

# Pharmaceutical Society of Northern Ireland

Performance Review  
Periodic review 2023/24

## Key findings and areas for improvement

For much of this review period, many aspects of the Pharmaceutical Society of Northern Ireland's (PSNI's) performance have been poor, and this is reflected in our assessment against the Standards. We recognise that the PSNI, as a small regulator, has been significantly impacted by turnover of senior staff. We also recognise the efforts that the PSNI has made since September 2024 to improve its performance, and we hope this will bear fruit in 2024/25. However, we have identified weaknesses in multiple regulatory functions during 2023/24 which have led us to conclude that the PSNI has not met seven of our 18 Standards of Good Regulation this year.

- Standard 1: for the large majority of the review period, the PSNI's Council papers were not published ahead of the Council meeting and contained minimal information about its operational, corporate, policy and statutory functions.
- Standard 2: we saw the PSNI make little progress on key projects such as publication of a new Corporate Strategy, the review of The Code, guidance for registrants, education reform and improvements to its website.
- Standard 3: from 2023/24 we have introduced a new approach to assessing regulators' performance on Equality, Diversity and Inclusion (EDI). We had concerns across all four of the outcomes within this Standard and identified many gaps in fundamental areas.
- Standard 4: we continued to encounter problems contacting and obtaining information from the PSNI for the majority of 2024, and this only improved following a letter on this issue from the PSA Chair to the PSNI President in September 2024. In addition, for the large majority of the review period, the PSNI's public Council papers contained few substantive items in general, and no items on its operational performance.
- Standard 5: we saw examples of inactivity across a number of different areas and workstreams and stakeholders had sought, but not received, updates from the PSNI on a number of key projects, including The Code review.
- Standard 7: the PSNI made little progress against its plans to update its 2016 guidance on internet pharmacy, despite this being a known and growing risk to patient safety.
- Standard 15: the PSNI took too long to deal with fitness to practise cases and the number of open cases, including older cases, has increased.

In line with our escalation policy, we have written to the Minister of Health for Northern Ireland and the Chair of the Northern Ireland Assembly Committee for Health to make them aware of our concerns. We will be closely monitoring the PSNI's performance in 2024/25.

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## About our performance reviews

We have a statutory duty to report annually to Parliament on the performance of the 10 regulators we oversee. We do this by reviewing each regulator's performance against our Standards of Good Regulation and reporting what we find. The judgements we make against each Standard incorporate a range of evidence to form an overall picture of performance. Meeting a Standard means that we are satisfied, from the evidence we have seen, that a regulator is performing well in that area. It does not mean there is no room for improvement. Where we identify areas for improvement, we pay particular attention to them as we continue to monitor the performance of the regulator. Similarly, finding that a regulator has met all of the Standards does not mean perfection. Rather, it signifies good performance in the 18 areas we assess.

Our performance reviews are carried out on a three-year cycle; every three years, we carry out a more intensive 'periodic review' and in the other two years we monitor performance and produce shorter monitoring reports. Find out more about our review process [here](#). We welcome hearing from people and organisations who have experience of the regulators' work. We take this information into account alongside other evidence as we review the performance of each regulator.

This is a periodic review report on the Pharmaceutical Society of Northern Ireland and covers 1 January 2024 to 31 December 2024.

## About the PSNI

The PSNI regulates the practice of pharmacists in Northern Ireland. It has 3,034 pharmacists and 538 pharmacy premises on its register (as at 31 December 2024).

## About the PSNI's performance for 2023/24

The PSNI met 11 out of 18 of our Standards of Good Regulation. These Standards provide the benchmark against which we review performance. Meeting or not meeting a Standard is not the full narrative about how a regulator is performing. Our report provides more detail about the PSNI's performance this year.

Standards of Good Regulation met 2023/24		
	General Standards	0 out of 5
	Guidance and Standards	1 out of 2
	Education and Training	2 out of 2
	Registration	4 out of 4
	Fitness to Practise	4 out of 5
	<b>Total met</b>	<b>11 out of 18</b>
Standards met 2022-23		
	2022/23	15 out of 18
	2021/22	18 out of 18
	2020/21	17 out of 18

# General Standards

## 1

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

### Council papers

- 1.1 Last year we encouraged the PSNI to publish its Council papers on its website ahead of each Council meeting for transparency purposes and to make the information more accessible to interested parties. However, for most Council meetings this year, papers were published either on the day of the meeting or after the meeting had taken place. We raised this with the PSNI on multiple occasions throughout the year.
- 1.2 Through our ongoing engagement with the PSNI we also raised our concerns about the lack of content and information contained in the Council public papers, particularly regarding operational, corporate, policy and statutory function agenda items. Additionally, the PSNI did not report on its performance adequately during the year through Council papers as we see other regulators do. (This is discussed further under Standard 4.) The PSNI has a process for deciding what items and papers should be discussed in public/private.<sup>1</sup> In light of our concerns, the PSNI is considering what more it can publish and said it is currently developing a new policy to improve transparency.
- 1.3 The PSNI Council held its final Council meeting of the review period on 9 December 2024. The agenda contained more substantive items than for the previous four Council meetings held during the review period (discussed below under Standard 4) and the papers were published a week in advance. We will continue to monitor the timeliness, transparency and content of the PSNI's Council papers.

### PSNI website

- 1.4 Last year we reported that PSNI was to carry out an urgent refresh of the material published on its website and had plans to develop a new website. During the review period we did not see evidence that the PSNI had carried out the planned refresh of material and we received feedback from stakeholders who said that the PSNI's website "*is not fit for purpose*". The PSNI did relaunch its website on 25 November 2024, although this was near the end of the review period and the content overall remained the same. The PSNI has told us that it is continuing to make improvements to its website following user feedback.

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<sup>1</sup> The current approach is set out in the [PSNI Corporate Governance Manual](#) – page 15

## PSNI Business Plan

- 1.5 Last year we noted that the PSNI did not publish its Business Plan on its website and recommended during the course of our engagement that, in the interests of transparency, it should reconsider its position. The PSNI told us that its Business Plan was drafted for internal use only but it had taken our suggestion on board and would ensure that a high-level Business Plan for 2024/25 would be available on its website in 2024. The PSNI did not publish its 2024/25 Business Plan (for the year starting 1 June) until October 2024; the PSNI told us that work had been delayed by a number of staff changes.<sup>2</sup>

## Communication and Engagement Plan

- 1.6 Last year we reported concerns we received regarding the PSNI's approach to communicating relevant legislative changes to the pharmacy sector. In response the PSNI said it has developed a revised Communications and Engagement Plan which it said was approved at the September 2024 Council meeting in private session. We will monitor further developments. The PSNI also publishes a quarterly Newsletter and recently added a new section where it provides information on work it has completed and any upcoming planned work. This is a positive step and we will continue to monitor the information provided.

