on the PSNI's communications during the pandemic.

further work, such as the need to address continuing confusion about the different roles of the regulator and the representative body.

What we heard from stakeholders

1.5 We received feedback from third parties about the PSNI's communications and the information it provides.

1.6 We were told there could be clearer information about the relationship between the PSNI and the Pharmacy Forum Northern Ireland (Pharmacy Forum).[4] This reflects some of the responses the PSNI received to its registrant survey and the PSNI has recognised the need to do further work in this area.

1.7 We were also told that information about certain fitness to practise processes could be clearer, including the PSNI's approach to progressing cases subject to external investigations. The PSNI has a *Parallel Investigations policy* and a *FTP Communications policy,* both of which it published on its website this year.[5]

Council papers

1.8 We saw this year that the PSNI is the only regulator we oversee that does not publish at least some of its Council/Board papers on its website. We think it is good practice to publish this information and, by doing so, the PSNI would improve the transparency and accessibility of information about its work.

Conclusion against this Standard

1.9 This Standard was met last year and since then there have been no significant changes in the way the PSNI provides information about its work.

1.10 We are therefore satisfied that this Standard is met. However, we consider the PSNI should improve the transparency and accessibility of information about its work and processes by publishing:

- Council papers, particularly as the PSNI is the only regulator that does not publish at least some of its papers
- information about its interpretation of the powers of its Statutory Committee.

Standard 2: The regulator is clear about its purpose and ensures that its policies are applied appropriately across all its functions and that relevant learning from one area is applied to others.

2.1 The PSNI carried out activities in line with its statutory functions this year. It also:

[4] The PSNI is the only regulator we oversee that has a statutory professional leadership role in additional to its role as a regulator. In order to manage this conflict of interest, the PSNI devolved the leadership functions to an arms-length body, the Pharmacy Forum.

[5] The PSNI published the policies after we asked whether it had considered doing so, as part of our targeted review of Standard 18.

- extended the duration of its Corporate Strategy until 31 May 2021, inserting an addendum to reflect progress so far, as well as adaptations made in response to the pandemic
- carried out several pieces of work to improve governance, including a skills audit of Council members and developing a Council Training and Development Strategy.

What we heard from stakeholders

2.2 As mentioned under Standard 1, we were told that there could be more clarity about the relationship between the PSNI and the Pharmacy Forum. This reflects some of the responses the PSNI received to its registrant survey on communications during the pandemic. The PSNI is sharing the feedback from its survey with the Pharmacy Forum and considering further work to address this.

Conclusion against this Standard

2.3 We have not seen any evidence to suggest that the PSNI lacks clarity about its role and purpose. We are pleased that it is taking on board the feedback in respect of its relationship with the Pharmacy Forum. We are satisfied that this Standard is met.

Standard 3: The regulator understands the diversity of its registrants and their patients and service users and of others who interact with the regulator and ensures that its processes do not impose inappropriate barriers or otherwise disadvantage people with protected characteristics.

3.1 The PSNI did not meet this Standard last year because it was not collecting diversity data about its key decision-makers; Committee and Council members.

3.2 This year, the PSNI:

- started collecting and analysing data on the diversity of its Associates, which include Committee members. It identified some potential areas for improvement as a result, although it is exercising caution when drawing conclusions because the small numbers involved limit the statistical reliability of the data
- reported that the response rate to its annual equality and diversity survey of registrants was around 50%, which is an improvement on the previous rate of 40%. The improvement is welcome but there is room for further improvement
- published 'Phase 2' of its Equality Impact Assessment (EIA) for its new *Guidance on Provision of Services*. The EIA was of a good standard and considered appropriate factors.

  We also know that the PSNI uses:

- the diversity data it holds about registrants and publicly available diversity data about the Northern Ireland population to inform its EIAs
- similar tools to the other regulators to ensure its processes are free from bias, such as training, equality and diversity policies and EIAs.

3.3 The PSNI still does not collect diversity data about its Council members. Its reasons for this are unchanged: the recruitment and appointments process for Council members is run by the Public Appointments Unit of the Department; the Northern Ireland Statistics and Research Agency (NISRA) collects and analyses EDI data for all public appointments in Northern Ireland; and the PSNI sees no legitimate reason for it to also collect this sensitive information from its Council members.

