professional standards authority
for Health and Social Care

performance review 2019/20

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 2019/20

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

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The Pharmaceutical Society of Northern Ireland

key facts & stats

The PSNI regulates pharmacists and registered pharmacies in Northern Ireland.

As at 30 September 2020, the PSNI was responsible for a register of:

2,766 pharmacists,
554 registered pharmacies

Annual registration fee is: £348 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 2019/20 performance review

General Standards	4/5
Guidance and Standards	2/2
Education and Training	2/2
Registration	4/4
Fitness to Practise	3/5

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.

The 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 Pharmaceutical Society of Northern Ireland (PSNI) and covers the period from 1 November 2019 to 31 October 2020. The Covid-19 pandemic began impacting the PSNI's work in March 2020 and we have commented on this where relevant. The PSNI 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. We revised our Standards in 2019; this is the first performance review of the PSNI under the new Standards.

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.

The PSNI's performance during 2019/20

We conducted a targeted review of the PSNI's performance against Standards 3, 15, 16 and 18. Following our targeted review, we concluded that the PSNI had not met Standard 3 because the PSNI does not collect or analyse data on the diversity of its Council and Committee members, and had not met Standards 15 and 18 because we have not yet seen tangible evidence of the impact of improvement actions taken by the PSNI in response to concerns we reported last year.

The PSNI disagreed with the outcome in Standard 3, in relation to Council recruitment, and in relation to Standards 15 and 18 on all counts. It has published **a response** to our report on its website.

[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).

General Standards

When we revised the Standards, we introduced a new set of General Standards. There are five Standards covering a range of areas including: providing accurate, accessible information; clarity of purpose; equality, diversity and inclusion; reporting on performance and addressing organisational concerns; and consultation and engagement with stakeholders to manage risk.

We saw evidence of the PSNI providing accurate and accessible information about different areas of its work, although we noted there is no published information about the powers of the PSNI's Statutory Committee to extend conditions of practice orders or the PSNI's approach to this type of sanction being extended.

Although the PSNI's legislation does not set a statutory over-arching objective of protection of the public, its publications and corporate strategy have a clear focus on public protection. The PSNI is the only regulator we oversee that has a statutory professional leadership role. It is seeking legislative changes to separate the two functions but, in the meantime, it manages this conflict of interest by devolving the leadership functions to an arms-length body, the Pharmacy Forum.

The PSNI regularly reports on its performance and carries out monitoring and horizon scanning activities. It implemented action plans in response to the Authority's *Lessons Learned Review* (LLR), the NMC's *Independent audit to review the NMC's handling of documentation relating to midwives at Furness General Hospital* and the concerns we reported in our performance review last year. It also took steps to identify and implement learning by commissioning a Lessons Learned report after concerns were raised internally about a number of linked Scrutiny Committee decisions.

The PSNI has a clear framework in place which guides its consultation process and stakeholder engagement strategy. We saw these in operation through several consultations issued by the PSNI this year and we also saw an increased level of collaboration amongst the regulators and their stakeholders in response to the Covid-19 pandemic.

After our targeted review, we concluded that Standard 3 is not met because the PSNI does not take any steps to collect or analyse EDI data about its Council and Committee members. It is the only regulator that does not do so. The number of Committee members and associates varies amongst the regulators but they all have a comparable number of Council members. The Minister for Health in Northern Ireland is responsible for the recruitment and appointments of PSNI Council members and the process is managed by the Public Appointments Unit of the Department of Health in Northern Ireland. We recognise that the PSNI operates in a different context to the other regulators because it is the only regulator that solely operates in Northern Ireland, which has different demographics to other parts of the UK. We also recognise there will be limitations to the statistical significance of the data due to the small numbers involved. However, we consider collecting and analysing this data, within those limitations, is an important part of understanding the diversity of these key decision-makers and how it compares to the PSNI's register and the Northern Ireland context in which it operates.

Other key developments

Reforms to the initial education and training for pharmacists

The PSNI has been working with the GPhC, and consulting with stakeholders, on significant reforms to the initial education and training for pharmacists. This year, the PSNI was part of a working group reconvened by the GPhC to finalise changes to the GPhC's *Standards for the initial education and training of pharmacists*, which the PSNI adopts. The new standards were approved by both regulators shortly after the review period and will be implemented using a phased approach from July 2021. During the period under review, the PSNI issued a joint update with the GPhC and the Chief Pharmaceutical Officers of the UK on future proposals to introduce a foundation year and incorporate training on independent prescribing into the initial training programme.

Registration assessment

Last year, the PSNI and the GPhC agreed to introduce a joint common registration assessment and the first sitting was due to take place in June 2021. Due to the differing circumstances of the two regulators, each adapted their registration assessment differently in response to the Covid-19 pandemic meaning their dates are no longer aligned. To avoid unnecessary delays for pre-registration trainees in Northern Ireland, the first sitting of the common registration assessment has been pushed back and will take place no earlier than Autumn 2021. During the period under review, the PSNI prepared for the move to the joint assessment by reviewing and making changes to its pre-registration training and syllabus to ensure they are aligned with the new joint assessment and the new *Standards for the initial education and training of pharmacists*.

Registration process for applicants first registered in the EEA

Last year we expressed significant concerns about part of the application process for applicants first registered in the EEA. The process involved the option of inviting applicants for a voluntary interview without informing them that the interview was to assess their communication skills and could result in a fitness to practise referral against them. We were also concerned because there were no criteria in place to guide decisions on who should be invited for interview or when a fitness to practise referral should be made. The PSNI has addressed all of these concerns by discontinuing this process.

Guidance on decision-making for fitness to practise Committees

We did not identify any decisions made by the PSNI which we considered to be insufficient for public protection but we had concerns about the Scrutiny and Statutory Committees' understanding of their role and remit. The PSNI provides training and guidance to these fitness to practise Committees and it updated its tools during the period under review based on recommendations from a Lessons Learned report on some Scrutiny Committee decisions. In addition to the updates already made by the PSNI, we identified some other areas where the tools could be further strengthened. These areas arise from the Lessons Learned report, learning points we issued on a Statutory Committee decision and correspondence exchanged with the PSNI about the powers of the Statutory Committee. We had concerns about the PSNI's initial position on this latter point because we did not consider its proposed approach would have ensured the Committee was using all of the tools available to it to protect the public. However our concerns were allayed when the

PSNI revised its position and adopted our preferred approach. We expect the training and guidance provided to Committee members to be updated accordingly.

Changes in response to the Authority's 2018/19 performance review

The PSNI has implemented a number of changes to address the concerns we reported last year about the transparency and fairness of its fitness to practise process and about the information provided to parties to support them to participate effectively in the process. The changes were prompt and appear appropriately focused on the areas of concern. The PSNI has controls in place to ensure and monitor compliance with the new processes it has introduced, although compliance checks are not documented. We welcome the PSNI's clear commitment to addressing the concerns we reported. However, there was an absence of tangible evidence of the impact the changes have had, partly due to the timing of the changes within the context of the period under review. In addition, there appear to be early indicators of a deterioration in the timeliness of case progression. We therefore determined that Standards 15 and 18 were not met.

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.

1.1 Information about the PSNI's work is published on its website, which contains downloadable versions of guidance, processes and application forms amongst other documents. The PSNI also provides information through social media, regular newsletters and direct communications with its registrants and other stakeholders.

1.2 The Google translate tool is available on the PSNI's website and this allows users to translate the information into over 50 languages. The PSNI can provide reasonable adjustments or documents in alternative formats on request.

1.3 In March 2020, the PSNI added a new section to its website dedicated to information related to the Covid-19 pandemic, including FAQs and process changes. The PSNI worked with the Patient Client Council during the pandemic to direct members of the public to this resource. Regular updates and statements were published by the PSNI as circumstances evolved.

1.4 The PSNI told us that it ensures the accuracy of the information it publishes through verification checks.

1.5 Our review of the PSNI's website identified some sections which were not up-to-date:

- a change in the PSNI's governance structure was not reflected on the relevant page of the website but was reported in Council papers
- the Newsletters and Communications section was not up-to-date
- when the second sitting of the registration assessment was rescheduled,[2] the date was published on the Pre-registration section of the website but not on the News or Covid-19 sections

1.6 We were satisfied that the instances listed above were omissions in updating each and every section of the website because there was evidence of the information being provided by the PSNI through other channels, such as a direct communication to pre-registration trainees about the rescheduled date for the registration assessment. We also recognise that the Covid-19 pandemic will have placed unavoidable and unpredictable pressures on the PSNI's resources, so we did not view this small number of omissions as concerning.

[2] Further details about changes to the registration assessment this year are reported under Standard 9.

1.7 The PSNI has a *Policy on the disclosure and publication of fitness to practise information* which sets out the fitness to practise information the PSNI will publish and for how long. On reviewing the hearing determinations on the PSNI's website, we found that approximately two thirds of them were published beyond the timeframes set out in the policy. The PSNI told us this was due to an administrative error and removed the determinations. It did not report putting any other measures in place to prevent further errors of this type occurring. This was of concern to us, as was the proportion of determinations that were published when they should not have been. We expect the root cause of the errors to be addressed in order to reduce the likelihood of recurrence and will monitor any information about preventive measures put in place. However, we recognise that the determinations themselves were accurate and their extended publication did not give rise to public protection risks.

1.8 Under Standards 2 and 16, we have mentioned a matter that arose in relation to the powers of the PSNI's Statutory Committee. Besides the points discussed under Standards 2 and 16 about the PSNI's understanding of and approach to its legislation, we noted that the PSNI's website and published information does not provide full details of the Statutory Committee's powers and on the approach the PSNI takes. We were concerned by this absence of information because we would expect a regulator to provide this type of information to its registrants and the public, particularly given the PSNI's view that the legislation is open to interpretation.