## Conclusion

For most of this review period, the PSNI's Council papers were not published ahead of the Council meeting and contained minimal information about its operational, corporate, policy and statutory functions. We raised these issues with the PSNI on multiple occasions but did not see any improvement until the final Council meeting in December. We also saw delays to the PSNI's website refresh project and publication of the PSNI's 2024/25 Business Plan. Therefore, this Standard is not met.

# 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.**

## The Corporate Strategy

- 2.1 Last year we noted that the PSNI Corporate Strategy 2017-22 had been extended for a second year and that the PSNI was working with a team of consultants to develop a new strategy. During this review period, the PSNI has again extended the 2017-22 Corporate Strategy for a third successive year and said it has commissioned further work to develop it. The PSNI did not report publicly on this

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<sup>2</sup> [PSNI 2024/25 Business Plan](#)

work during the review period. The PSNI told us that it intends to launch its 2025-30 Corporate Strategy in Quarter 1 of 2025.

- 2.2 It is concerning that, by the time the PSNI's new Corporate Strategy takes effect, the PSNI will have been without an updated Corporate Strategy for three years. This raises concerns as to whether the PSNI can demonstrate clarity of purpose as a healthcare professional regulator and is able to develop and deliver a clear strategic vision.

### Wide range of issues and delays to projects

- 2.3 As we set out against a number of Standards in this report, we have seen issues across a wide variety of regulatory functions and delays to significant projects during this review period. These include:

- PSNI website (Standard 1)
- Lack of transparency in Council papers and lack of performance reporting (Standards 1 and 4)
- The Corporate Strategy (Standard 2)
- Ongoing issues obtaining information (Standard 4)
- The Code review (Standard 5 and 6)
- Guidance for registrants (Standard 7)
- Education reform (Standards 8 and 9)

- 2.4 As is discussed under the relevant Standards, we did see some improvements against some of these issues in the final months of the review period. However, the range of delays and issues we identified across different regulatory functions indicated that, for much of the review period, the PSNI lacked appropriate clarity and focus on delivering its core functions.



#### ***What we heard from stakeholders***

“...one of the key and ongoing concerns... centres on the difficulties encountered when attempting to contact the Society - whether it be on the regulatory or professional leadership side.

Registrants have raised concerns...that when attempting to contact PSNI, phones go unanswered; that there are no accurate organograms to clarify who has responsibility for specific areas; and that calls are redirected to staff members who are either not in post or are covering and have no in depth understanding of the matters to be discussed. We understand that, at the time of writing, there may be as few as a single pharmacist employed in the PSNI team and we feel that this does not give the appropriate breadth and depth of knowledge and understanding which is required to deal with complex, sensitive and urgent professional and regulatory matters.”

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- 2.5 The PSNI told us that it responded to this feedback at the time, improved its service and has received no further complaints in respect of contact. It also said it is developing a network of peers to support staff on complex professional matters.

## Conclusion

For much of the review period, we saw the PSNI make little progress on key projects such as publication of a new Corporate Strategy, the review of The Code, guidance for registrants, education reform and improvements to its website. We considered these in our assessments against the relevant Standards, and also took into account the challenges the PSNI has faced this year, particularly in terms of senior staff turnover. However, taken together, the issues we identified are sufficiently serious to determine that Standard 2 is not met.

# 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 This year, we have used a new approach to assessing regulators against this Standard.<sup>3</sup> As part of our new approach, we have broken down the Standard into four separate outcomes. For a regulator to meet the Standard, we would need to be assured that the regulator has met all four of the outcomes. Our assessment of the PSNI's performance against the four outcomes is set out below.

*Outcome 1: The regulator has appropriate governance, structures and processes in place to embed EDI across its regulatory activities*

- 3.2 The PSNI does not hold data covering all relevant characteristics for its senior leadership, Council, committees, decision-makers nor fitness to practise panellists. We note that the PSNI is a small organisation and operates in a different legal framework to our other regulators. However, these factors do not, in themselves, prevent the PSNI from collecting and analysing EDI data. The PSNI has told us that it would seek this data from relevant staff and decision-makers and we will monitor developments during the next review.
- 3.3 Last year we reported that the PSNI lacked a public-facing EDI Strategy, although we noted the PSNI said it planned to publish one in 2024. We also encouraged the PSNI to accelerate its work in this area and that we would be assessing regulators against more demanding outcomes over the next three years. Despite this, the PSNI still did not have a public facing EDI Strategy in place during the review

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<sup>3</sup> More information is available in our [guidance document](#).

period and only began consulting on a draft strategy towards the end of December 2024.

- 3.4 The PSNI confirmed that, once launched, progress against the EDI Strategy and Action Plan will be monitored by Council and Finance and Performance Committee. Following implementation of the action plan, key milestones and expectations will be agreed and monitored through the appropriate committees on an ongoing basis. Despite the governance structures the PSNI has outlined, we have not seen evidence of these structures embedding EDI across the organisation as the PSNI has yet to launch and implement its EDI Strategy and Action Plan. We also note reporting arrangements and structures to support EDI are in development and the extent and detail of the PSNI's public reporting has not yet been evidenced during the review period.

*Outcome 2: In terms of EDI, the regulator ensures that registrants and students are equipped to provide appropriate care to all patients and service users, and have appropriate EDI knowledge and skills*

- 3.5 The initial education and training standards for pharmacists contains a learning outcome for pharmacy students/trainees which states they must assess and respond to the person's particular health risks, taking account of individuals' protected characteristics and background<sup>4</sup>. The Foundation Training Year (FTY) takes place after students graduate with their MPharm degree and is delivered by the Northern Ireland Centre for Pharmacy Learning & Development (NICPLD). We have seen evidence of how EDI considerations are embedded in the FTY programme.
- 3.6 The PSNI Code 2016 requires registrants to treat those in their care with respect and dignity but is not explicitly designed to equip registrants to provide appropriate care to all patients and service users<sup>5</sup>. The PSNI is currently developing a new Code for registrants, which it intends to launch in 2025. We will monitor any developments.
- 3.7 We have not seen evidence that the PSNI publishes material to support registrants to improve their EDI knowledge and skills. The PSNI said that the Pharmacy Forum's EDI Hub<sup>6</sup> contains resources and material for registrants.<sup>7</sup> However, the most recent resource on the EDI Hub was published in December 2021 and there is no guidance about the need to challenge discriminatory behaviour.
- 3.8 The PSNI explained that its current Continuous Professional Development (CPD) framework does not encompass EDI knowledge and skills as a mandatory component, however, in preparation for the next CPD period it intends to update its CPD framework "to modernise it and the inclusion of EDI is one [of] the

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<sup>4</sup> [Standards for the initial education and training of pharmacists January 2021](#)

<sup>5</sup> [PSNI Code of Practice 2016](#)

<sup>6</sup> <https://www.pfni.org.uk/edi-hub/>

<sup>7</sup> The Pharmacy Forum is the professional leadership body for pharmacists registered in Northern Ireland. It is an Arm's Length Body under the legislative remit of the PSNI and lies outside the scope of our performance reviews.

potential changes that will be assessed for inclusion in the planned update." The PSNI has told us it plans to promote EDI material produced by Pharmacy Forum Northern Ireland and NICPLD in 2025. It also plans to promote EDI through CPD by encouraging registrants to utilise its EDI hub and employer-provided training materials to enhance and apply their EDI knowledge.