3.4 We maintain that collecting EDI data on Council members after they are appointed will provide the PSNI with an understanding of their diversity and may enable it to identify areas where improvements could be made and share insights with the Department to inform the recruitment and appointments process. The PSNI has recognised it can do this in relation to Council members' skills sets.[6]

Conclusion against this Standard

3.5 We remain concerned by the PSNI's decision not to collect diversity data about its Council members. While the data collection and analysis carried out by NISRA provides a level of assurance that the diversity of the Council is being monitored, we would expect a regulator to have an understanding of the diversity of its own senior decision-makers, including its Council. It is also important, and in the public interest, for organisations to show leadership on issues relating to EDI.

3.6 We considered this issue in the context of the PSNI's wider work in EDI. The PSNI has improved on its performance from last year by starting to collect and analyse data on its Associates, which include Committee members. It has identified potential areas for improvement as a result, although we have not yet seen what actions will arise from this. The PSNI's EIAs are of a good standard and consider appropriate factors. The amount of data the PSNI holds about the diversity of its registrants could be improved, but it holds a reasonable amount and it uses this data to inform its EIAs.

3.7 Our assessment was finely balanced but when weighing the concerns about Council member information, we concluded that the PSNI's wider work in relation to EDI is sufficient for the Standard to be met this year.

3.8 However, there are three areas where we expect to see improvements:

- the PSNI should consider whether different strategies used by other regulators to improve data collection could also work for the PSNI[7]

[6] In discussions about the training and development of Council members, as reported in the public minutes of the Council meeting on 25 January 2022.
[7] For example, the GDC increased the amount of data it holds by reviewing best practice in capturing EDI data and launching an active communications and engagement campaign with its associates to explain why it collects EDI data.

- the PSNI should report on any further work, or actions, arising from its consideration of data about its Associates
- the PSNI should expand the ways it uses and reports on the data it holds. Again, the PSNI may want to consider whether the approaches taken by some of the other regulators could also work for the PSNI.[8]

Standard 4: The regulator reports on its performance and addresses concerns identified about it and considers the implications for it of findings of public inquiries and other relevant reports about healthcare regulatory issues.

4.1 There have been no changes to the way the PSNI reports on its performance. It continues to do so through statutory reports, such as its annual report, and non-statutory updates to its Council, for example, its reports on progress against its strategy.

4.2 The PSNI monitored, and acted on, events affecting the healthcare regulatory landscape, including:

- the Covid-19 pandemic
- Brexit
- the regulation of pharmacy technicians in Northern Ireland
- expected legislative changes, such as the rebalancing legislation[9] and the Pharmacy Regulation Board Section 60 Orders.[10]

4.3 The PSNI also identified learning for itself by carrying out:

- its usual programme of internal audit and accepting all recommendations made
- two registrant surveys and using the responses to inform its work

Conclusion against this Standard

4.4 The PSNI continues to report on its performance and to monitor and act on events in the regulatory landscape. It took action to address the concerns we reported in 2018/19 and also takes steps to identify learning for itself.

4.5 We are satisfied that this Standard is met.

[8] For example, the GCC, which has a similar-sized register to the PSNI, publishes an annual registration report with an analysis of diversity characteristics for registrants. The GOsC, which has a slightly larger register than the PSNI, also publishes an annual equality and diversity report which sets out objectives in relation to equality and diversity and actions taken to meet them.
[9] This legislation will extend the legal defences for dispensing errors so they apply to a wider range of pharmacy professionals and services.
[10] These S60 Orders would include powers for the PSNI to introduce a Fit and Proper Person test and to delegate the authority of the Registrar to other individuals.

Standard 5: The regulator consults and works with all relevant stakeholders across all its functions to identify and manage risks to the public in respect of its registrants.

5.1 The PSNI did not carry out any consultations this year but it:

- responded to other organisations' consultations
- worked with the GPhC, the Chief Pharmaceutical Officers, education providers, employers and representative bodies on education reform
- agreed a Memorandum of Understanding (MoU) with the Northern Ireland Centre for Pharmacy Learning and Development (NICPLD) in relation to the new Foundation Training Year developed as part of the education reforms
- met regularly with the other health and social care regulators
- met regularly with the Department about matters that impact its work, including recruitment of Council members and progress of legislative change
- entered into a post-Brexit data sharing arrangement with the Pharmaceutical Society of Ireland (PSI).

5.2 The PSNI worked with stakeholders throughout the year to identify and manage risks to the public in respect of its registrants. We are satisfied that this Standard is met.