1.9 Overall, we identified three separate issues under this Standard, two of which we had concerns about. We carefully considered the impact of these concerns on our assessment of performance against this Standard. In doing so, we also took account of the evidence we have seen of the PSNI providing information, which shows that the PSNI uses various channels to provide a range of information about its work across all of its functions. We have found the information provided by the PSNI to be predominantly accurate and accessible. In light of this, we do not consider the concerns identified warrant the overall Standard not being met.

1.10 We therefore concluded that this Standard is met.

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 Unlike the majority of the other health and social care regulators we oversee, the PSNI's legislation[3] does not set a statutory over-arching objective of protection of the public. The PSNI is also the only regulator whose legislation confers on it a statutory professional leadership role.

[3] The PSNI was established by the Pharmacy and Poisons Act (Northern Ireland) 1925. Further powers and responsibilities were conferred upon it by the Pharmacy (Northern Ireland) Order 1976 and the Pharmacy (NI) Order 1976 (Amendment) Order (NI) 2012.

2.2 Nonetheless, the PSNI's website, publications and Corporate Strategy 2017-2022 show a clear focus on public protection. The website states that the PSNI seeks to protect the public by:

- setting and promoting standards for pharmacists' admission to the register and for remaining on the register
- maintaining a publicly accessible register of pharmacists, and pharmacy premises, in Northern Ireland
- handling concerns about the fitness to practise of registrants, acting as a complaints portal and taking action to protect the public
- ensuring high standards of education and training for pharmacists in Northern Ireland.

2.3 In order to manage the conflict of interest arising from the PSNI holding both a regulatory role and a professional leadership role, the PSNI devolved the leadership functions to an arms-length body, the Pharmacy Forum, with which it has a MoU. There is a *Scheme of delegation* in place which explicitly prevents members of the PSNI's Council serving as members of the Pharmacy Forum Management Board. The PSNI is seeking legislative changes which would bring about a separation of the two functions.

2.4 The PSNI does not have a formal framework in place to ensure policies are applied across its functions and that learning is applied from one area to others. It does not consider a formal framework necessary as it has a small team with a structure that enables it to share information effectively across the organisation.

2.5 The PSNI has a three-year programme of internal audit, set by its Audit and Risk Committee, which includes reviews of processes, policies and compliance. The PSNI reported that the controls were found to be satisfactory in the following audits completed since 2017:

- continuing professional development (CPD) processes, which led to changes in activity and to standards and guidance
- GDPR across all functions, which involved a document review to scope appropriateness of policies and will be followed up next year with a compliance review
- risk management and corporate planning, which reviewed the application of risk management to policy and other developments.

2.6 The PSNI told us about two instances where fitness to practise matters had prompted it to issue guidance to registrants; one case related to the inappropriate supply of medication online and the other related to the use of volunteers to distribute medicines during the Covid-19 pandemic.

2.7 We also saw recommendations from a Lessons Learned report produced for the PSNI's fitness to practise function[4] leading to improvements in the documentation available for pre-registration trainees in the PSNI's education and training function.

[4] The PSNI commissioned a Lessons Learned report when concerns were raised about a number of Scrutiny Committee decisions. The report is discussed in further detail under Standard 16.

2.8 Although we do not consider that the size of the PSNI would preclude it from implementing a formal framework to apply and embed policies and ensure learning is applied across its functions, we consider its approach to be reasonable. We have not identified any evidence which suggests that the absence of a formal framework has given rise to concerns. The PSNI uses internal audit as a tool to identify issues within its processes and compliance and we note no concerns have been identified.

2.9 Under Standard 16, we have discussed an issue that arose about the PSNI's understanding of the powers of its Statutory Committee which, in our view, limited the powers of that Committee in a way which was not justified by its legislation and which might not protect the public. Following discussions with us, the PSNI has agreed to adopt an approach which, in our view, is consistent with its powers and is more likely to achieve public protection.

2.10 We carefully considered whether these matters suggested a lack of clarity of purpose on the part of the PSNI. Given the PSNI's careful consideration of the points that we raised, together with the other evidence we have mentioned, 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 We carried out a targeted review of this Standard to better understand how the PSNI ensures it understands the diversity of its Council and Committee members and to obtain further information about the PSNI's future plans in relation to equality, diversity and inclusion (EDI).

3.2 The PSNI carries out a voluntary equality and diversity survey of its registrants on an annual basis to collect data against the equality characteristics set out in Section 75 of the Northern Ireland Act 1998.

3.3 The PSNI uses the data it collects, together with publicly available information about the diversity of the wider population of Northern Ireland, to inform its work, such as equality screening assessments and equality impact assessments (EIA). We saw examples of this in the equality screening assessments published by the PSNI this year when it developed new *Guidance on Provision of Services* and made changes to its *Guidance on patient consent.*

3.4 The PSNI also uses EDI reports and research published by other organisations to inform its work. The equality screening assessment for the introduction of a joint common registration assessment[5] took account of the qualitative research commissioned by the GPhC in 2016 into registration assessment performance among Black-African candidates. The PSNI recognised that the research was based on data from Great Britain but nonetheless considered how the issues identified could be mitigated. The PSNI also gave consideration to Public Health England's report *Beyond the data: Understanding the impact of COVID-19 on*

[5] This was previously referred to as the joint four-country or UK-wide registration assessment.

BAME groups as part of its initial equality screening assessment when developing its *Guidance on Provision of Services*.

3.5 As a small regulator, the PSNI typically deals with smaller numbers in most areas of its work, such as fitness to practise cases. The PSNI recognises that this will impact the statistical significance of any analysis undertaken and will also limit its ability to publish data as individuals may be identifiable when dealing with small numbers. The PSNI has, to date, taken a position of not collecting data in areas of the business, where the findings will not provide any statistically significant information. However, this is a position it is keeping under review and it will be meeting with the Northern Ireland Equality Commission (NIEC) to seek advice on what might be an appropriate, proportionate, and valid approach to collecting and analysing such data in the future.

3.6 When it meets with the NIEC, the PSNI also plans to explore how it can build on and improve the current mechanisms it has in place to ensure its processes do not impose inappropriate barriers or otherwise disadvantage people with protected characteristics. The PSNI's current mechanisms include:

- training for staff, Council and Committee members
- the use of equality impact assessments
- proactively seeking the views of organisations who represent people with protected characteristics
- its recruitment and appointment processes in relation to fitness to practise Committees.

3.7 The timeframes for the meeting with the NIEC and any subsequent work are yet to be confirmed due to the pandemic restrictions. We will monitor this activity as it progresses.

EDI data on Council and Committee members

3.8 One of the areas where the PSNI does not collect EDI data is on its Council and Committee members. It relies on the recruitment process to ensure fairness when recruiting by making sure promotion is done in a manner which does not exclude, that criteria are framed in a way which reflects no potential bias and by making sure that there is no part of the recruitment process that would disadvantage any Section 75 group.

3.9 The PSNI told us it does not collect data about its Council or Committee members for a range of reasons but primarily because it does not directly manage the recruitment processes. It also considers that collecting this data would be a largely redundant exercise of limited statistical significance due to the small numbers involved.

3.10 The Minister for Health in Northern Ireland is responsible for the recruitment and appointments of PSNI's Council members and the process is managed by the Public Appointments Unit of the Department of Health in Northern Ireland (the Department), in line with the Code of Practice for Ministerial Public Appointments. Equality monitoring is part of that process and is handled across all public appointments by the Northern Ireland Statistics and Research Agency (NISRA). The PSNI told us it does not see the merit in duplicating the process

carried out by NISRA and that it recognises the Minister's authority in making appointments.

3.11 The process for recruiting Fitness to Practise Committee members is outsourced to recruitment and HR specialists and the PSNI reports this brings several benefits. It supports the separation of case management and presentation from adjudication and provides an assurance that the recruitment practices are sensitive to longstanding equality and diversity categories and issues in Northern Ireland. The PSNI has been assured by the recruitment specialist that they meet the requirements of the relevant legislation and has confirmed that they collect equality data to this effect. Nonetheless, the PSNI accepts that it could collect data separately and provide feedback to the recruitment agency.

3.12 The PSNI is one of two regulators for which the Authority does not have an advisory or oversight role in relation to the appointment of its Council members.[6] It is also the only regulator we oversee which does not attempt to some degree to collect EDI data on its Council and Committee members. While the other regulators may have a larger pool of Committee members, they all have Councils[7] ranging from eight to 14 members.[8] Although the recruitment and appointment of the PSNI's Council members is the responsibility of the Department (which is discharged through its Public Appointments Unit), we are of the view that there are benefits to collecting EDI data on members that have been appointed.

3.13 We recognise that the PSNI operates in a different context to the other regulators as it is the only one that operates solely in Northern Ireland, which has different demographics to other parts of the UK. The PSNI's EDI considerations are therefore likely to be different to those of the other regulators. We would therefore expect the PSNI to consider the data within its own context, using comparisons against its own registrant population and the wider Northern Ireland population in the same way that we have seen it use these data to inform EIAs. We understand that it may not be possible to publish information when the numbers are so small that individuals could be identifiable. However, this does not mean that the PSNI cannot collect and analyse the data to assure itself of the diversity of Council and Committee members, or to identify issues or opportunities to improve diversity, whilst recognising there will be limitations on the statistical significance of the data due to the small numbers.

Conclusion against this Standard

3.14 We have seen evidence of the PSNI collecting data to understand the diversity of its registrants and using this information, together with public data about the diversity of the wider population of Northern Ireland, to inform its work. The PSNI has mechanisms in place aimed at ensuring its processes do not impose inappropriate barriers or otherwise disadvantage people with protected characteristics and it will be working with the NIEC to identify any areas where these processes could be strengthened.

[6] The Authority also does not hold this role for Social Work England.
[7] Social Work England is an arm's length body with a non-executive unitary board, rather than a Council.
[8] The PSNI can have up to 14 Council members and currently has 10.