*Outcome 3: In terms of EDI, the regulator makes fair decisions across all regulatory functions*

- 3.9 The PSNI has increased the EDI data held on its registrants to approximately 73%. It has now embedded data collection within its renewals process for registrants, which should further increase the completeness of its EDI registrant data.
- 3.10 The PSNI provided basic EDI training to staff and Council members. A commitment to provide further EDI training is set out in the draft EDI Strategy.
- 3.11 During the review period, the PSNI did not have fitness to practise processes and guidance which specifically address how allegations of discriminatory behaviour should be considered nor what factors decision-makers should have regard to when addressing allegations of racist and other discriminatory behaviour. At the start of 2025, the PSNI shared with us draft guidance in this area and we will monitor developments in the next review period.
- 3.12 The PSNI does not use data and/or other evidence to identify unfairness in its processes and decisions, nor has it taken action to reduce the potential for bias. It also does not currently collect EDI data from those raising fitness to practise concerns. The PSNI said it is "consulting with other regulators to understand how they collect this data without creating a barrier or discouraging people from raising concerns."

*Outcome 4: The regulator engages with and influences others to advance EDI issues and reduce unfair differential outcomes*

- 3.13 The PSNI carried out pre-consultation engagement with stakeholders representing people with disabilities and acted on the feedback received in developing the draft Code. The PSNI's draft EDI Strategy contains a number of actions to improve its engagement with a more diverse range of stakeholders. However, the PSNI's plans are all forward-looking, with the draft EDI Strategy outlining all the actions that need to be completed.
- 3.14 We have seen little tangible evidence of the PSNI making use of external research or other evidence regarding EDI issues. Apart from publishing its registrant EDI data, we have seen no evidence of the PSNI publishing other EDI data, research or analysis this year.

## Conclusion

We have not been assured that the PSNI is meeting outcomes 1, 2, 3 and 4 and have identified a number of significant gaps. It is notable that the PSNI did not have an EDI Strategy in place during the review period. We also saw no evidence of the PSNI undertaking activities designed to embed EDI in its work and identify and improve processes across different areas of its work such as registration and fitness to practise. The PSNI is working to improve EDI data collection at registration/renewal and is developing its EDI Strategy and Action Plan which should begin to embed EDI and address the weaknesses identified. We will monitor the PSNI's progress. However, the PSNI's overall performance meant that Standard 3 is not met.

## 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 did not meet this Standard last year because of the PSNI's inability to provide timely and accurate information to us. We reported that these issues raise serious questions about the confidence we and the PSNI's Council can have on the PSNI's reporting and ability to address our concerns.

### Reporting to the Professional Standards Authority

- 4.2 During this review period, although the PSNI continued to report on its performance to us through timely submissions of the quarterly dataset, we experienced ongoing difficulties and delays in contacting the PSNI and obtaining information which in turn was impacting on our ability to fulfil our statutory duty to undertake our work in a timely fashion. Because of these issues, the Chair of the PSA wrote to the PSNI President in September 2024 to outline our concerns and request they be promptly addressed. The PSNI's President responded swiftly taking our concerns on board. Since then, we have held fortnightly meetings with the PSNI's Senior Management Team to review progress and information has been provided which we have been able to assess as part of this performance review.

### Reporting on performance

- 4.3 In October the PSNI published its Annual Report 2023-24.<sup>8</sup> However, as mentioned under Standard 1, public agendas for Council meetings during the large majority of the year contained few items and no items on operational performance. This is in stark contrast to Council papers for the other regulators we oversee.

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<sup>8</sup> [Annual Report Accounts 2023-24 Pharm Soc Final Version](#)

- 4.4 We recognise that the PSNI has developed performance reporting dashboards that were presented for the first time at the December Council meeting. However, this has not been done throughout the review period.

## Conclusion

We continued to encounter problems contacting and obtaining information from the PSNI for the majority of 2024, and this only improved following a letter on this issue from the PSA Chair to the PSNI President in September 2024. We also noted that, until the final Council meeting in December, the PSNI's public Council papers contained few substantive items in general, and no items on its operational performance. This Standard was not met last year and performance has, if anything, been worse for the majority of the review period. Therefore, the Standard remains not met.

# 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 Last year we noted that the PSNI had:
- consulted in October 2023 on Regulations and the associated Guidance in respect of the Knowledge of English for pharmacists.
  - conducted pre-consultation work on revising its Code by establishing an Advisory Group of internal and external stakeholders, hosted a number of engagement events and launched a formal consultation on the Code which closed on 18 December 2023.
- 5.2 During this review period we have not seen evidence that the PSNI has published details of its findings following the above consultations, nor provided any information on its website about further work it has carried out to develop either workstream. The PSNI has not conducted formal consultation exercises on any other issues this year save for on its draft EDI Strategy (see Standard 3) which it launched at the end of the review period in December.



### ***What we heard from stakeholders***

“[We] responded to the PSNI [Knowledge of English Regulation] consultation which closed on 10 October 2023. However, we are not aware of any further progress which has been made in this reporting timeframe”

“In 2023, [we] received an invitation to be part of the Code Review Advisory Group established by the [PSNI]. This Group, which consisted of key stakeholders, was set up to provide advice in respect of the review of professional standards of conduct, ethics and performance for pharmacists in Northern Ireland. [We] found this group to be well structured and Chaired, and the overarching

impression was that the [PSNI] was willing and eager to listen to concerns, to look at issues from a stakeholder perspective, and to incorporate change into the Code on the basis of discussion and agreement.

[We] responded to the consultation which closed on 18 December 2023. However, we are not aware of any further progress which has been made in this reporting timeframe.”

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- 5.3 Regarding the Knowledge of English Regulation consultation, the PSNI said it has *“forwarded its recommendations and findings following public consultation and is awaiting approval from [the Department of Health Northern Ireland] to enable it to commence regulation laying procedure. Further communication will [be] issue[d] to notify members of any changes and when they are effected.”*
- 5.4 Regarding the development of the Code, the PSNI said it is *“considering the responses from this consultation and very significant issues raised through the process, which will also inform our new strategic plan and internal improvement agenda. It is expected further update in respect of this work will be provided early in 2025.”*
- 5.5 As mentioned under Standard 2 (above) we heard from stakeholders who raised examples about difficulties registrants have faced when trying to contact the PSNI. We have also seen examples where stakeholders have sought, but not received, updates from the PSNI on a number of projects (see also Standards 7, 8 and 9 for further details). Finally, as mentioned under Standard 4 (above) we also experienced difficulties contacting and obtaining information from the PSNI.
- 5.6 In response the PSNI has told us that it has re-established contact with key stakeholders and is working to improve its engagement moving forward. It has sought to improve its engagement and information sharing with the PSA’s performance review team from late September onwards.