Guidance and Standards

Standard 6: The regulator maintains up-to-date standards for registrants which are kept under review and prioritise patient and service user centred care and safety.

Standards for pharmacists

6.1 The PSNI introduced *The Code (Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland)* in 2016. Planned reviews are usually done every five years but the review of *The Code* is slightly delayed and will be carried out in 2022. We do not have any concerns about the delay as there is no evidence that *The Code* is not currently fit for purpose.

Standards for pharmacies

6.2 The current *Standards for Registered Pharmacy Premises* have been in place since January 2010. The PSNI approved new *Premises Standards* in June 2018 but they will not come into effect until a Commencement Order brings The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 into operation. The delay in bringing the Order into operation is not within the PSNI's control and it continues to closely monitor progress with any legislative changes that are relevant to its role and functions.

6.3 We will monitor the PSNI's review of *The Code* and the Commencement Order that will bring the new *Premises Standards* into effect but have no concerns at present.

6.4 We are satisfied that this Standard is met.

Standard 7: The regulator provides guidance to help registrants apply the standards and ensures this guidance is up to date, addresses emerging areas of risk, and prioritises patient and service user centred care and safety.

7.1 The PSNI continued using the dedicated Covid-19 section of its website to publish updated information and guidance throughout the year. It published joint statements with:

- the Chief Pharmaceutical Officers supporting pharmacy professionals
- the other health and social care regulators, re-iterating previous statements on how they will regulate in the context of the pandemic.

7.2 The PSNI's new *Guidance for provision of services*, which we reported on last year, came into effect this year in February 2021. In May 2021, the Northern Ireland Human Rights Commission (the Commission) published a *Monitoring Report on Reproductive Healthcare Provision in NI*. It recommended that the Department of Health and relevant agencies should issue guidance for healthcare professionals and other staff which reflects the law and how it should be implemented and should make provisions for conscientious objection, which reflects United Kingdom case law and human rights principles. The PSNI's guidance covers the areas recommended by the Commission and we have not identified any concerns with it.

7.3 We are satisfied that this Standard is met.

Education and Training

Standard 8: The regulator maintains up-to-date standards for education and training which are kept under review, and prioritise patient and service user centred care and safety.

8.1 The PSNI has been working closely with the GPhC in recent years on reforming pharmacist education and training to ensure future registrants have the training and skills needed for the new and extended clinical roles pharmacists are taking on. This work is spanning several performance review periods.

8.2 During this review period, the PSNI:

- in January 2021, adopted the GPhC's new *Standards for the initial education and training of pharmacists*. These new Standards took effect from July 2021 and are being implemented in a phased approach

- replaced its pre-registration training year with a foundation year run by the Northern Ireland Centre for Pharmacy Learning and Development (NICPLD). The PSNI will no longer manage or administer this aspect of pharmacist training but will retain responsibility for quality assurance.

8.3 The PSNI is working with the GPhC on incorporating independent prescribing into the new five-year training program. We will continue to monitor developments in the education reforms.

8.4 The work being done by the PSNI with the GPhC is aimed at ensuring the standards for education and training remain fit for purpose. We have seen no evidence that raises concerns about this Standard and are satisfied that it is met.

Standard 9: The regulator has a proportionate and transparent mechanism for assuring itself that the educational providers and programmes it oversees are delivering students and trainees that meet the regulator's requirements for registration, and takes action where its assurance activities identify concerns either about training or wider patient safety concerns.

Accreditation

9.1 There are two MPharm course providers in Northern Ireland. A joint GPhC/PSNI accreditation team carried out remote interim visits[11] of both providers this year. The team took account of adaptations made in response to the pandemic. Both providers had their accreditation confirmed without conditions or recommendations.

Registration assessment

9.2 We reported last year that the first sitting of the PSNI and GPhC joint common registration assessment was initially due to take place in June 2021 but was deferred because of the pandemic.

9.3 To avoid delays for candidates in Northern Ireland, the PSNI proceeded with its own separate registration assessment in June 2021. There were no reported issues with the sitting and the pass rate was comparable to previous years.

9.4 The first sitting of the common registration assessment took place just after the review period, in November 2021, and there were no reported issues.

What we heard from stakeholders

9.5 We received feedback about the registration assessment from a professional body. It welcomed the PSNI's decision to proceed with the registration assessment but mentioned delays in replies to communications about the assessment.