3.15 However, we are concerned by the PSNI's decision to not collect or analyse data about its Council or Committee members. These members are responsible for making key decisions across a range of the PSNI's statutory and non-statutory functions. We recognise that the small numbers mean there will be limitations to the statistical significance of the data but we nonetheless consider there is value in collecting and analysing it. Doing so would enable the PSNI to demonstrate an evidence-based understanding of the diversity of these key decision-makers and how this compares to the PSNI's register, as well as the wider population of Northern Ireland. It could also give further insight to the effectiveness of the recruitment and appointments processes and provide an opportunity to identify issues or areas for improvement which could be shared with the organisations that operate these processes on behalf of the PSNI. This would allow the PSNI to assure itself, as far as possible, that the diversity of Council and Committee members is representative of the register and the wider population of Northern Ireland.

3.16 We have given careful consideration to the fact that these concerns relate to only one discrete aspect of the PSNI's performance under this Standard. However, we consider that the potential impact of this is much wider as it relates to the PSNI's understanding of the diversity of its key decision-makers. Consequently, we have concluded that this Standard is not met.

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 The PSNI publicly and regularly reports on its performance throughout the year. By statute, it is required to publish an annual report[9] and its Scrutiny Committee is also required to provide an annual report on its work.[10] In addition, the PSNI provides its Council with non-statutory updates on its performance, such as reports on progress against the corporate strategy and updates on work being undertaken, which this year included its ongoing review of guidance and standards, the introduction of a joint registration assessment with the GPhC, a new CPD framework and new threshold criteria for referring cases to the Scrutiny Committee.

4.2 As we noted under Standard 2, the PSNI also has a programme of internal audit. Full details are reported to its Audit and Risk Committee and public Council papers contain high-level information about the areas which will or have been audited, the overall rating of completed audits and whether recommendations have been accepted. We have not seen any reported instances of serious concerns being identified by audit, or of audit recommendations not being accepted by the PSNI.

4.3 The PSNI uses its *Monitoring and horizon scanning policy and procedure* to identify any emerging themes or issues in the healthcare regulatory landscape

[9] In accordance with Article 4D of The Pharmacy (Northern Ireland) Order 1976.
[10] In accordance with Article 7(1)(a) of The Council of the Pharmaceutical Society of Northern Ireland (Statutory Committee, Scrutiny Committee and Advisers) Regulations (Northern Ireland) 2012.

which it may need to be aware of or respond to. It developed an action plan in response to the Authority's *Lessons Learned Review* (LLR) and the NMC's *Independent audit to review the NMC's handling of documentation relating to midwives at Furness General Hospital*.

4.4 The PSNI also developed a fitness to practise action plan in response to the concerns we reported in our performance review last year. Some of the actions identified overlapped with those set out in the LLR action plan. The majority of actions have been completed and are discussed in more detail under the fitness to practise Standards.

4.5 The PSNI also notified us of a Lessons Learned report it commissioned this year in response to concerns raised internally about the conduct of Scrutiny Committee proceedings which had taken place. The PSNI is implementing the recommendations from the report, which are discussed in more detail under Standard 16.

4.6 We have seen evidence of the PSNI reporting on its performance and taking action to address concerns identified about it. The PSNI identified actions for itself in response to external reports about healthcare regulatory issues and we have seen this work progress during the period under review. In addition, the PSNI increased the frequency of its monitoring and horizon scanning activities during the Covid-19 pandemic to ensure that all relevant healthcare regulatory issues were identified and addressed where necessary.

4.7 We are satisfied that this Standard is met.

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 When consulting and working with stakeholders, the PSNI implements its *Policy and Procedure for carrying out a Public (Major) Consultation* in conjunction with its communication and engagement strategy 2017-2020.

5.2 The PSNI's strategy recognises that as a smaller regulator with limited resources and staff numbers, it must take a proportionate and targeted approach to stakeholder engagement and its policy provides a flexible approach, enabling the PSNI to adapt the type of consultation according to the proposals that need to be consulted on. Where proposed changes are considered major, the PSNI undertakes a full public consultation. Where proposed changes are minor, the PSNI may decide to undertake a targeted engagement exercise, directly seeking the views of a relevant group of stakeholders, rather than a full consultation which would place more demands on resources.

5.3 During the period under review, we saw the PSNI use both types of consultation. Between October and November 2019, a targeted consultation was conducted on minor revisions to the *Guidance on Patient Consent*. This involved seeking the views of 30 organisations representing different stakeholders, including health and social care organisations, pharmacist

representative bodies and organisations representing groups with Section 75 protected characteristics. Full public consultations were conducted on:

- a new CPD framework
- new *Guidance on Provision of Services*
- new fitness to practise threshold criteria.

5.4 Each consultation was followed by the publication of a report[11] setting out the responses received and the impact of the responses on the PSNI's proposals. Where suggestions are not adopted, the PSNI explains the reasons for this. The PSNI also published a report in November 2019 on the consultation it conducted last year about plans to introduce a joint common registration assessment with the GPhC.

5.5 The PSNI works closely with the Department and the Health and Social Care Board Northern Ireland (HSCB). It has MoUs in place with the GPhC and the Pharmaceutical Society of Ireland (PSI).

5.6 We also saw the PSNI identify and work with relevant stakeholders when developing its new *Guidance on Provision of Services.* The PSNI identified different service user groups that may be impacted by the new guidance and it engaged with organisations representing these groups. Organisations were contacted at the policy development stage and at the consultation stage. Groups contacted included the Alzheimer's Society, Mencap, Women's Resource and Development Agency and the Patient Client Council.

Covid-19

5.7 We saw significant collaboration amongst the regulators during the Covid-19 pandemic as well as joint working with other health and social care organisations, such as professional bodies like the Royal Pharmaceutical Society (RPS) and Association of Pharmacy Technicians UK (APTUK). The PSNI was part of a working group led by the RPS to produce an Ethical Decision Making Framework to assist practitioners during the pandemic. Under Standard 7 we have listed a number of joint statements published by the PSNI and its stakeholders in response to Covid-19.

5.8 The PSNI has a clear framework in place which guides its consultation process and stakeholder engagement strategy. We have seen this process being followed and we have seen clear evidence of the PSNI working with a wide range of relevant stakeholders, including patient representative groups.

5.9 We saw collaboration amongst the regulators increase in response to the Covid-19 pandemic with frequent communication and joint-working taking place in order to identify and manage risks to the public.

5.10 We are satisfied that this Standard is met.

[11] With the exception of the report on the consultation on *Guidance on Provision of Services*, which was published in January 2021, all the reports for the listed consultations were published during the period under review.

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.

6.1 The PSNI sets standards for pharmacists, *The Code*, and for pharmacy premises, *Standards for Registered Pharmacy Premises*.

6.2 *The Code* was introduced in March 2016. The PSNI conducts planned reviews every five years so *The Code* will be due for review in 2021. We have not identified any events in the regulatory landscape which would warrant an early review.

6.3 The current *Standards for Registered Pharmacy Premises* have been in place since January 2010. The powers to inspect and investigate pharmacies rest with the Department, however the PSNI will be given new powers to set and enforce standards for pharmacy premises when The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 comes into operation. In preparation for this, the PSNI developed new *Premises Standards*, which it consulted on from 2 October 2017 to 27 November 2017 and were approved by Council in June 2018.[12]

6.4 The *Standards for Registered Pharmacy Premises* contain thirteen overarching standards and provide a 'self-audit tool' in the form of a checklist with a number of essential or desirable indicators under each standard. The new *Premises Standards* instead set out the minimum standards required and are grouped under five mandatory and outcome-focused principles which relate to:

- governance arrangements
- working environment
- patient-centred pharmacy services
- equipment and facilities
- staff training.

6.5 The new *Premises Standards* also have a more explicit emphasis on supporting the safe and effective provision of pharmacy services. We provided a response to the PSNI's consultation on its new *Premises Standards* and supported the shift from a prescriptive approach to compliance to an outcomes-based approach.

6.6 We note that the new *Premises Standards* are not yet in operation as the Commencement Order which would bring The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 into force has been subject to delays, with further delays caused by the Covid-19 pandemic. A commencement date for the new powers is yet to be confirmed. We are satisfied that the standards

[12] Although this work took place prior to the period under review, we are reporting it as our new Standards of Good Regulation capture the work of regulators in respect of premises and businesses, where applicable.

the PSNI has in place in the meantime prioritise patient and service user centred care and safety.

6.7 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 continues to work on its ongoing review of all of its standards and guidance documents. Although the review is taking longer than initially anticipated, the PSNI is taking a structured approach to this substantial piece of work, having completed a preliminary assessment of each existing document and using a Decision Making Framework to ensure it is making clear and consistent decisions. The Framework references the role of standards and guidance in addressing an identified risk to patient safety.

7.2 We have not identified any concerns or public protection risks arising from the length of time the review is taking. Nor have we identified any concerns about the guidance produced by the PSNI this year, which included a revised version of its *Guidance on Patient Consent* and a consultation on new *Guidance on Provision of Services.*

Guidance on Patient Consent

7.3 Following the targeted stakeholder consultation mentioned under Standard 5, the PSNI published a revised version of its *Guidance on Patient Consent* in November 2019*.* The PSNI had previously intended on making more substantial revisions to the guidance to reflect changes in law resulting from the implementation of the Mental Capacity (Northern Ireland) Act 2016. However, the implementation of the legislative changes has been delayed. In light of this, the PSNI deferred making the substantial revisions, instead making minor changes primarily designed to improve the clarity and structure of the guidance. Some minor suggestions made by respondents to the consultation were incorporated while other, more substantial suggestions will be considered when the guidance is subject to the deferred review.

Guidance on Provision of Services

7.4 From 8 July to 30 September 2020, the PSNI consulted on its draft *Guidance on Provision of Services.* The guidance covers three main areas:

- the impact of a pharmacist's religion and/or beliefs on their willingness to provide a specific service
- a patient or service user who is violent, threatens violence or is verbally abusive
- the medicine, service or medicinal device not being currently in stock or available.