## Conclusion

While it is not always good practice, it is not unusual to have long delays in government or public body responses following consultations. However, there has been inactivity across a number of different areas and workstreams and stakeholders have sought, but not received updates from the PSNI on these projects. The PSNI is a small regulator and has faced significant internal challenges during the review period. However, certain fundamental tasks relevant to this Standard have not been done. Therefore, this Standard is not met.

## Guidance and Standards

### 6

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

#### Standards for registrants

- 6.1 The PSNI introduced *The Code (professional standards of conduct, ethics and performance for pharmacists in Northern Ireland)* in March 2016. The PSNI's policy was to review this every five years, however, as mentioned under Standard 5 above, we have not seen evidence of further progress since the PSNI consulted on a draft Code in December 2023. It is a concern that, despite working on developing a revised Code for over two years, the PSNI has not yet completed this work. The PSNI said the consultation "*received a range of responses which are being considered and discussed both internally and with external stakeholders.*" We will continue to monitor developments.
- 6.2 During this review period the PSNI said it is currently reviewing the standards and guidance that support The Code and prioritising those it will identify for update. It said it has been in contact with the General Pharmaceutical Council (GPhC) and is working with them to develop standards and guidance for Chief Pharmacists, Responsible Pharmacists and Superintendent Pharmacists. The PSNI said it plans to consult on Superintendent Pharmacist rules and guidance and plans to consult on relevant rules and guidance for Chief Pharmacists and Responsible Pharmacists in 2025.
- 6.3 The PSNI said it is also liaising with the Department of Health Northern Ireland (the Department) on the necessary changes to legislation and regulations to enable regulation of pharmacy technicians, as the GPhC already does in Great Britain. It is planned that the initial registration of pharmacy technicians will occur in the year 2026/27 and both draft regulations and draft guidance will go to consultation in 2025. We will monitor developments.

#### Standards for pharmacy premises

- 6.4 Last year we said the PSNI was still waiting for the Department to introduce a Commencement Order to give effect to the Premises Standards the PSNI approved in 2018. We said we recognised that this work remained on hold given there was no Northern Ireland Assembly.
- 6.5 Despite the formation of a Northern Ireland Assembly in February 2024 we understand there has been no further progress in this area. The PSNI has told us that "*We will continue to escalate this matter to [the Department] on a frequent basis.*" We will continue to monitor developments.

## Conclusion

The PSNI has made little progress in revising its Code during this review period, following the conclusion of the consultation exercise in December 2023. However, we have not seen evidence that the Code is not fit for purpose. We also recognise that the PSNI is in a unique position in that, due to circumstances outside its control, it has not been able to implement its 2018 Premises Standards. On balance we are satisfied that this Standard is met. We will continue to monitor progress and will report on any further developments.

## 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.

### Guidance on internet pharmacy / remote supply of medicines

- 7.1 In 2021/22 we reported that the PSNI planned to update its existing standards and guidance on internet pharmacy (published January 2016) in the financial year 2022/23.<sup>9</sup> However, last year we reported that this work had been delayed and we have not seen any progress during this review period. The PSNI has told us that it intends to consult on draft guidance in early 2025.
- 7.2 Last year we also said we would monitor PSNI work carried out in relation to the risks arising from online pharmacy, including work it carried out to understand the scale of risks from online pharmacy in Northern Ireland (apart from analysis of fitness to practise referrals) and engagement with stakeholders and other regulators.
- 7.3 During this review period the PSNI said “*discussions are in progress with the registration team to collect baseline data on the extent and risk of internet pharmacy and the remote supply of medicines in Northern Ireland. This data will be collected during the retention and registration premises process in 2024.*” We will monitor progress and report on the PSNI’s findings in our next review.

### Position statement on Premises Standards and guidance on safe staffing levels

- 7.4 In our last two previous performance reviews we have reported the PSNI’s work to produce guidance on safe staffing levels in light of the recommendations and action plan from the Pharmacy Workforce Review 2020. The PSNI consulted on proposed guidance in late 2022 but has not published the results. The PSNI has told us that its guidance on safe staffing is inextricably linked to the Premises

<sup>9</sup> The PSNI’s financial year runs from 1 June to 31 May.

Standards, which has been delayed (see Standard 6 above), but that it would publish a position statement in the first half of 2024.

- 7.5 Between July and October 2024, the Department consulted on its proposals to introduce Safe and Effective Staffing Legislation in Northern Ireland. The PSNI said that it would publish its position statement on premises standards and safe staffing once this consultation process had concluded, and that it is in ongoing communication with the Department. We will monitor developments next year.



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### ***What we heard from stakeholders***

“[We] responded to the PSNI consultation [on safe staffing] which closed on 9 December 2022 but received no update or further correspondence throughout the 2023 and 2024 period to date.”

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## **Sale and supply of puberty-suppressing hormones**

- 7.6 On 29 August, the PSNI published a statement following the decision of the Northern Ireland Government to align the approach in Northern Ireland with the rest of the United Kingdom in introducing a temporary ban on the sale and supply of puberty-suppressing hormones to people under 18. The PSNI provided guidance and signposting to the Department statement on this issue through its website and, at the same time, withdrew the guidance the PSNI had published in June 2024 on gender identity services for children and young people.

## **Conclusion**

In our last two performance review reports, we noted it was important that the PSNI should take prompt action to ensure it understands, and is managing, the risks arising from online pharmacy. The pharmacy sector and indeed the wider healthcare regulatory landscape have identified this as a clear area of risk and the GPhC published updated guidance on this topic in 2022. However, the PSNI again made little progress this year against its plans to update its 2016 guidance. Therefore, this Standard is not met.

## Education and Training

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.

### Education reform

- 8.1 The PSNI adopted new education standards in January 2021<sup>10</sup> which will be fully implemented by 2025/26. Last year we said “the PSNI continued working with key stakeholders on the implementation of these new Standards through its Education Reform Implementation Group ERIG.” However, during this review period we saw minimal evidence in public Council papers, nor updates on the PSNI’s website as to what work the PSNI has carried out to advance this work.



#### *What we heard from stakeholders*

“[We] have repeatedly asked for sight of the draft legislative changes required to fully implement the changes to [new Standards for initial education and training for pharmacists] [IETP]. Neither draft changes or an expected timeline for these have been shared with us in 2024 despite numerous approaches. This is complex work and change is required to fully implement the IETP reform.”

- 8.2 In response the PSNI said it has developed a specific lead contact point who is working closely to progress this including the necessary legislative reforms.