[11] Once accreditation is granted to a course, full reaccreditation visits take place every six years with an interim visit every three years.

9.6 Given the context of the pandemic, some delays will have been inevitable and unavoidable. In addition, the small size of the PSNI means its performance is more susceptible to being affected by any unplanned or extended staff absence. We understand that no candidates were prevented from sitting the registration assessment as a result of delays this year. Consequently, we do not consider the delays to be sufficiently serious to adversely impact our assessment of this Standard.

Conclusion against this Standard

9.7 The pandemic impacted the assurance activities of all the regulators. The PSNI did not cancel or defer any of its activities but carried them out remotely.

9.8 The PSNI took steps to ensure that problems caused by the pandemic caused as little inconvenience as possible to candidates for its registration assessment. Although some people experienced delays when contacting the PSNI about the registrant assessment, we cannot reasonably expect the PSNI to have been able to avoid all delays during the pandemic.

9.9 We are satisfied that this Standard is met.

Registration

Standard 10: The regulator maintains and publishes an accurate register of those who meet its requirements including any restrictions on their practice.

10.1 The PSNI continued to operate the temporary register set up in response to the Covid-19 pandemic. We saw no evidence of inaccuracies in the main register or the temporary register. The PSNI received no concerns about temporary registrants.

10.2 We are satisfied that this Standard is met.

Standard 11: The process for registration, including appeals, operates proportionately, fairly and efficiently, with decisions clearly explained.

11.1 The PSNI's registration processes have not changed and it continues to process applications for registration efficiently.

11.2 We have seen no evidence that raises concerns about this Standard and are satisfied that it is met.

Standard 12: 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.

12.1 Under the Medicines Act 1968, the Department, rather than the PSNI, has powers to investigate instances of illegal practice and take action where

necessary. The PSNI regularly meets with the Department to share information about ongoing investigations.

12.2 The PSNI has not reported any changes in this area and we have seen no evidence that raises concerns about this Standard.

12.3 We are satisfied this Standard is met.

Standard 13: The regulator has proportionate requirements to satisfy itself that registrants continue to be fit to practise.

13.1 Last year, in response to the pandemic, the PSNI:

- reduced its CPD requirements for the 2020/21 CPD year[12]
- deferred the introduction of its new CPD framework to June 2021.[13]

13.2 The PSNI reviewed those decisions this year and reaffirmed them in light of the ongoing pandemic.

13.3 Submissions based on the new CPD framework will be due by 31 May 2022. The PSNI will be assessing the impact of the new framework using feedback from registrants and analyses of outcomes for registrants, including of compliance levels and pass rates. We will monitor this activity.

13.4 We have no concerns this year and are satisfied that this Standard is met.

Fitness to Practise

Standard 14: The regulator enables anyone to raise a concern about a registrant.

14.1 The PSNI receives concerns from a variety of sources, with most concerns raised by members of the public or as self-referrals.

14.2 The PSNI continues to close a high proportion of cases without a referral to its Scrutiny or Statutory Committees. This has been the case for a number of years. When we audited the PSNI's closed fitness to practise cases in 2018/19, we found that reasonable decisions were being made. This Standard was not subject to audit this year, but our audit of Standards 15 and 18 found that the PSNI continues to make reasonable decisions. Consequently, we are not concerned by the high proportion of cases closed without being referred to an independent panel, but we will continue to monitor the data.

14.3 We have no concerns about this Standard this year and are satisfied that it is met.

[12] The PSNI's CPD year runs from 1 June to 31 May to align with registration.
[13] The new framework was initially due to be introduced from June 2020.

Standard 15: The regulator's process for examining and investigating cases is fair, proportionate, deals with cases as quickly as is consistent with a fair resolution of the case and ensures that appropriate evidence is available to support decision-makers to reach a fair decision that protects the public at each stage of the process.

15.1 The PSNI did not meet this Standard last year because we had not seen tangible evidence that the concerns we reported in 2018/19 about fairness and transparency had been fully addressed and the data showed early indicators of a deterioration in timeliness. We said we would monitor the timeliness of case progression and the rate of hearing adjournments.[14]

15.2 This year:

- the data raised no concerns about timeliness or hearing adjournments
- we carried out a targeted review, including an audit of closed fitness to practise cases[15] to assess whether the PSNI had addressed our concerns from 2018/19.