7.5 We responded to the consultation, limiting our comments to the section on religion and beliefs, and:

- welcomed the fact that the guidance addresses some of the areas that we previously commented on in response to the draft of the GPhC's equivalent guidance
- suggested the guidance could be stronger on outlining how pharmacists should respond when it is clear that declining to provide a service will have a detrimental impact on the patient or service user
- suggested that the section on factors to be assessed to inform the pharmacist's decision on providing services could be strengthened by including potential risks to the patient resulting from a delay in the service being provided.

7.6 In January 2021, the consultation report was presented to Council and the final version of the guidance was approved and came into effect in February 2021. The final version incorporated responses to the consultation, which were received from a range of stakeholders, including registrants, members of the public, pharmacy representative bodies and patient/public representative bodies.

Covid-19

7.7 As we noted under Standard 1, the PSNI launched a dedicated Covid-19 page on its website in March 2020. It used this webpage to publish statements and guidance, several of which were issued jointly with other regulators or healthcare organisations. Some of the statements were also sent directly to registrants. Topics covered included:

- regulation during the pandemic
- the approach of the pharmacy regulators during the pandemic followed by a statement clarifying it is unacceptable to normalise operating a pharmacy without a responsible pharmacist
- social distancing in pharmacies
- collection and delivery services, including the use of volunteers
- the RPS' Ethical Decision Making Framework
- sources of health and wellbeing help and advice for registrants
- discouraging the sale and supply of rapid antibody testing kits.

7.8 A number of the statements provided information to help registrants understand how to apply the standards in the circumstances. For example, the joint statement about regulation during the pandemic encouraged health professionals to continue using their professional judgement informed by guidance and the principles of professional standards and also confirmed that circumstances would be taken into account should concerns be raised about their practice.

7.9 The joint statement on the approach of the pharmacy regulators, and the subsequent clarifying statement, confirmed that it may be acceptable to operate a pharmacy without a responsible pharmacist in exceptional circumstances but this should not become the norm as it is not in strict accordance with the law.

7.10 The statement of July 2020 on rapid antibody testing kits discouraged their sale and supply, in line with guidance published at the time by the Medicines and Healthcare products Regulatory Agency (MHRA), whilst delineating the different jurisdiction and roles of the MRHA and the PSNI in respect of the matter.[13]

Conclusion against this Standard

7.11 The Decision Making Framework that the PSNI is using for its ongoing review of its standards and guidance sets out criteria to be considered which should ensure that the guidance addresses risk and prioritises patient and service user centred care and safety. We have not identified any concerns about the guidance which has been amended or developed by the PSNI during the period under review.

7.12 When the unprecedented circumstances of the Covid-19 pandemic began unfolding, the PSNI published information about the approach it would be taking and how its standards applied. We saw the PSNI update this information throughout the pandemic. It is clear from the joint statements produced and the topics covered that the PSNI worked with stakeholders to develop guidance that was aimed at addressing emerging areas of risk.

7.13 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 adopts the GPhC's *Standards for the initial education and training of pharmacists*. We reported last year that the GPhC consulted on proposed changes to these standards and was undertaking further stakeholder engagement before finalising its proposals.

8.2 The changes being taken forward are intended to ensure the education and training of pharmacists remains fit for purpose and reflects the changing nature of pharmacy practice, with a focus on patient safety.

8.3 The PSNI participated in the development of the changes and was part of a working group reconvened by the GPhC to finalise the new standards. The working group also included education and training organisations in each country, professional and student representative bodies, trade unions and employers.

[13] The MHRA has since updated its position and is no longer discouraging the sale and supply of these testing kits. We have not identified an updated statement from the PSNI but we note the MHRA's position changed after the current period under review so any associated changes in the PSNI's position will be considered as part of next year's performance review.

8.4 The finalised standards were approved by GPhC's Council in December 2020 and in January 2021 the PSNI's Council approved their adoption by the PSNI. The final version of the standards:

- re-named the learning outcomes, which are now more aligned with post-qualification education and training
- incorporates information and standards relating to the foundation year training which will be introduced and distinguishes between the knowledge and competency levels expected on completion of an MPharm degree from the completion of the foundation training year
- incorporates the requirements for independent prescribing to reflect the move towards including independent prescribing in the initial five-year education and training of pharmacists
- includes requirements for the admissions and selections process for MPharm degrees and the foundation training year
- includes strengthened EDI requirements with more explicit reference to taking account of protected characteristics in the learning outcomes, requires providers to take account of protected characteristics and socio-economic and education backgrounds and analyse data on admissions profiles and student performance at least on an annual basis.

8.5 The PSNI and GPhC expect to begin implementing the new standards using a phased approach from July 2021 and the GPhC has set up an Advisory Group to assist with the transition and implementation.

8.6 In July 2020, the PSNI issued a joint letter with the GPhC and the Chief Pharmaceutical Officers of the UK providing an update on the proposed reforms to initial education and training for pharmacists and the planned next steps. The letter also mentioned proposals to introduce a foundation year to replace the current pre-registration year. This would incorporate training on independent prescribing so trainees can practice as independent prescribers on registration without having to complete a separate training course as currently required. This letter was followed by an update in September 2020 directed at MPharm students summarising the key changes that will be taking place from 2021 and how these will affect students. The regulators have committed to provide regular updates on the progress of this work.

8.7 This joint work is evidence of the PSNI keeping its standards for education and training under review and taking steps to ensure they remain up-to-date. As we reported last year, the new standards have learning outcomes set around four domains which mirror four of the principles in *The Code* and which prioritise patient and service user care and safety. We have not identified any concerns arising from the work completed to date and will continue to monitor its progress.

8.8 We are satisfied that this Standard 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.

9.1 The PSNI works with the GPhC on the accreditation of training programmes. Accreditation visits were paused this year because of the Covid-19 pandemic, however we note that neither of the two education providers in Northern Ireland were due an accreditation visit during the period under review.

9.2 The GPhC had plans to review its accreditation methodology in 2020 but we understand the timeframes for completing this work are likely to have been affected by Covid-19. This review will impact the PSNI's quality assurance process so we will monitor developments and progress in this work.

9.3 Last year, we reported that the PSNI and GPhC had agreed to introduce a joint common registration assessment to replace the existing approach of having two different assessments for Northern Ireland and Great Britain. The first sitting was due to take place in June 2021 but this is now expected to take place in Autumn 2021 due to Covid-19.

9.4 In preparation for this change, the PSNI reviewed and made changes to its pre-registration training and syllabus to ensure they are aligned with the new joint assessment.

9.5 The GPhC's *Standards for the initial education and training of pharmacists* will continue to form the broad framework for the pre-registration training year. The more specific performance standards framework for pre-registration training, which is developed and controlled by the PSNI, will be aligned with the GPhC's *Standards for the initial education and training of pharmacists* from the 2020/21 training year. The PSNI will retain control of the framework's development and Council will retain responsibility for its approval.

9.6 The pre-registration training year includes five compulsory training days and 16 compulsory e-modules, with the topics specified by the PSNI. The five training days will be retained but the number of compulsory e-modules has been reduced to nine. The seven modules that have been removed all relate to minor ailments and will instead be made available as optional modules. In reaching this decision, the PSNI took account of responses received to the consultation on the joint assessment and feedback received from trainees as part of the PSNI's quality assurance processes, as well as the move to the new joint assessment.

9.7 The syllabus produced by the PSNI for the pre-registration year will be replaced with a common registration assessment framework set by the Board of Assessors, which will be accountable to the PSNI and GPhC Councils as per a partnership agreement signed by both regulators.

Covid-19

9.8 There are usually two sittings of the registration assessment each year, in June and October. In March 2020, the PSNI announced that both examinations would be postponed due to the Covid-19 pandemic. When restrictions were eased, the PSNI was able to make arrangements for the exam to be held in

person at venues with social distancing and other safety measures in place. The first sitting was held on 11 August 2020 and the second sitting was arranged for 7 December 2020.

9.9 The pass rate for the August 2020 assessment was 97.8% (132 out of 135 candidates). This is consistent with the high pass rate of previous years; in June 2018, 151 out of 156 (96.8%) candidates passed and in June 2019, 130 out of 139 (93.5%) candidates passed.[14]

9.10 As noted above, the first sitting of the joint common registration assessment was originally due to take place in June 2021. Due to the pandemic, the GPhC's usual assessment sittings in June and September 2020 were cancelled and existing plans to introduce an online assessment were brought forward. Assessments were subsequently scheduled for March, July and November 2021. In certain circumstances candidates were eligible to sit the assessment remotely, however the majority were required to attend designated test centres to sit the exam. The situation in Northern Ireland was different to that in Great Britain, with the PSNI catering to a smaller number of candidates than the GPhC and consequently being able to source sufficient alternative venues to proceed with a paper-based assessment whilst meeting social distancing requirements. As a result, the PSNI decided to defer the introduction of the common registration assessment and to continue to deliver a separate Northern Ireland assessment in June 2021.

Conclusion against this Standard

9.11 The PSNI has not made any changes to its quality assurance process for educational providers and programmes but it is making changes to its pre-registration assessment and consequently to aspects of its pre-registration training year materials and syllabus.

9.12 The changes have not yet been introduced but we have seen the PSNI consider and assess the different options available to it. It carried out a consultation in respect of its preferred option for the joint registration assessment and took account of the consultation responses. The changes that will be made will bring the registration assessment in line with current best practice and will also bring further alignment of education and training standards for pharmacists across the UK. We also saw evidence of the PSNI taking account of feedback received from trainees through its quality assurance process in the course of this work.

9.13 We are satisfied that this Standard is met.

[14] Comparative data from the 7 December 2020 sitting has not been included here as there were only four candidates, three of which passed the assessment.

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's website holds a searchable register, which contains links to fitness to practise information and practise restrictions where applicable.

10.2 We checked the register entries for all appealable decisions[15] reported to us during the period under review. We also checked the entries for all registrants[16] removed by the PSNI following fitness to practise proceedings. All register entries were accurate and in accordance with the PSNI's *Policy on the disclosure and publication of FTP information*.