### Independent prescribing

- 8.3 We have previously reported that, following the wider education reforms, independent prescribing training would be incorporated into the five-year training programme with implementation expected in June 2025. We note that the PSNI has prepared the necessary draft legislation to change the requirements for annotation as an Independent Prescriber so that it would not be a requirement to have been qualified for more than two years. This is part of an ongoing consultation at the time of the publication of this report.
- 8.4 Last year the PSNI told us it expects the legislative change to happen and confirmed that it had secured Departmental approval for the work to be completed. The PSNI said ownership of this legislative reform piece rests with the PSNI itself and the “work has been initiated with an implementation of June 2025”.

<sup>10</sup> These new Standards were launched by the GPhC and adopted by the PSNI in January 2021. They are being implemented in a phased manner.

- 8.5 We said the PSNI would be working with the GPhC and other relevant stakeholders to develop guidance to further define the requirements for course entry in advance of the changes being introduced. We noted that no further developments had been made during last year's review period however we said the PSNI expected to develop this guidance in 2024.<sup>11</sup>
- 8.6 During this review period we have not seen any evidence of progress in the publicly available documents we have reviewed. The PSNI needs to act swiftly to carry this work out or risk not fully implementing the new standards for education and training in time.



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### ***What we heard from stakeholders***

“[We] received concerns from pharmacy contractors and their Educational Supervisors who are preparing to undertake the training of FTY trainees in 2025/26. These Foundation Training Year (FTY) trainees will be the first cohort to join the register having completed the new five-year training programme mapped to the GPhC's updated standards for initial education and training and will therefore be the first cohort to join the register as annotated independent prescribers.

Community pharmacy contractors have queried what plans are in place to update the PSNI's Standards and Guidance for Pharmacist Prescribers 2013, given that this guidance relates to experienced pharmacists who obtain prescribing status following at least two years on the register. Community pharmacy teams are concerned that as of July 2025 they will be required to train pharmacy graduates to become prescribers, in the absence of regulatory guidance as to what these new pharmacist prescribers will be authorised to do.

[We] have not received any indication of plans to update the PSNI's guidance for pharmacist prescribers. Furthermore, we remain concerned that the necessary legislative changes required to allow the new FTY trainees to join the register as independent prescribers in 2026 has not yet been shared or consulted upon.”

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- 8.7 In response the PSNI said it is aware of the necessary regulatory reforms and is progressing these at pace and is confident of meeting the required timescales. Following the end of this review period, the PSNI launched a consultation exercise regarding amendments to legislation to allow newly qualified pharmacists to prescribe independently from their first day of registration.<sup>12</sup>

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<sup>11</sup> [Annual report](#): President and Chief Executive foreword page 5

<sup>12</sup> The consultation period runs from 13 February to 10 April 2025.

## Conclusion

During the review period we have seen little evidence of the PSNI progressing the work needed to ensure the successful implementation of education reforms which are required to take effect in 2025. Key stakeholders have also raised similar concerns. We note that the Education Standards are not out of date and we have received no feedback to suggest they are not fit for purpose. We therefore determined that the Standard is met but noted that there are a range of actions that would need to be completed for this Standard to remain met next year.

## 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.**

### Reaccreditation of existing courses

- 9.1 The PSNI has worked with the GPhC to accredit courses and follows the GPhC's quality assurance process. There are two MPharm course providers in Northern Ireland: Queen's University Belfast and Ulster University. Last year we understood that existing courses would be reaccredited by the GPhC and PSNI against the new initial education and training (IET) standards in 2023/24.
- 9.2 Last year the PSNI confirmed that the first part of the accreditation took place in April and May 2023; the second and final part of the accreditation would take place in 2024. During this review period, the PSNI confirmed that the second part is now scheduled for March 2025. We will monitor developments in our next review.

### Quality assurance of Foundation Training Year (FTY)

- 9.3 The FTY takes place after students graduate with their MPharm degree and is delivered by the Northern Ireland Centre for Pharmacy Learning & Development (NICPLD). In our 2021/22 performance review we said that the PSNI would be developing a more formal quality assurance arrangement for the 2022/23 FTY onwards.
- 9.4 In our 2022/23 performance review we noted the PSNI had continued to carry out and present its annual Quality Assurance (QA) Report of the FTY at its Council meeting in January 2023. However, during this review period, we did not see evidence that the PSNI had carried out any further quality assurance reporting on the FTY. The PSNI said that requirements for quality assurance of the FTY are not the PSNI's responsibility any longer. It confirmed that the current FTY remains

accredited and that the PSNI is working with the GPhC and NICPLD on full accreditation of the FTY by March 2025.

- 9.5 However, during the review period, we heard from stakeholders who said they had been given conflicting advice from the PSNI on matters relating to the FTY. This led to stakeholders being confused about roles and responsibilities. In response the PSNI said it has established a contact point and is working with relevant stakeholders in this area.

### **Common Registration Assessment (CRA)**

- 9.6 During the review period, published pass rates of the common registration assessment (CRA) remained comparable to previous years. However, one stakeholder contacted us with concerns regarding trainee eligibility to sit the registration assessment in November 2024. The PSNI confirmed no candidates were impacted and we have also seen no evidence to suggest that they had been. The PSNI said it is looking to improve the process to verify the list of registered students eligible to sit the CRA. The PSNI has also developed a Standard Operating Procedure (SOP) outlining the processes to be undertaken for students to successfully register on the PSNI student register. We will monitor any further developments in the next review period.
- 9.7 After each sitting of the CRA, information on pass rates categorised by different demographic data is published. However, we note that the PSNI does not provide such data for students in Northern Ireland. In response the PSNI said it has “commenced engagement with interested parties with a view to completing a risk assessment and options to achieve a solution which would facilitate transparency and ensure that [the PSNI] meets all of its legal obligations in respect of privacy and confidentiality.”

### **Conclusion**

We noted two issues relevant to this Standard where stakeholders have raised concerns about the PSNI’s role and the clarity of its processes: Foundation Year Training and the Common Registration Assessment. We have not identified any risks to the public arising from these issues, and we therefore consider the Standard is met this year. However, next year we will want to be assured that the PSNI has published clear information on its processes, with clear lines of accountability.

## Registration

### **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 did not meet this Standard last year because we saw evidence there had been a number of registration errors on the PSNI's register. We reported that the PSNI did not have robust processes and controls in place throughout the review period to ensure the accuracy of the register and had not yet taken action to reduce the risk of similar errors occurring in the future. In light of those errors, the PSNI produced a Critical Incidents Report including lessons learned and made various changes to its processes and quality control measures.
- 10.2 As part of our review, we checked the register entries for cases where there had been a fitness to practise hearing between January 2024 and September 2024. We also broadened out the register check by reviewing the entries for registrants removed from the register for failing to comply with CPD requirements or failing to pay the registration fee. All entries were as expected, and we identified no concerns.

### **Conclusion**

The PSNI has taken action to rectify the issues that led to the Standard not being met last year. We did not identify any inaccuracies through our checks of the register and we have not seen any other evidence of significant problems with the register during this review period. We are satisfied this Standard is met.