Our audit findings

15.3 The PSNI implemented a number of changes in response to our concerns about its fitness to practise process. Our audit this year found clear evidence that the changes have improved the fairness and transparency of the process.

15.4 The PSNI introduced:

- written guidance on its jurisdictional test and new information leaflets explaining the test. We saw the information leaflets being routinely shared with complainants at the outset of the investigation and with registrants when they were contacted by the PSNI[16]
- a new *FTP Communications policy* setting out the frequency of communications with all parties. We saw updates and decisions being routinely sent to parties, in compliance with the new policy[17]
- new decision-making templates which we saw being routinely used, leading to decisions and reasons being recorded contemporaneously. Reasons shared with the parties usually reflected the reasons recorded on the decision-making templates. Reasons were sometimes brief but

[14] Half of the hearing adjournments from the 2018/19 and 2019/20 performance review period were due to there being insufficient time to conclude the hearing. We wanted to ensure this was not an ongoing issue this year.
[15] We audited 15 of the 31 cases closed by the PSNI's Registrar during the review period.
[16] Our audit in 2018/19 found that the PSNI did not have written guidance on its jurisdictional test. Processes were not always explained to parties, particularly registrants. The jurisdictional test was not explained and parties were not explicitly told when it had been met or not met.
[17] Our audit in 2018/19 found that case updates were not routinely sent to parties and the internal guidance in place at the time set out timeframes for updating complainants but had no equivalent timeframes for updating registrants.

generally contained enough information to understand the PSNI's decision.[18]

15.5 We are, therefore, satisfied that the PSNI has addressed the concerns we reported in 2018/19 and we welcome the work done by the PSNI.

15.6 However, our audit raised concerns about three other aspects of the PSNI's fitness to practise process.

Notifying registrants they are under investigation

15.7 Letters to registrants imply, but do not explicitly say, that the registrant is the subject of the investigation. During the course of an investigation, it is not uncommon for a regulator to request information from one or more registrants who are not themselves under investigation. There will be times when information received during an investigation means a registrant's status may change from being a source of information to being the subject of an investigation. Registrants should be clearly told whether they are a source of information or the subject of the investigation and, if this status changes, this should be made clear. Registrants should also be made aware of the possibility that this status may change. Any ambiguity in this area impacts the transparency and fairness of the process for registrants.

Investigating serious cases without the consent of the complainant

15.8 In order to investigate, the PSNI will usually seek a complainant's consent to share their concerns and information with relevant parties. When a complainant does not consent, the PSNI can still investigate if the concerns are capable of verification from an independent source. Some types of cases will be more difficult to investigate without the consent and cooperation of the complainant, for example where the complainant was the only person to witness an incident.

15.9 The PSNI told us it does not consider it appropriate to disclose a complainant's details against their wishes, even in more serious cases, as this would undermine trust in the regulator, may dissuade people from reporting concerns and may breach data protection law. The PSNI also highlighted that serious concerns are likely to be verifiable independently in any event.

15.10 We were concerned by the PSNI's position. In the context of the recent Hyponatraemia[19] and Muckamore Abbey Inquiries[20] into serious public safety failures in Northern Ireland, we would be concerned by a blanket approach which would not share information in any circumstance. We know that serious cases involving a complainant who does not consent to their information being shared may be rare and may present practical difficulties for investigations. However, a regulator should be prepared to take action to protect the public in

[18] Our audit in 2018/19 found that decisions and their accompanying reasons were not recorded contemporaneously and in a small number of cases information had been presented in a way that was not fully accurate or omitted certain details.
[19] http://www.ihrdni.org/
[20] https://www.mahinquiry.org.uk/

serious cases, even where this breaches a complainant's confidentiality. This is a standard approach taken in investigations related to public protection.[21]

Conflicts of interest

15.11 The PSNI's legislation specifies that certain actions and decisions can only be carried out by the Registrar. These include decisions to close cases or refer allegations to the Scrutiny Committee.[22] Given the relatively small population of Northern Ireland, and of the pharmacy community, it is not unusual for the PSNI to encounter potential conflicts of interest, perceived or actual. To manage and mitigate potential conflicts, the PSNI uses joint decision-makers so all relevant decisions are made by the Registrar in conjunction with one other person.

15.12 We highlighted a case to the PSNI where the registrant indicated they knew the Registrar but the decision contained no record of this potential conflict of interest being identified or how it was managed. The PSNI initially told us the potential conflict was considered but did not impact the decision as it was managed by its approach of having joint decision-makers. However, the PSNI later told us it did not accept that the registrant knowing the Registrar amounts to a conflict of interest, perceived or otherwise.