Temporary register in response to Covid-19

10.3 With the enactment of the Coronavirus Act 2020, the PSNI was empowered to temporarily register fit, proper and suitably experienced persons as pharmacists. The temporary register went live on 3 April 2020 and a separate search function was added to the PSNI's website with a note that 'Before engaging a Pharmacist on the Covid-19 Temporary Register employers should satisfy themselves of their: identity, health, character, competence and skills.'

10.4 The temporary register launched in two phases:

- the first phase added registrants who had left the register in good standing within the previous three years unless they had opted out
- the second phase allowed individuals to apply for registration if they could demonstrate they were, or had been, registered with the GPhC, PSI or other EEA pharmacy register within the previous three years and had left in good standing if not currently registered.

10.5 Before the first phase, the PSNI wrote to prospective temporary registrants to provide them with the opportunity to opt-out. It also published information on its website about its approach and how individuals could opt out.

10.6 Shortly after the temporary register went live, the PSNI published its policy on the use of the powers for temporary registration.[17] The policy set out the approach taken by the PSNI to concerns raised about temporary registrants: all evidence will be reviewed, including a submission from the registrant where possible, and the Registrar will remove a person only if the evidence suggests that removal is:

- necessary to protect the public
- otherwise in the public interest

[15] These are decisions that we can refer to the Court to be considered by a judge under Section 29 of the NHS Reform and Health Care Professions Act 2002 (as amended).
[16] This included one premises registration.
[17] https://www.psni.org.uk/wp-content/uploads/2020/04/Use-of-powers-for-temporary-registrations-of-persons-pdf.pdf

- in the interests of the temporary registrant.

10.7 We have not identified any concerns about the PSNI's main register or the temporary register it set up in response to the Covid-19 pandemic.

10.8 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 Last year we were satisfied that the PSNI's process for registration was efficient and we noted that it consistently processes applications within two weeks. However we expressed significant concerns about the transparency and fairness of one discrete aspect of the registration process which related to voluntary interviews for applicants first registered in the EEA.

11.2 The PSNI's legislation requires it to register applicants who meet its education and indemnity requirements. It cannot refuse registration on the basis of knowledge of English. In order to address this, the PSNI was operating a process whereby applicants may be invited for a voluntary interview if potential concerns about their knowledge of English were identified from their application form. Our concerns arose because:

- applicants invited for interview were not told in a clear and unambiguous way that the purpose of the interview was to assess their communication skills, nor were they told that it may result in a fitness to practise referral being made against them once they are registered
- there were no criteria in place to guide decisions on who should be invited for interview or when a fitness to practise referral should be made.

11.3 In last year's report, we said that our concerns could have led to us concluding that the Standard was not met. It was because the PSNI had not used the process during the review year, combined with the general efficiency of the remainder of the process, that we decided that the Standard was met. We said that should the process remain the same in future years, we may not be able to take a similar view.

11.4 The PSNI told us this year that it is no longer operating the interview process. Instead, applicants are registered and any potential concerns are investigated through the fitness to practise process. This mirrors the process the PSNI uses when applicants make a health and character declaration because the PSNI's legislation does not empower it to refuse registration on the basis of concerns about health or character.[18]

11.5 The discontinuation of the voluntary interview process addresses the concerns we had last year about the fairness and transparency of the process.

[18] We have previously reported on these legislative challenges and the ongoing engagement between the PSNI and the Department about progressing legislative changes. The Department has recently begun re-engaging with the PSNI on the Knowledge of English Regulations so the PSNI anticipates there will be progress soon.

11.6 The PSNI's registration process remains efficient, with applications consistently processed within two weeks. The PSNI did not receive any registration appeals during the period under review.

11.7 The process to apply for registration of a pharmacy premises is set out on the PSNI's website with links to the necessary application forms. The PSNI passes application forms on to the Pharmaceutical Inspectorate in the Department of Health and Social Services and Public Safety (DHSSPS), which is responsible for carrying out inspections. On notification from DHSSPS that the premises meets the necessary standards, the PSNI registers the premises. We have not identified any concerns about the process for registration of pharmacy premises.

Temporary register in response to Covid-19

11.8 As detailed under Standard 10, the PSNI was granted powers to set up a temporary register in response to the Covid-19 pandemic and it did so in two phases. Before the temporary register went live, the PSNI published information on its website and wrote directly to prospective registrants to explain how phase one would work and the process for opting out. The process for applying to the temporary register under phase two was also set out on the website.

11.9 The PSNI identified a number of registrants who had not renewed their registration or provided a CPD submission but had attempted to join the temporary register. The processes introduced by the PSNI to manage temporary registration enabled it to make a decision about whether these individuals should be added to the temporary register. It decided the risks outweighed the benefits in the circumstances.

11.10 The PSNI has addressed the concerns we reported last year by discontinuing the process we were concerned about. We have not identified concerns about the PSNI's registration process this year or the process it introduced for temporary registration and the data shows that the PSNI continues to process applications efficiently.

11.11 We are satisfied that this Standard 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 The PSNI does not have powers to take action in instances of illegal practice. Under the Medicines Act 1968, it is the Department that has powers to investigate these types of concerns and take action where necessary.

12.2 We know that the PSNI works closely with the Department and regularly meets with them to share information about ongoing investigations. There have been no reported changes in this area.

12.3 We are satisfied that this Standard is met.

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

13.1 The PSNI uses a CPD framework to assess whether its registrants continue to be fit to practise. As alluded to under Standards 6 and 12, it is the Department, not the PSNI, that is responsible for conducting inspections or investigations of pharmacy premises but as the PSNI sets the standards for pharmacy premises, it will be working with the Department to develop and test criteria for the Medicines Regulatory Group's[19] inspection team to use. This work is ongoing as it is tied to the commencement of The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016, which is yet to come into effect. We will monitor this work as it continues.

13.2 In previous reports we have documented the PSNI's work to develop and introduce a new CPD framework. Last year we reported that the PSNI had finalised its proposals and publicly consulted on the new framework between October 2019 and January 2020. It was due to be introduced from June 2020 but, as we reported last year, this was deferred until 1 June 2021 because of the Covid-19 pandemic.

13.3 The PSNI publishes statistics relating to CPD activity in its annual report which includes the number of registrants removed for non-compliance with CPD and the percentage of CPD submissions that met the required standard. The data reported in recent years shows that the numbers remain relatively consistent.

13.4 We have not identified any concerns about the existing framework being used or the new framework that will be introduced. The PSNI will be monitoring and assessing the implementation and impact of the new framework upon its introduction. It plans to assess the impact using feedback from registrants and analyses of outcomes for registrants, including of compliance levels and pass rates. We will monitor this activity in future performance reviews.

Covid-19

13.5 The deadline for CPD submissions is usually 31 May each year, which is also the deadline for registration renewals. Registrants who do not comply with the requirements are removed from the register in mid-August and the PSNI then publishes a list of registrants who have been removed. All of these activities were delayed this year because of Covid-19. The PSNI extended the registration year, and the accompanying deadline for CPD submissions, to the end of August. These changes do not appear to have had a significant impact on the submission rate or numbers of registrants removed from the register for non-compliance. The submission rate was 98.4% and 18 registrants were removed from the register for non-compliance with CPD.[20] In Summer 2019, the submission rate was 99.38% and 15 registrants were removed for non-compliance.[21]

[19] The Medicines Regulatory Group is part of the Department and provides specialist and professional advice on key matters relating to medicines regulation. The pharmacy inspectorate sits within this Group. https://www.health-ni.gov.uk/articles/about-medicines-regulatory-group

[20] Submission rate and number of removals taken from information published on the PSNI's website.

[21] Data for Summer 2019 taken from the PSNI's *Annual Report and Accounts 2019-20*.

13.6 When the PSNI initially announced the new CPD submission deadline of 31 August 2020, it received a number of complaints concerned about the additional pressures this placed on pharmacists during the pandemic. Some of the complaints highlighted the GMC and GPhC decisions to postpone CPD requirements. Council reconsidered its initial decision in light of the points raised and reaffirmed its decision on the basis that postponing further would pose a greater risk to the public and may be counterproductive in the event of a new deadline coinciding with a second wave.

13.7 As a consequence of the extended registration year in 2020, the CPD year for 2020/21 will be reduced from 12 months to nine (1 September 2020 to 31 May 2021). The PSNI has reduced the time requirements accordingly; from 30 hours to 22.5 hours for full submissions and from 15 hours to 13 hours for partial submissions.

Conclusion against this Standard

13.8 We do not have any concerns about the CPD framework the PSNI has in place or the framework it will be introducing in June 2021. We have seen evidence of the PSNI reviewing and adapting its requirements in light of Covid-19 to try to alleviate pressure on registrants at the height of the pandemic whilst also balancing this against the potential risks to the public, taking account of the future consequences of its decision as well as the concerns expressed by a small number of registrants. We consider that the PSNI adopted a proportionate way of satisfying itself that its registrants continue to be fit to practise in the circumstances of the pandemic.

13.9 We are satisfied that this Standard is met and will be monitoring the introduction of the new CPD framework.

Fitness to Practise

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

14.1 Last year, we carried out a targeted review, which included an audit, of the equivalent Standard[22] because the data showed that approximately 50% of referrals received by the PSNI were closed at the initial stages of its fitness to practise process without a referral to its Scrutiny or Statutory Committees. This appeared to be a high proportion of closures so we wanted to understand the reason(s) for this.

14.2 There are two decision-making points at which the PSNI may decide to administratively close a case without a referral to one of its committees:

- at initial screening for not meeting the jurisdictional test
- following investigation for not meeting the threshold criteria.

[22] Standard 1 of the previous Fitness to Practise Standards.

14.3 Our audit last year did not identify any significant concerns about the closure decisions made at either the initial screening stage or the threshold criteria stage.