### **11** | The process for registration, including appeals, operates proportionately, fairly and efficiently, with decisions clearly explained.

- 11.1 The PSNI did not make any substantial changes to its registration process and continued to process applications for registration efficiently. During the review period, the median time taken to process registration applications remained between two to three weeks for UK graduates. The PSNI receives very few international applications each quarter, and we continued to see fluctuations in the time taken to process these applications.
- 11.2 We did see a sharp increase in the median processing times between January and March 2024. The PSNI has told us the Registrar was unavailable for a period of approximately 3.5 weeks and this impacted processing times. The time taken to process applications has decreased from March 2024 onwards.

- 11.3 To mitigate future disruptions to progressing applications for registration, in September 2024 the PSNI put in place a delegation scheme to ensure registration decisions can continue to be made by a Deputy Registrar, if the Registrar is unavailable.

## Conclusion

The time taken to process UK applications has remained steady during the review period. We have not received any negative feedback from stakeholders about the PSNI's registration processes and timeliness. We are satisfied that this Standard is met.

## 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 investigate instances of illegal practice. The powers and responsibility for this lie with the Department of Health, Social Services and Public Safety Northern Ireland assumed by the Medicines Regulatory Group (the Group), and this position has not changed.
- 12.2 We have previously reported that the PSNI meets with the Group regularly to share information about ongoing investigations so that each can act within their particular area of responsibility. The PSNI told us that it has not met with the Group over the last 12 months, but it is re-establishing these meetings to share information. We will monitor any further developments.

## Conclusion

Previously, we have been assured that the PSNI had mechanisms in place to manage any risk arising from this area. We know that these mechanisms have not been in place during this review period. However, as the PSNI does not have the powers to investigate illegal practice, and in the absence of any concerns, we are satisfied that this Standard is met.

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

### CPD Quality Assurance

- 13.1 In July 2024, the PSNI informed us that it had not carried out all elements of its quality assurance process in respect of registrants' Continuing Professional

Development (CPD) submissions for the 2021/22 and 2022/23 CPD periods. The PSNI told us that its Audit & Risk Committee discussed this issue and concluded that, on balance, there had been demonstrable adherence to the other parts of the CPD assessment process. Registrants who had been removed for non-compliance in terms of a submitted portfolio not being of adequate standard had been given at least three opportunities to achieve compliance. The PSNI told us that it also provided three registrants with an additional opportunity to submit a CPD portfolio “as a counterbalance to the lack of compliance in performing a QA process in year 2022/23.”

- 13.2 We did not see evidence of major risks from the PSNI not carrying out part of its quality assurance processes for 2021/22 and 2022/23. The PSNI has told us that a more complete CPD quality assurance process is now in place and implemented for the 2023/24 CPD submission year onwards. We also note that the PSNI has conducted the element of its quality control process for the 2023/24 CPD round that had not been conducted properly in 2021/22 and 2022/23. We will monitor further developments in this area in our next review.



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#### ***What we heard from stakeholders***

“...many of [our registrants] find the platform for CPD submission to be difficult to navigate, prone to crashing (particularly during CPD submission periods) and subject to periods of site maintenance which can be conducted during May (the busiest time of year for CPD recording ahead of the annual 31 May submission date). This can prove inconvenient and stressful for registrants. For example, [we] noted that a [PSNI] email issued to all registrants by the then acting Registrar on 15 May 2024 provided less than one hour's notice of a scheduled maintenance period.

[We] understand that some registrants lost work as a result, as they did not see the email in time to take action.

Additionally, [we] are aware of concerns that the [PSNI's] CPD system does not provide registrants with any confirmation, certification or evidence when their CPD submission has been made. Registrants report resorting to taking screenshots of the system so that they can have proof that they have made their submission.

[We] understand that this area is under review, and we would urge the [PSNI] to simplify both the requirements and the recording in line with other professional bodies.”

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- 13.3 We note the concerns from stakeholders concerning the accessibility and functionality of the PSNI's CPD portal. The PSNI said it has taken some steps to address these points and has actions planned to improve the CPD process for registrants. We will continue to monitor these developments.

## Conclusion

Although we have concerns that the PSNI did not adhere to all parts of its CPD quality assurance process for the last two years, we have not seen any evidence of risks arising from this. The PSNI has investigated the issue and has improved its quality assurance process for the 2023/24 CPD round. We are satisfied that this Standard is met.

## Fitness to practise

### 14 | The regulator enables anyone to raise a concern about a registrant.

- 14.1 The number of fitness to practise concerns received by the PSNI has been increasing since 2023/24. This appears to be a trend across several regulators we oversee and last year the PSNI told us that it has noted an increase in registrants with health concerns self-referring.
- 14.2 From April to June 2023, during the PSNI annual retention process, 24 registrants mistakenly selected the option to make a self-referral on health grounds. The PSNI told us that it had planned to amend the online self-referral page to remove the risk of this happening again for the 2024 retention process. However, these changes were not implemented and the PSNI received a further 40 incorrect self-referrals on health grounds between April and September 2024.<sup>13</sup> We understand that changes to the PSNI self-referral pages will be in place from the 2025 annual retention process and will monitor developments.
- 14.3 As we have noted in previous performance review reports, the Registrar has tended to close a high proportion of cases for not meeting the PSNI's jurisdictional test or threshold criteria; we have not had any concerns about the PSNI's approach. However, the data shows that in 2024 there had been a significant reduction in the number of cases closed by the Registrar. The PSNI confirmed that there was no Registrar in post for several periods during 2024. The Registrar scheme of delegation which the PSNI implemented in September 2024 (mentioned under Standard 11 above) aims to mitigate future disruptions to ensure decisions to close cases can continue to be made by a Deputy Registrar, if the Registrar is unavailable.

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<sup>13</sup> For comparison during the 2023/24 period last year the PSNI received a total of 92 referrals.

## Conclusion

We have seen no evidence to suggest there are barriers to people raising concerns with the PSNI and we have not received any concerns from stakeholders. We are satisfied that this Standard is met.