15.13 We sympathise with the challenges faced by the PSNI because of its restrictive legislation and recognise its ongoing commitment and work to have changes made. Using joint-decision makers is a reasonable and proportionate approach to managing potential conflicts. However, we were concerned that the PSNI did not agree there was a potential conflict of interest, or the possibility of a perceived conflict, in the case we identified. We would also expect the regulator to have a written policy setting out how it identifies and manages risks around conflicts of interest, particularly in the PSNI's circumstances as it is likely to encounter potential conflicts on a more regular basis than the other regulators. Where potential conflicts arise in cases, perceived or otherwise, there should be a clear record of how they have been managed.

Transparency about the PSNI's approach to the powers of its Statutory Committee

15.14 Aside from the concerns arising from our audit, we also had concerns about a matter which we commented on last year relating to the powers of the PSNI's Statutory Committee.

15.15 Last year, we reported concerns because the PSNI's interpretation of the powers of its Statutory Committee had influenced the way it decided to manage a case. While no public protection risks arose in that case, the PSNI's interpretation did not accord with our understanding of the legislation or the powers of other regulators. The PSNI subsequently agreed to adopt our approach and we reported that its Manual for the Fitness to Practise

[21] For example, the GMC, NMC and SWE make it clear that they will maintain confidentiality as far as possible but information may need to be shared if it is in the interests of public protection.
[22] The PSNI is fully aware of the challenges presented by its legislation and has been working with the Department to introduce changes, one of which would enable it to appoint a Deputy Registrar.

Committees (FtP manual) and published information would benefit from being updated with clear information setting out its approach.

15.16 The PSNI did not make the suggested changes to its FtP manual or its published information this year. It told us it intends to ensure panel members are aware of its approach through panel training. It also told us the issue did not arise this year as it did not review any Conditions of Practice Orders and it has no Conditions of Practice Orders that will require review in the near future.

15.17 We do not agree with the PSNI's decision not to publicise its approach to the Statutory Committee's powers. It is not appropriate to only share the information with the Statutory Committee and not with other interested parties. We recognise that this impacts a small number of cases but are concerned that the lack of transparency obviously unfairly disadvantages registrants who will be unaware of the approach.

What we heard from stakeholders

15.18 We received feedback from a professional body which raised concerns about:

- the timeliness of case progression, in particular where there were third party investigations
- the transparency of the fitness to practise process, in particular the outcomes the PSNI is seeking in cases.

15.19 The PSNI has policies on *Parallel Investigations* and *FTP Communications* and a Practice Direction issued by the Chair of its Statutory Committee on pre-hearing procedures for parties to share information about the case. The Practice Direction has been published on the PSNI's website since 2017. As mentioned under Standard 1, the fitness to practise policies were published on the PSNI's website this year.

15.20 Our audit found that the PSNI was generally progressing cases without delay and it was complying with its *Parallel Investigations* and *FTP Communications* policies. Now that the PSNI has published these policies on its website, the process is more transparent. We will continue to monitor any feedback we receive about the PSNI's fitness to practise process.

Conclusion against this Standard

15.21 Our assessment of this Standard was finely balanced.

15.22 We fully recognise the improvements made by the PSNI and are pleased to report that it has addressed all the concerns we raised following our audit in 2018/19. Our audit this year did not identify concerns about the quality or timeliness of the PSNI's investigations.

15.23 However, several other concerns have arisen this year. After our audit, we provided feedback to the PSNI on its approaches to notifying registrants they are under investigation, cases without consent and conflicts of interest. The PSNI did not accept our feedback so we currently have no assurances that our concerns in these areas will be addressed.

15.24 We did not see the issues we identified have an impact on public protection this year. However, our concerns are about the PSNI's underlying approaches

to several aspects of its fitness to practise process. Most of our concerns go to the fairness of the process, and we would expect the PSNI to address these. For these reasons, and despite the improvements elsewhere, we concluded that this Standard is not met.

Standard 16: The regulator ensures that all decisions are made in accordance with its processes, are proportionate, consistent and fair, take account of the statutory objectives, the regulator's standards and the relevant case law and prioritise patient and service user safety.