14.4 The data[23] from this year shows that the PSNI received a similar number of referrals to last year; it received 48 referrals in 2018/19 and 52 in 2019/20. The Registrar closed 48 cases in 2019/20[24] so the number of cases closed without a referral to one of its committees continues to be relatively high but, based on our audit findings from last year, we are satisfied that this is not indicative of any barriers to complaints being raised. The PSNI progressed more cases to its Scrutiny Committee this year than last, in both percentage and absolute terms. In 2018/19 the PSNI's Scrutiny Committee made four decisions, which is 8.3% when calculated as a proportion of the 48 referrals received during the same period. In 2019/20 the Scrutiny Committee made 11 decisions, which is 21.2% when calculated as a proportion of the 52 referrals received during the same period. We have not identified any concerns arising out of the data we have seen.

Covid-19

14.5 The PSNI continued to accept and log referrals received during the Covid-19 pandemic but it took a risk-based approach to progressing investigations, publishing this statement on its website: 'The majority of complaints we will not actively investigate at this time, rather we will prioritise those cases that may impact on immediate patient safety, making interim order applications where we consider the evidence suggests there is an immediate risk to patient and/or public safety.' The PSNI has since been able to resume progressing cases normally where the investigation is directly within the control of the PSNI and not subject to a third party investigation.

14.6 We have not identified any evidence which raises concerns about performance against this Standard. We are satisfied that this Standard is met.

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 We carried out a targeted review of this Standard to obtain further information about three areas of the PSNI's work:

- changes made in response to concerns we reported last year about the fairness and transparency of the fitness to practise process
- the impact of Covid-19 on case progression

[23] Unless otherwise stated, the data is the financial year data we collect from the regulators.
[24] This data was reported by the PSNI in its annual report for 2019/20 which covers the period 1 June 2019 to 31 May 2020.

- the high rate of hearing adjournments over the last two performance review periods.

15.2 Our concerns about fairness and transparency last year arose from our audit[25] which found that:

- processes were not always fully and clearly explained to the parties
- decisions and their accompanying reasons were not recorded contemporaneously
- the jurisdictional test applied by the PSNI at initial screening was not explained to the parties
- parties were not usually told explicitly that the PSNI had decided the jurisdictional test had been met/not met
- in a significant number of cases parties were not kept informed of the progress of their case, what the next steps would be or what the possible outcomes were at each stage
- in a small number of cases information had been presented to the registrant or a third party in a way that was not fully accurate or omitted certain details
- in almost all of the cases where the registrant was contacted, we did not see evidence of the process being clearly explained to them
- the PSNI's internal guidance set out timeframes for updating complainants but did not provide equivalent timeframes for updating registrants.

15.3 By the time we published our report last year,[26] the PSNI had already implemented a number of changes in response to our concerns and we recognised and welcomed this prompt action.

15.4 The following changes have been made by the PSNI:

- from May 2020, it reduced the use of verbal communications (where they are used they will be documented immediately)
- in June 2020, it introduced written guidance on its jurisdictional test and decision-making tools and templates for documenting decisions on whether concerns meet the jurisdictional test and the threshold criteria
- in October 2020, it introduced a new *FTP Communications policy* which sets out requirements for the frequency of communications with all parties.

15.5 The PSNI briefed and trained all relevant staff on the changes and it carries out weekly checks to ensure the new processes and tools are being complied with. These weekly checks involve a review of every live case with non-compliances being reported to the PSNI's Senior Management Team. No instances of non-compliance have been found, although the weekly checks are not documented.

15.6 We note that the PSNI decided to reduce its use of verbal communications in response to our audit finding last year that we were not able to assure ourselves

[25] The audit looked at all cases closed by the PSNI at the initial stages of its fitness to practise process during last year's review period; 1 November 2018 to 31 October 2019.
[26] Our 2018/19 performance review report was published in September 2020.

that processes had been fully and clearly explained to the parties because this was often done verbally without the conversations being documented. For the avoidance of doubt, we do not have concerns about the use of verbal communications but consider all communications should be documented. Notwithstanding this point, in our view, the changes made by the PSNI are appropriately focused on the areas where we raised concerns last year and we recognise that the PSNI is making progress in addressing those concerns. We have also recognised that the PSNI was prompt in implementing changes, having already made a number of changes before the publication of our report last year in response to feedback we provided after our audit. However, our performance review is retrospective and covers the period of November 2019 to October 2020. We must therefore consider the timing of the changes in the context of that time period. In this context, we note that the processes which gave rise to our concerns last year continued to operate for the majority of the period under review. The new *FTP Communications policy* was introduced in the last month of the period under review so its impact on this performance review is minimal. The other changes were made in the seventh and eighth months of the period under review so would have been in effect for less than half of the period. Consequently, we have not yet seen evidence that the changes have had the desired effect of addressing last year's concerns.

15.7 We are concerned by the PSNI's decision to not document its weekly compliance checks, particularly in light of views we expressed last year about the importance of accurate and contemporaneous record-keeping. The PSNI considers that, with a small fitness to practise team of two conducting both the investigations and the compliance checks, documenting the checks would be disproportionate and add no or limited value. It does not intend to change its approach. We do not agree that it would be disproportionate to record the checks contemporaneously in some way. In our view, documented checks would serve to provide internal and external assurance that processes and policies are being adhered to.

Timeliness of fitness to practise investigations

15.8 Last year, we were concerned by significant delays we saw in some of the cases we audited but we acknowledged that some of them were partly explained by the unplanned absence of a key staff member and we noted that the overall end to end median timeframe remained under 52 weeks. We decided that the Standard relating to timeliness[27] was met but we said we would monitor timeliness closely.

15.9 The Covid-19 pandemic first began impacting the regulators in March 2020; five months into the PSNI's review period. The PSNI initially placed investigations and hearings on hold, unless they were assessed as involving a risk to public protection. The PSNI was subsequently able to resume and progress cases that were not subject to third party investigations.

15.10 In response to our targeted review, the PSNI told us that since the initial outbreak, substantial work has been done to progress cases and cases that are

[27] Standard 6 of the previous Fitness to Practise Standards.

directly within its control are now progressing normally, albeit through virtual hearings. All new substantive referrals to the Statutory Committee are now case managed and progressed virtually with the consent of the parties involved. The PSNI told us this has resulted in no significant delays to date. It also told us that some investigations are subject to delay where external agencies are lead agencies in the investigation. We have therefore considered the data we have about timeliness in the context of this response.

15.11 The chart at Figure 1 below shows data on the number of open cases over 52 weeks old and shows that this has decreased since 2018/19. This confirms that the PSNI has been able to continue progressing its older cases.

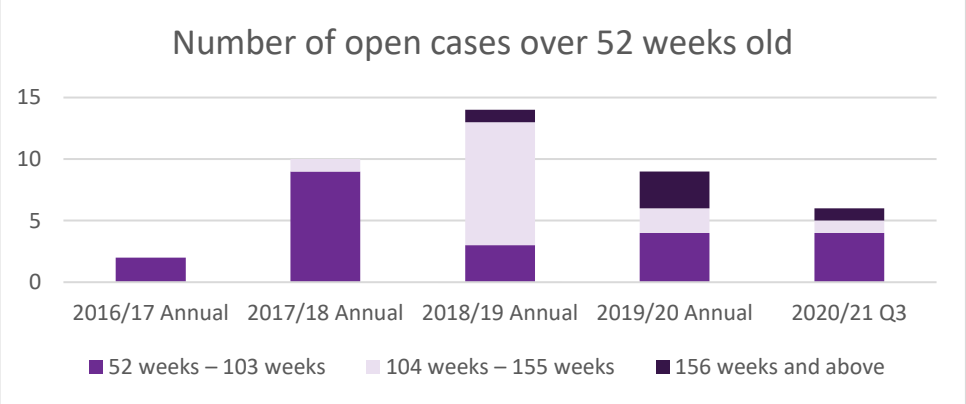

Figure 1

15.12 The chart in Fig. 2 below illustrates the PSNI's data on three of the key timeliness measures for fitness to practise investigations. It is common for the PSNI's data to contain large fluctuations because of its small caseload and this can be clearly seen in the chart, particularly in the quarterly data.

15.13 Due to the frequent fluctuations in the quarterly data, we have looked at the data across the last few years. All three timeliness measures are showing an upwards trend. There are small increases in the time taken from referral to final Scrutiny Committee decision and final Scrutiny Committee decision to final Statutory Committee decision or other final disposal. When reporting its timeliness data to us during the year, the PSNI highlighted that the median time taken from receipt of referral to final Scrutiny Committee decision included eight linked cases that were subject to a lengthy external investigation. As the increases in the median time from referral to Scrutiny Committee decision and final Scrutiny Committee decision to final Statutory Committee decision are small, we do not consider them to be significant at this time. However, the upwards trend in the time taken from referral to final Statutory Committee decision or other final disposal is more marked. The PSNI told us that the pandemic has not significantly impacted its timeliness and this leads us to conclude that the upwards trend is due to factors unrelated to the pandemic. We are therefore concerned that this is an early indicator of deterioration in performance in this area.