# 15

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

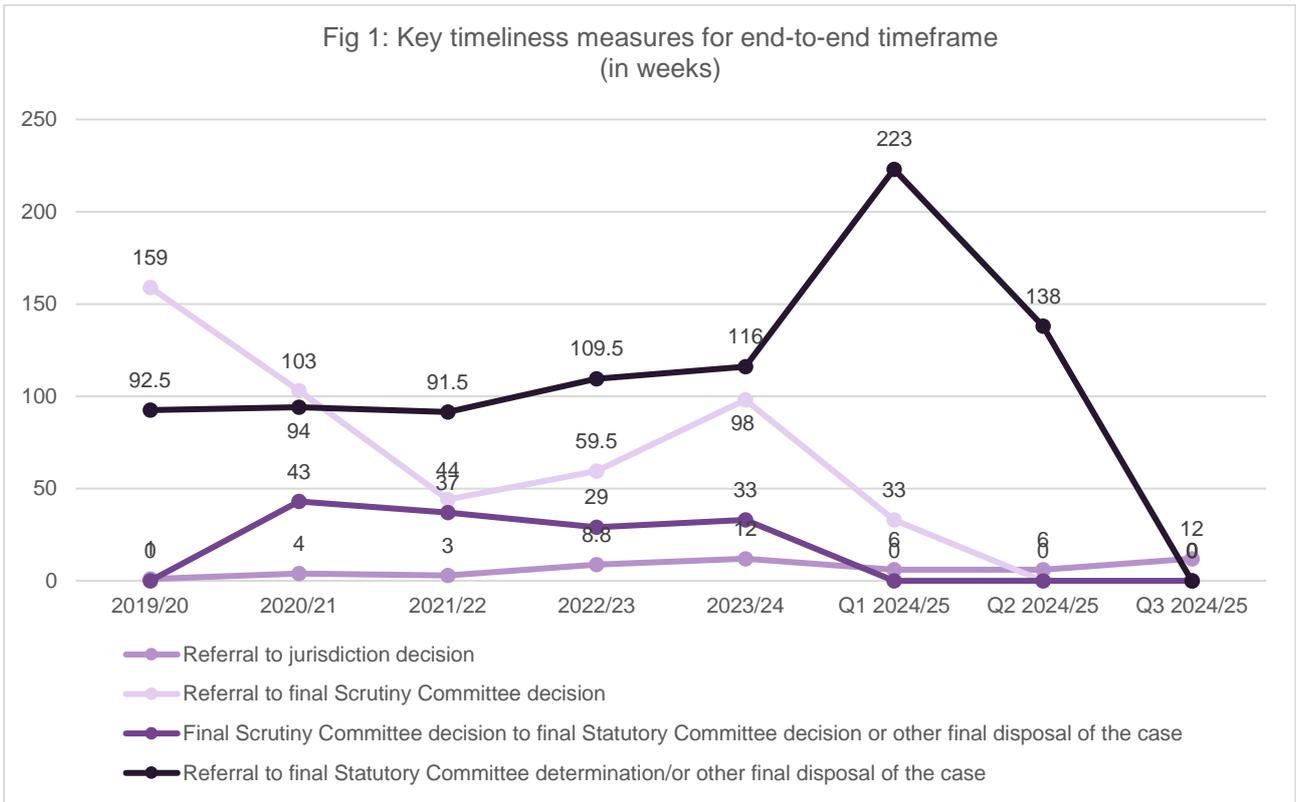
- 15.1 The PSNI did not meet this Standard last year because it was taking too long to progress cases through the fitness to practise process, and the number of open older cases had increased. We considered that, due to the small caseload, the PSNI should have been able to manage delays to cases more effectively and noted that the PSNI was not able to provide detailed information about the reasons behind the delays on cases closed by the statutory committee.
- 15.2 We also found a significant delay in a case in which a registrant had applied to be taken off the register using the PSNI's voluntary removal process. The PSNI has told us that it has clarified its process with staff to reduce the risk of this happening again. The PSNI has not received any applications for voluntary removal during this review period.

### Timeliness of fitness to practise investigations

- 15.3 The PSNI's timeliness data has been impacted by operational issues because the PSNI did not have a Registrar in post for a number of periods during 2024 and also had two changes of Deputy Registrar. The PSNI makes very few decisions at Scrutiny Committee or Statutory Committee each quarter and we therefore often see large fluctuations in the PSNI's quarterly data because of its small caseload. It is not unusual for the quarterly data to reflect one, or very few cases. However, the data shows that the PSNI's end-to-end timeframe has continued to increase since 2019/20.<sup>14</sup>

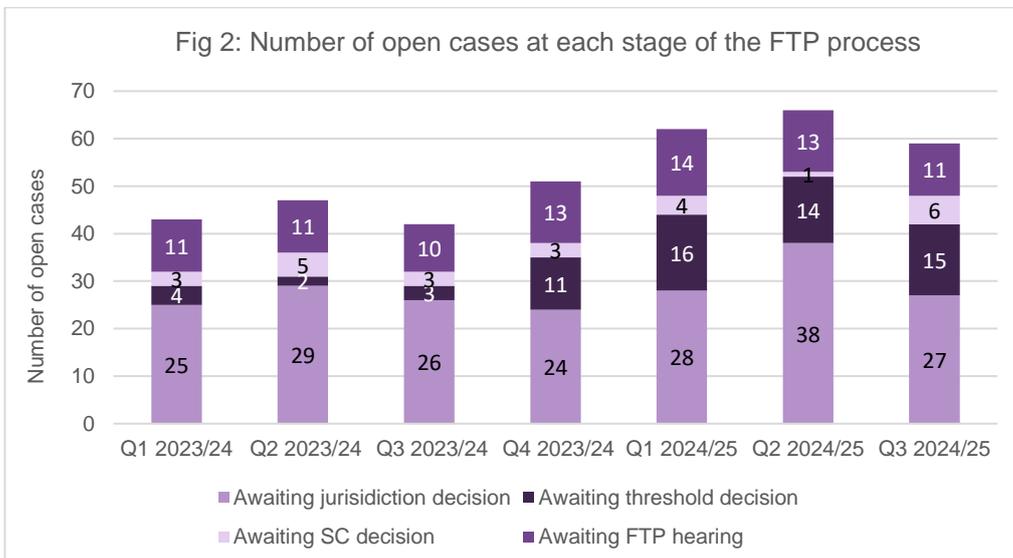
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<sup>14</sup> The PSNI did not dispose of any cases at the final hearing stage in Q3 2024/25 therefore the median time is recorded as 0.