16.1 The PSNI met this Standard last year, although we said:

- we would monitor the impact of the threshold criteria introduced in June 2020 as more information becomes available
- the PSNI's FtP manual and guidance could be strengthened in a number of areas

Threshold criteria introduced in June 2020

16.2 The PSNI receives a relatively small number of referrals each year so it may take time to gather enough evidence to assess the impact of the new threshold criteria. In the meantime, the PSNI has processes in place to monitor the application of the new criteria and identify learning from decisions.

16.3 Although this Standard was not subject to audit, we audited five cases that were assessed against the threshold criteria. We had no concerns about the application of the criteria in these cases or the decisions to close them.

FtP manual and guidance

16.4 Last year, we suggested that the PSNI's internal and published documents could be strengthened by including further details about:

- the role and remit of the Scrutiny Committee
- the inquiry role of the Statutory Committee
- the role of specialist advisers and the limitations of their role
- how the Statutory Committee should take account of interim conditions as well as interim suspensions
- the Statutory Committee's powers when reviewing conditions of practice orders.

16.5 The PSNI did not update its documents during the review period but it has commissioned an independent law firm to review its FtP manual and they will reflect on the areas we identified. Once the review is complete, training will be delivered to panel members.

16.6 We issued one learning point to the PSNI this year because we noted in one case that the template for medical experts contains questions that are matters for the panel. Last year we noted a similar issue about an instructed expert being asked to reach a view on matters which were the remit of the panel so

we asked the PSNI how it is ensuring all parties understand the role and remit of expert witnesses.

16.7 The PSNI uses:

- *Working Guidance – Clinical Advisers* which clearly states Clinical Advisers should not give an opinion on the fitness to practise of the registrant
- *Acting as an expert or professional witness – Guidance for healthcare professionals* produced by the Academy of Medical Royal Colleges
- its FtP manual, which will be updated to reference the two guidance documents above.

16.8 After we asked the PSNI about its approach, it moved its guidance documents to a more prominent section of its website, under health matters on the fitness to practise page. The PSNI is taking reasonable steps to ensure that expert witnesses understand their role and remit.

16.9 We will examine the changes made to the FtP manual after the external review is complete. However, the PSNI told us it does not intend to make any changes to its documents in relation to its approach to the Statutory Committee's powers when reviewing conditions of practice orders.

Statutory Committee's powers when reviewing conditions of practice orders

16.10 As mentioned under Standard 15, the PSNI told us it intends to ensure panel members are aware of its approach to the Statutory Committee's powers through training.

16.11 In the case that led us to identify this issue last year, it was the PSNI's case management that was impacted by its approach, not the Committee's decision. Training for panel members does not address this, nor does it ensure clarity and transparency for external stakeholders. We think the PSNI could, and should, take further steps to ensure that case management decisions, as well as Committee decisions, are made in accordance with its approach and that its approach is clear and transparent for all stakeholders.

Fitness to practise decisions

16.12 The PSNI reported four appealable hearing decisions to us and we considered they were all sufficient for public protection. As mentioned at paragraph 16.6 we issued a learning point in relation to one case.

16.13 Although this Standard was not subject to audit, we saw evidence relevant to this Standard. We had no significant concerns about the decisions we saw and found that the PSNI's contemporaneous recording of decisions and reasons has improved since the introduction of decision-making templates.[23]

[23] When we last audited in 2018/19, we reported concerns about the PSNI's record-keeping because decisions were not always fully, accurately or contemporaneously recorded.

Conclusion against this Standard

16.14 We do not have any significant concerns about the decisions made by the PSNI during the review period, either at the initial stages or the final stages of its fitness to practise process.

16.15 The PSNI has a range of mechanisms in place aimed at ensuring good decision-making. It uses training and guidance and has processes to review decisions to identify learning.

16.16 We remain concerned about the limited controls in place to ensure decisions comply with the PSNI's approach to the Statutory Committee's powers when reviewing conditions of practice orders. We do not think panel member training alone is sufficient to address this issue.

16.17 However, we considered this issue in detail under Standard 15 and it contributed to that Standard not being met. We do not consider the issue sufficiently serious to also impact this Standard when we have no other concerns about the PSNI's decision-making.

16.18 We are satisfied that this Standard is met.

Standard 17: The regulator identifies and prioritises all cases which suggest a serious risk to the safety of patients or service users and seeks interim orders where appropriate.