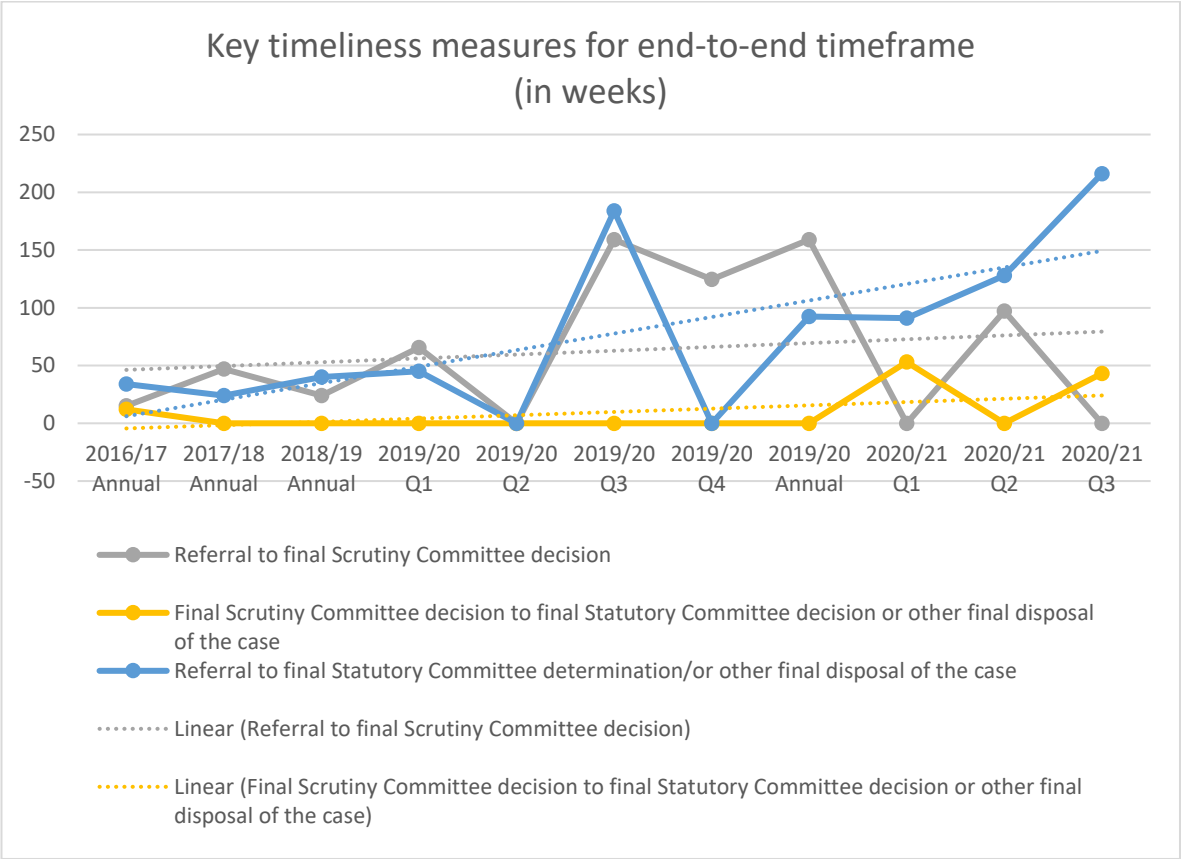

Figure 2

Hearing adjournments

15.14 During the last two performance review periods, the PSNI's Statutory Committee concluded 10 hearings.[28] Seven of them were subject to one or more adjournments before they concluded. There were a total of 12 adjournments across these seven cases. A small number of adjournments were due to the Covid-19 pandemic and the PSNI provided further details about the other adjournments which showed that they were granted for a range of reasons, some of which were outside the PSNI's control.

15.15 The most common reason, which applied to six of the 12 adjournments, was that there was insufficient time to conclude the hearing. The PSNI has a process in place to estimate the likely length of a hearing, which involves requesting information from the parties about witnesses and time estimates.

15.16 There will always be cases that exceed the scheduled hearing length due to unforeseen and unpredictable circumstances. The PSNI's process for estimating hearing lengths appears reasonable as it takes account of relevant factors. However, should there be a continued pattern of cases adjourning due to insufficient time to conclude, this may suggest that the process needs reviewing. We are currently in receipt of data from the PSNI up to and including

[28] The PSNI holds a low number of hearings each year so we also considered last year's data when checking for evidence of patterns or trends.

Q3 of 2020/21 and four hearings have taken place with no adjournments. This is promising but we will monitor this to ensure performance is sustained.

Conclusion against this Standard

15.17 This Standard captures elements of fitness to practise Standards 3, 5, 6 and 8 of our previous *Standards of Good Regulation*. Last year, of these four Standards, fitness to practise Standard 5 was not met because of our concerns about the transparency and fairness of the PSNI's fitness to practise process. While fitness to practise Standard 6 was met last year, we expressed some concerns about the timeliness of case progression and said we would monitor this closely.

15.18 It is clear that the PSNI is committed to addressing our concerns as it took prompt action to implement changes. We welcome these steps and carefully considered whether we had seen sufficient evidence of improvement for the Standard to be met this year.

15.19 We did not conduct an audit of fitness to practise cases this year. However, the timing of the changes means that they will not have had an impact on the majority of the period under review and as such we have not seen tangible evidence to assure us that the changes have fully remedied our concerns from last year. Documented compliance checks could have provided useful assurance that the changes were embedded and having an impact. In addition, we are concerned by what appear to be early indicators of a deterioration in timeliness of case progression. We have therefore 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 We carried out a targeted review of this Standard to obtain further information about three areas of the PSNI's work:

- changes made in response to concerns we reported last year about the recording of decisions and their reasons and the absence of written guidance explaining the jurisdictional test applied by the PSNI
- the impact of the new threshold criteria introduced by the PSNI in June 2020
- the guidance provided to the Scrutiny and Statutory Committees to support decision-making.

16.2 Last year, the Standard relating to decision-making[29] was met because we did not identify any significant concerns about decisions made by the PSNI. However, we expressed concerns because our audit found that decisions made at the initial stages of the FTP process were not always fully, accurately or contemporaneously recorded and the PSNI was applying a jurisdictional test

[29] Standard 8 of the previous Fitness to Practise Standards.

without having written guidance explaining what the test was or how it was applied.

16.3 In order to address these concerns, the PSNI introduced:

- a decision-making tool and accompanying templates
- written guidance on its jurisdictional test, which explains the criteria a concern must meet to fall within the PSNI's jurisdiction and provides examples of concerns which do not fall within its jurisdiction.

16.4 In our view, these are positive improvements as the introduction of these documents should support consistent decision-making and improved record-keeping.

16.5 As mentioned under Standard 15, the PSNI has been carrying out weekly checks to ensure the changes it has introduced are being complied with and it has not identified any instances of non-compliance. This provides some assurance that the new documents are being used as intended. However, as we also noted under Standard 15, we are concerned that these checks are not documented in any way by the PSNI given the views we previously expressed about the importance of accurate and contemporaneous record-keeping.

New threshold criteria

16.6 The PSNI introduced new threshold criteria in June 2020. The criteria are used to decide whether concerns should be referred to the Scrutiny Committee.

16.7 Due to the relatively small number of cases managed by the PSNI, it may take some time to produce sufficient information to enable an assessment of the impact of the new criteria. In the meantime, the PSNI is monitoring the use of the new criteria to ensure they are applied properly.

16.8 We have not seen any evidence that is indicative of concerns about the new criteria or their application. We will monitor this as more information becomes available.

Guidance for the Scrutiny and Statutory Committees

16.9 Our targeted review to seek further information about the guidance provided to the Scrutiny and Statutory Committees was prompted by three separate factors:

- the PSNI began holding hearings remotely as a result of the Covid-19 pandemic
- a Lessons Learned report commissioned by the PSNI identified concerns about the Scrutiny Committee acting beyond its role and remit
- the Authority issued learning points to the PSNI about a Statutory Committee decision because we had concerns about the panel's approach and its failure to fully carry out its role as a panel of inquiry.

16.10 In response to the pandemic, the PSNI moved from in-person hearings to remote hearings. We wanted to understand whether the PSNI had provided any additional guidance to support decision-making in this new environment.

16.11 The PSNI did not anticipate decision-making in remote hearings to be different to in-person hearings so its usual training and guidance documents were still applicable. These primarily comprise regular training by an external law firm, its Manual for the Fitness to Practise Committees (FtP manual) and Indicative Sanctions Guidance (ISG). These were supplemented by a Standard Operating Procedure for remote hearings and the Authority's guidance on virtual hearings. The PSNI also ensured that all substantive referrals were subject to case management so that any issues relating to the remote nature of the hearing could be resolved.

16.12 The PSNI notified us of five appealable hearing decisions during the period under review, all of which took place remotely. We did not identify any significant concerns about decision-making arising out of the hearing being held remotely. Nor have we identified any concerns about the PSNI using the same decision-making guidance for remote hearings as it does for in-person hearings.

16.13 The Lessons Learned report commissioned by the PSNI looked at a number of linked Scrutiny Committee decisions after concerns were raised with the PSNI about the conduct of proceedings. The review was conducted by an external law firm and found that the Scrutiny Committee decisions were reasonable but made a number of recommendations, including the re-training of all Scrutiny Committee members with a particular emphasis on the scope and extent of their role and the addition of new procedures around seeking further information and providing the parties with the opportunity to comment on any new information received as a result.

16.14 The PSNI updated its training and FtP manual with a new procedure to be followed in the event the Scrutiny Committee directs further investigations to be undertaken. New training was delivered to all Scrutiny Committee members in October 2020, which also covered additional details on the role of the Committee and highlighted matters that usually fall outside its remit. We noticed that the updated version of the FtP manual did not contain the same level of detail about the role and remit of the Scrutiny Committee as the new training. We commend the steps taken by the PSNI in commissioning the Lessons Learned report when concerns were raised and implementing the recommendations from that report. In our view, the measures implemented by the PSNI to prevent a recurrence of the issues could be strengthened by including further detail in the FtP manual about the role and remit of the Scrutiny Committee and the limitations of its role.

16.15 Turning to the final factor that prompted our targeted review of this Standard, similar matters arose around whether the Statutory Committee properly fulfilled its role in reaching a decision that we subsequently reviewed under our Section 29 powers.