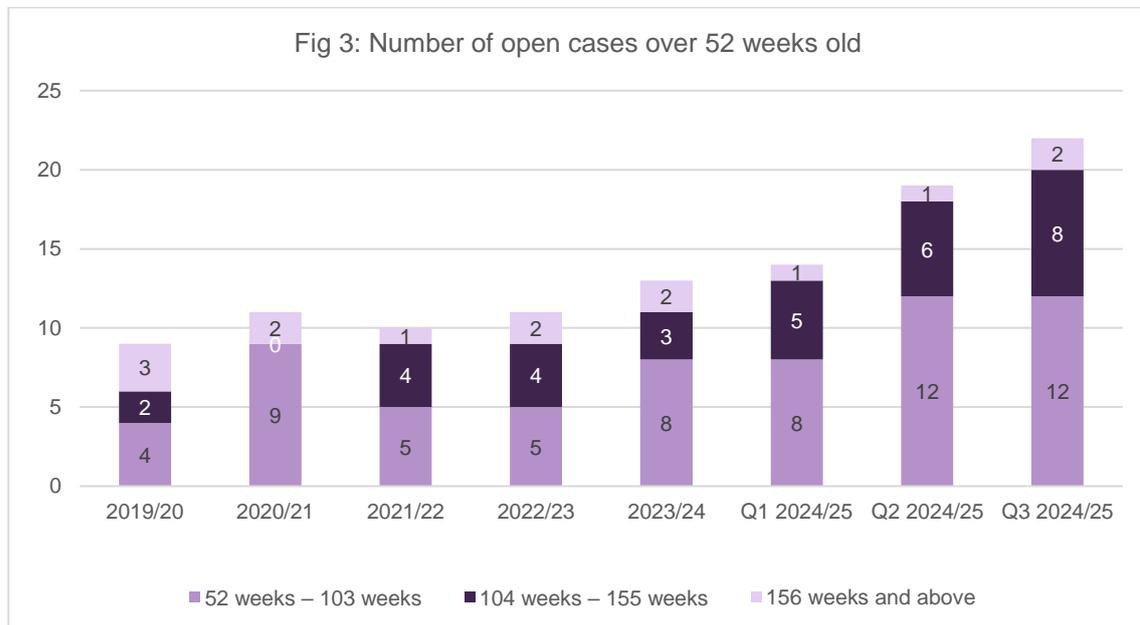


## Open cases

15.4 As Figure 2 shows, the number of open cases has been higher throughout this review period compared to the previous review period, driven by a significant increase in the number of cases awaiting threshold decision. The PSNI told us that this was partially due to the constraints within the fitness to practise department, the experience of the team and the vacant Registrar position. The PSNI has contracted an external consultant with specific expertise in its fitness to practise processes to support the team and expand their skill base to enable cases to be dealt with more quickly.



15.5 Figure 3 shows that the number of open older cases has increased since 2023/24 and has continued to increase during this review period.



15.6 The PSNI’s Fitness to Practise Strategy has a focus on timeliness and commits to clear the backlog of fitness to practise cases by 30 June 2025. During this review period, the PSNI has taken a number of steps to improve timeliness:

- a dedicated paralegal to work on cases which the PSNI has classified as “backlog”
- a consultant pharmacist to provide expert advice
- a new case tracker to understand the full extent of its backlog which will allow it to prioritise older cases, and the context for any delays
- appointing an internal case presentation lawyer in order for cases to be dealt with in-house, rather than through external legal providers
- developing a fitness to practise procedure manual, which will be a comprehensive guide for staff.

15.7 We will monitor the implementation of the Fitness to Practise Strategy and procedure manual and the impact of the additional resourcing on the PSNI’s fitness to practise function and timeliness in future performance reviews. We intend to audit the PSNI’s fitness to practise function as part of our 2024/25 performance review.

## Conclusion

We recognise that the PSNI's small caseload means that median timeframes can be impacted by outliers, which may have delays caused by factors outside the PSNI's control. However, the data also shows an overall increase in the caseload, an increase in older cases, and the number of cases awaiting hearing, which is higher than the number of hearings the PSNI usually holds each year. Therefore, the Standard is not met. We note the PSNI has reprofiled resources to progress cases and it expects to see the impact of this next year.

# 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 last audited the PSNI's fitness to practise jurisdiction and threshold criteria decisions in 2020/21, and we had no significant concerns. Due to operational issues within the PSNI we did not undertake an audit this year. However, we have seen no evidence to indicate performance has declined since our audit.
- 16.2 One of the actions set out in the PSNI's Fitness to Practise Strategy is to consider how it records decision-making at all stages of the fitness to practise process, and it expects to have a revised approach in place by early 2025. This also includes a quality assurance mechanism. We welcome this change to how the PSNI records and quality assures its decision-making and will assess the implementation of these changes in the next performance review year.
- 16.3 Last year, our Section 29 team issued one learning point to the PSNI. This year the team has not identified any performance issues during the review period.

## Conclusion

This Standard was met last year, and we have seen no changes in the PSNI's decision-making processes this year. The PSNI has committed to strengthening its decision-making processes and how it records the decisions it makes. It will also be exploring ways it can enhance its quality assurance mechanisms, and we will monitor the impact of any changes. We are satisfied that this Standard is met.

# 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.**

## Timeliness of interim orders

- 17.1 The data we have seen for this review period indicates that the PSNI acts within a reasonable timeframe when it identifies a need for an interim order. The majority of cases with interim orders are at the later stages of the fitness to practise processes and includes cases awaiting fitness to practise hearings. As there is a high proportion of cases awaiting hearings with interim orders, we expect the PSNI to prioritise these cases.

## Risk assessments

- 17.2 The PSNI confirmed a risk assessment is documented on every case it receives and includes a requirement for staff to complete a narrative to support their assessment. The PSNI said it continues to carry out weekly reviews of all its open cases, which include assessing whether there have been any changes to the level of risk. The PSNI told us that it has introduced further controls to ensure that risk assessments were being carried out, such as:
- calendar reminders to prompt staff to complete risk assessments;
  - creating and assigning risk assessment tasks to staff;
  - tracking the progress of risk assessments; and
  - monitoring the completion of risk assessments to ensure they are not overlooked.
- 17.3 The PSNI explained that it will be implementing more robust processes, including checklists to ensure risk assessments are being carried out consistently, and to provide a structured approach to assessing risks. It will also look at the functionality of its case management system for prompting risk assessments.

## Conclusion

The data we have available suggests that the PSNI is identifying and acting on high risk cases. A high proportion of cases awaiting final hearing have interim orders, and we recommend that the PSNI prioritises these high-risk cases. We have no concerns about the PSNI's identification of risk. We are satisfied that this Standard is met.

# 18

## All parties to a complaint are supported to participate effectively in the process.

- 18.1 The PSNI signposts registrants involved in the fitness to practise process to the Pharmacists' Advice and Support Service (PASS) and is reviewing its correspondence and website to ensure that registrants involved in the process are directed to PASS. The PSNI's policy is that the fitness to practise process should be explained to complainants at the triage stage, and support provided where needed. The PSNI has told us that updates to its fitness to practise manual will also set out how PSNI staff should support those involved in the fitness to practise process and that the fitness to practise team will also be undergoing training in this area.
- 18.2 The PSNI's Fitness to Practise Strategy includes a commitment to ensuring that its communications are clear, empathetic, informative, professional and compliant with its statutory obligations. To meet this objective, the PSNI will be reviewing all its template correspondence and will review the support it provides to complainants and registrants, including taking a more 'sensitive, supportive and compassionate' approach. It will also develop a joined-up approach with its stakeholders including the Department of Health and Strategic Planning and Performance Group to ensure that pharmacists going through the process are not being sent correspondence from different agencies, ensuring that investigations are streamlined. We will continue to monitor this work.

### Conclusion

The PSNI has committed to strengthening its communications with parties involved in the process, making this a key area in its Fitness to Practise Strategy and we will consider the impact of that work in the next performance review period. We have not seen any evidence to suggest that performance against this Standard has declined and we are satisfied that this Standard is met.

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