17.1 The PSNI met this Standard last year, but we were concerned that it had not yet addressed the concerns we reported in 2018/19 about its approach to documenting risk assessments. Risk assessments did not always include enough information to explain the factors that had influenced the risk rating.

Risk assessments

17.2 This year, the PSNI revised its risk assessment template, adding sections so more narrative can be recorded on the nature of the concerns and the reasons for the decision. We welcome this improved template and saw it used appropriately in one of the cases we audited.[24]

17.3 However, we audited five cases that should have had a risk assessment on file and were concerned that only one of these cases had a risk assessment recorded. We know that the PSNI conducts weekly case reviews which include assessing whether there have been any changes to the level of risk. If changes are identified, a further formal risk assessment is recorded on the case file. This process provides some assurance that the PSNI is regularly reviewing risk on its open cases. We are also reasonably assured by the fact that we did not see any instances of the PSNI failing to identify serious risks.[25]

[24] Although this Standard was not subject to audit, some of our audit findings were relevant as they related to risk assessments. Where relevant, the findings were considered in our assessment of this Standard.

[25] We caveat this point by highlighting our audit sample was skewed towards cases that are less serious because we were reviewing cases closed at the initial stages of the fitness to practise process.

Nonetheless, we emphasise the importance of ensuring risk assessments are properly documented on all cases.

Interim order application

17.4 During the review period, interim order applications on four cases were delayed. One application was delayed on more than one occasion and some of the delays were administrative while others were formal postponements or adjournments. We explored the reasons for these delays and were satisfied that most of them were reasonable. We had concerns about three of the delays because we thought they were avoidable,[26] but the small numbers mean we cannot say whether these were isolated or systemic issues. We were satisfied that none of the delays exposed the public to any risks but will closely monitor the data to ensure these issues were isolated.

Conclusion against this Standard

17.5 Although we have concerns about some of the delays to interim order applications and the documenting of risk assessments, the delays did not expose the public to risks and we did not see any evidence of the PSNI failing to identify serious risks. Overall, the evidence suggests that the PSNI is identifying and managing serious cases appropriately. We are satisfied that this Standard is met.

Standard 18: All parties to a complaint are supported to participate effectively in the process.

18.1 The PSNI did not meet this Standard last year because we had not yet seen tangible evidence that it had addressed the concerns we reported in 2018/19 about parties not being updated and the fitness to practise process not being explained to them.

18.2 This year, we carried out a targeted review of this Standard, including an audit of closed fitness to practise cases, to assess the impact of changes introduced by the PSNI to address our concerns.

18.3 As mentioned under Standard 15, our audit found several improvements:

- parties were contacted or updated regularly during investigations, in compliance with the PSNI's new *FTP Communications policy*
- the updated information leaflets were shared with complainants at the outset of investigations and with registrants when they were contacted
- parties were always notified of the final decision in their case

[26] One application was delayed because the registrant was on remand. We did not think this delay was necessary, nor did it properly take account of the wider public interest given the concerns were serious enough for the registrant to be in custody. One adjournment application could have been avoided had an appropriate expert been instructed, as directed by the Statutory Committee. There was a two-month delay in reconvening the same interim order application after a further adjournment and this delay appeared unduly long to us.

- registrants were signposted to the Pharmacists' Advice and Support Service (PASS) and told they could seek legal advice.

18.4 The changes made by the PSNI clearly had a positive impact and we are pleased to report that our concerns from 2018/19 have been addressed.

18.5 However, one of the new concerns mentioned under Standard 15 is also relevant to this Standard. If registrants are not explicitly told that they are the subject of the investigation, this could impact their ability to effectively participate in the process.

18.6 While we are concerned by this, the issue was considered under Standard 15 and contributed to that Standard not being met. It is the only issue we have identified under this Standard. In the context of the other customer service improvements made by the PSNI, we do not consider it sufficiently serious to also adversely impact this Standard.

18.7 We are satisfied that this Standard is met.

Useful information

The nature of our work means that we often use acronyms and abbreviations. We also use technical language and terminology related to legislation or regulatory processes. We have compiled a glossary, spelling out abbreviations, but also adding some explanations. You can find it on our website here.

You will also find some helpful links below where you can find out more about our work with the 10 health and care regulators.

Useful links

Find out more about:

- the 10 regulators we oversee
- the evidence framework we use as part of our performance review process
- the most recent performance review reports published
- our scrutiny of the regulators' fitness to practise processes, including latest appeals

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