16.16 In the case in question, the PSNI and the registrant had jointly proposed disposing of it with a seven year undertaking which would then lapse without review. The proposal was agreed by the Statutory Committee. Having regard to the particular circumstances of the case, we considered the outcome was not insufficient for public protection but we issued learning points about:

- the panel and the PSNI taking a flawed approach to the overarching objectives which gave undue priority to evidence of remediation

- the rationale in the decision being lacking at times
- the instructed expert being expected to simultaneously fulfil the role of clinical adviser, performance assessor and independent expert and being asked to reach a view on matters which were the remit of the panel
- the PSNI mentioning remediation undertaken in response to interim conditions without providing the panel with details of the interim conditions
- the panel mentioning it had misgivings without elaborating on what those were or ensuring the issues were interrogated

16.17 From reviewing the PSNI's FtP manual and ISG, we know that at the time the decision in question was made, there was guidance in place for the Statutory Committee on when undertakings might be appropriate, the type of factors to take account of and the need to provide clear reasons for various aspects of its decision-making. The PSNI has not indicated whether it intends to make any changes to its FtP manual or ISG in light of the learning points we issued but, in our view, they highlight some aspects of the guidance which could be strengthened. Further details could be included on:

- the inquiry role of the Committee and its responsibility to fully interrogate all the issues before it, regardless of whether a particular outcome is being jointly proposed by the PSNI and the registrant
- the role of specialist advisers and the limitations of their role
- how the Committee should take account of interim conditions as well as interim suspensions.

Statutory Committee powers

16.18 In correspondence about the case discussed at 16.16, the PSNI explained that its approach had been partly influenced by its interpretation of the powers of its Statutory Committee in respect of whether conditions could be reviewed. We were concerned about this because the PSNI's approach did not accord with our understanding of the legislation or the powers of other regulators. Following discussions, the PSNI agreed to adopt an approach which accords with our understanding of its powers.

16.19 We had significant concerns about the PSNI's initial position on the powers of its Statutory Committee, particularly as this had a real impact on the outcome of a case. However, now that it has revised its position, we are assured that its approach should ensure public protection.

16.20 When describing the Statutory Committee's powers, the FtP manual mainly quotes the section of the PSNI's legislation[30] without elaboration. We therefore consider the FtP manual and published information would benefit from being updated with clear information setting out the PSNI's position.

[30] Schedule 3, Paragraph 7(3)(b)(i) of the Pharmacy Order 1976.

Conclusion against this Standard

16.21 In assessing this Standard, we have looked at information available about the decisions made at each stage of the PSNI's fitness to practise process:

- at triage based on the jurisdictional test
- following investigation against the new threshold criteria
- by the Scrutiny Committee
- by the Statutory Committee.

16.22 Last year, we did not identify any significant concerns about fitness to practise decisions through our audit of cases closed at the initial stages or through our Section 29 review of appealable decisions. We expressed concerns about the recording of decisions at the initial stages of the process but those concerns did not result in the Standard not being met.

16.23 This year, we have not identified any decisions which we considered insufficient for public protection and the PSNI has taken steps to address our concerns about the recording of decisions at the initial stages of the process.

16.24 However, our assessment identified concerns about some of the decisions made at the later stages of the process by the Scrutiny and Statutory Committees, which in particular raised questions about the Committees' understanding of their role and remit. We also initially had significant concerns about the PSNI's position on the powers of its Statutory Committee but these were allayed when the PSNI revised its position and agreed to adopt our preferred approach, which, in our view, ensures public protection.

16.25 When considering the concerns about the Committees' understanding of their role and remit, we looked at the mechanisms the PSNI has in place to support good decision-making. The evidence shows that the PSNI uses a number of different tools aimed at supporting and ensuring good decision-making. It took action to identify and implement improvements in these tools when concerns were raised about a number of Scrutiny Committee decisions. Based on the recommendations from the Lessons Learned report, the learning points we issued about a Statutory Committee decision and the correspondence we exchanged about the powers of the Statutory Committee, we have identified some areas where we consider the tools could be further strengthened. However, we recognise that we have not identified any decisions made during the period under review which we considered insufficient for public protection. As a result, although we have identified some areas for improvement, we consider that the PSNI generally takes steps to ensure 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.

16.26 Consequently, 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 Last year, the equivalent Standard[31] was met because the dataset showed that the PSNI continued to act promptly in applying for an interim order when it identified one as necessary, and our audit did not find any evidence to suggest the PSNI was not identifying risks or prioritising serious cases. We did however note that there were some limitations to our audit data because the cases we saw were mostly about low level concerns. We also reported concerns about the PSNI's approach to documenting risk assessments because there were limited narratives recorded which meant we could not always establish whether all relevant factors had been assessed.

Interim orders

17.2 The table below shows data on the length of time taken for an interim order committee decision.

Median time (in weeks) to IO committee decision:	Annual 2015/16	Annual 2016/17	Annual 2017/18	Annual 2018/19	Annual 2019/20
From receipt of referral	8	3	18	0	4
From decision that there is information indicating the need for an IO	4	3	2	0	4

17.3 The median timeframe for both measures increased in 2019/20 when compared to 2018/19. We do not consider this increase to be indicative of concerns because we know that the PSNI's data is particularly susceptible to fluctuations due to its small caseload. This can be seen in the fluctuation in the time taken from receipt of referral to interim order committee decision between 2016/17 to 2018/19. In addition, we do not consider a median timeframe of four weeks for both dataset measures to be a concerning length of time.

Approach to documenting risk assessments

17.4 In response to our audit findings last year, the PSNI accepted that a greater narrative could have been recorded in each case regarding the factors which influenced the risk rating. It told us that this issue is being assessed as part of the development of a bespoke Case Management System (CMS), which is currently scheduled for implementation in April 2021. In our view, it is not

[31] Standard 4 of the previous Fitness to Practise Standards.

necessary to await the introduction of a bespoke CMS to improve the documenting of risk assessments. However, the PSNI has not reported making any changes to its approach to documenting risk assessments in the intervening period.

17.5 The PSNI has monthly meetings with the Department and HSCB where risks associated with ongoing investigations are discussed and considered. Our view is that some assurance can be taken from these regular discussions with external organisations that there are mechanisms in place to ensure that risks are being actively monitored and identified. We have not seen any evidence to the contrary.

Covid-19

17.6 During the Covid-19 pandemic, the PSNI continued to receive and log complaints but used a risk-based approach in deciding whether to progress the investigation or place it on hold. Risk assessments were conducted and cases assessed as presenting an immediate risk to the public were advanced if they met the threshold for interim order. Other cases were advanced where the risk assessment changed or where it was possible to progress safely. The PSNI also took a risk-based approach to holding fitness to practise hearings, continuing to list interim order application and interim order review hearings, and substantive review hearings.

Conclusion against this Standard

17.7 The data shows that the PSNI continues to act promptly to seek an interim order when it identifies the need for one. When national restrictions were imposed as a result of the Covid-19 pandemic, the PSNI took a risk-based approach to managing fitness to practise hearings and investigations by prioritising cases which posed a risk to the public.

17.8 The PSNI has not yet addressed the concerns we raised last year about its approach to documenting risk assessments. We consider improvements could have been implemented independently of the introduction of a bespoke CMS so we expect to see changes next year even if there are delays to implementing the new CMS.

17.9 Last year, we did not consider the PSNI's approach to risk assessment to be sufficiently concerning to warrant the equivalent Standard not being met and there is no evidence of a deterioration in performance this year.

17.10 We are satisfied that this Standard is met this year, and we will monitor the introduction of the new CMS and any changes that are made to the risk assessment process either as a result or in the interim.

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

18.1 We carried out a targeted review of this Standard to obtain further information about the work done by the PSNI to address the concerns we reported last year and the impact of any changes made.

18.2 Last year, the equivalent Standard[32] was not met because, based on our audit findings, we could not conclude that parties were routinely updated on the progress of their case or that parties were provided with the information they needed to enable them to participate effectively in the process.

18.3 Under previous Standards, we have already mentioned a number of changes made by the PSNI to address our concerns, including the introduction of written guidance on its jurisdictional test in June 2020 and a new *FTP Communications policy* in October 2020, expanding on the previous guidance for when parties should be updated.

18.4 The PSNI also:

- updated its fitness to practise information leaflets for registrants and complainants, improving the level of detail and incorporating information about the jurisdictional test which reflects its new written guidance on the same
- produced tools to support participation in remote hearings when it began holding hearings in this way due to the pandemic, including a Standard Operating Procedure for remote hearings, case management meetings and test meetings in advance of the hearing
- provided training to panel members on the mental health impact of participation in fitness to practise proceedings.

18.5 Last year we reported that we would be monitoring progress of the PSNI's plans to introduce a *Supporting Participation policy* and explore the introduction of a bespoke CMS. The PSNI also had plans to review its *FTP Feedback policy*, which it uses to proactively seek feedback from parties involved with proceedings once a case has concluded. These pieces of work were not completed during the current period under review, mainly due to the Covid-19 pandemic, so we will continue to monitor their progress.

18.6 With regards to the changes that were made during the period under review, we welcome them and believe that they demonstrate the PSNI's commitment to addressing the concerns we reported last year. In our view, the changes improve the framework the PSNI has in place to ensure parties are supported to participate effectively in the process. While this is positive, the framework will only be effective if it is being applied and complied with in practice. Our audit last year found that the framework in place at the time was not being fully complied with in practice.

18.7 There is no public information about how the PSNI's updated framework is being applied in practice but, as we have mentioned under previous Standards, the PSNI conducted weekly compliance checks of every live case which found no instances of non-compliance. However, we again note that these compliance checks are not documented by the PSNI.

18.8 We have also taken account of the timing of the changes made by the PSNI. As we acknowledged under Standard 15, the PSNI was prompt in implementing changes, having introduced a range of improvement measures in response to

[32] Standard 7 of the previous Fitness to Practise Standards.

our audit and final report last year. However, the timing of the changes must be considered in the context of the period that is under review. In particular we note that the new *FTP Communications policy* was introduced in the last month of the period under review, so its impact on our assessment is very limited.

18.9 We did not conduct an audit of the PSNI's fitness to practise cases this year and we have carefully considered whether we have seen sufficient evidence of improvement for the Standard to be met this year. We are satisfied that the PSNI's framework for supporting participants has been improved, but we have seen limited evidence of the impact the changes have had during the period under review. Documented evidence of the PSNI's internal compliance checks would have been useful evidence to assess the impact of the changes.

18.10 It is clear that the PSNI has made improvements during the period under review, but having balanced this with the timing of the changes made and the limited evidence available of the impact those changes have had, we have concluded that this Standard is not met this year.

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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