

# Report of the Registrar Council Meeting 24<sup>th</sup> April 2025



## Highlights from the Registrar

#### Launch of PSI Corporate Strategy

We were delighted to officially launch our Corporate Strategy 2025-2028 in PSI House on Friday, 4 April. The launch event was attended by the Minister for Health, Jennifer Carroll McNeill TD, and 50 invited guests. The event provided an important opportunity to engage with all who attended and to share our commitment and enthusiasm for the work we will undertake over this strategic period.

The President, Katherine Morrow, provided the welcome and an overview of the Strategy and priority projects for the PSI. The Minister took the time to meet with Council members, staff and our guests and expressed strong support for our work. In her speech, she spoke of her commitment to the implementation—and potential expansion—of the Expert Taskforce recommendations, highlighting the valuable and growing role of pharmacists in delivering patient and community-centred care. The Registrar provided an update on pharmacy workforce matters and the progress being made by the multi-stakeholder Pharmacy Workforce Working Group.









#### Election for pharmacist member appointments to the Council

The nomination period for pharmacists seeking appointment to the Council concluded on 19 March. Sixteen candidates are participating in an election process that concludes on Wednesday, 16 April, when all ballot papers must be received. The counting of votes takes place on Thursday, 17 April, after which the Minister will be notified of the five pharmacists selected in order that she may make appointments to the Council this June. The outcome of the election will be published on the PSI website.

# Supporting pharmacist involvement in the Spring COVID-19 Booster Vaccination Campaign

On 15 April, the Registrar approved the National Immunisation Office (NIO) training in respect of Comirnaty KP.2 10mcg, as training for the purposes of Regulation 4F(b) of the Medicinal Products (Prescription and Control of Supply) (Amendment)(No.7) Regulations 2020 (S.I. No. 698 of 2020)(as amended), for the purposes of facilitating pharmacist vaccinators in supplying and administering this vaccine as part of the Spring COVID-19 booster campaign.

The Spring COVID-19 Booster campaign will run from April until the end of May. Data on pharmacy participation in the campaign will be shared with Council in future updates, once available from the HSE.

#### Annual Report submitted to the Minister for Health

Following approval by the Council at the end of March, the Annual Report and Financial Statements for 2024 were submitted per our requirement to the Minister for Health. We await notice of the report being laid before the Houses of the Oireachtas, at which time we will publish it on our own website.

## Changes to the Registrar's Report

Based on feedback from the Special Purposes Committee and in order to help streamline the information contained within the Registrar's Report, content relating to meetings attended by colleagues within the PSI and communications issued will now be included as appendices.

## Ongoing Regulatory Work Programmes in 2025

| Activity  | Outputs   | Update  |
|---|---|---|
| Review our vaccination and emergency medicines training requirements and prepare a report with recommendations for updates. | A report recommending updates to vaccination and emergency medicines training requirements will be developed by Q4 2025 for consideration by the Regulatory and Professional Committee and Council. | An internal cross- organisational working group with representation from teams across PSI, including Professional Standards, Strategic Policy and Research, Quality and Safety, and Governance and Programme Delivery, continues to meet every two weeks.  The group are conducting research and benchmarking analysis, stakeholder engagement and issued a survey to all pharmacists on 15 April to inform the development of recommendations. |
| Continue implementation of the reform of the Continuing Professional Development (CPD) process for pharmacists.             | Proposed legislative amendments provided to the Minister for consideration in Q1 2025.  | The proposed legislative amendments were approved by the PSI Council at its meeting of 6 March. These will be submitted to the Minister shortly. Section 53 of the Regulated Professions (Health and Social Care) Amendment Act 2020 is expected to be commenced imminently and is contingent on the consideration of the proposed amendments.  |
|   | Implementation Pathway Plan was developed in conjunction with the IIOP by Q4 2025.  | A meeting was held with the IIOP on 4 April to commence the planning and drafting of an Implementation Pathway Plan.  |
| Implementation of CPD system for Pharmaceutical Assistants  | Proposed legislative amendments provided to the Minister for consideration regarding the new CPD system in Q1 2025.   | The proposed legislative amendments were approved by the PSI Council at its meeting of 6 March. These will be submitted to the Minister   |

|  |   | for Health shortly. Section 53 of the Regulated Professions (Health and Social Care Amendment) Act 2020 is expected to be commenced imminently and is contingent on the consideration of the proposed amendments. |
|--|---|---|
|  | Implementation Pathway Plan developed, in conjunction with the IIOP by Q4 2025.   | A meeting was held with the IIOP on 4 April to commence the planning and drafting of an Implementation Pathway Plan.  |
| Submit to the European Foundation for Quality Management (EFQM) in Q3 2025 to maintain four-star recognition.  | EFQM Recognition  | A presentation was made to the Wider Management Team group on the EFQM model and timelines regarding the submission. The drafting of the submission has commenced.  |
| Develop and implement year one of a Communications Strategy 2025-2028, aligned to the PSI Corporate Strategy and our mission, vision and values.   | New Communications Strategy is approved by Council in Q1 2025, including a detailed plan for executing the year-one initiatives. Year one initiatives are delivered by Q4 2025.   | The four-year Communications Strategy is on the agenda for approval by the Council at its 24 April meeting.   |
| Advance our actions to contribute to Ireland's second National Action Plan on Antimicrobial Resistance 2021-2025 (known as iNAP2) to address antimicrobial resistance (AMR) and help advance Ireland's response to AMR by improving awareness and knowledge of AMR amongst the pharmacy profession, including pharmacy students, to ensure that it is an integral part of the delivery of pharmacy services. | Participation of pharmacists in continuing professional development (CPD) and education on AMR, infection prevention and control (IPC) and antimicrobial stewardship (AMS) is encouraged by the promotion of resources and increased awareness of the importance of these areas for practice. | In the March edition of our newsletter, we highlighted an educational resource developed by HSE-AMRIC, tailored for community pharmacy settings, available to pharmacists through the IIOP website.               |

# Key updates under each of our three Strategic Objectives as we implement our Corporate Strategy 2025-2028.



## **Objective 1**

Regulate Pharmacists and Pharmacies to Deliver Essential and Expanded Pharmacy Services in the Healthcare System

#### **Open Disclosure**

The National Open Disclosure Framework aims to further embed structures of transparency and open communication between health professionals and patients following a patient safety incident or an adverse event. As a professional regulator, the PSI has various responsibilities under the Framework to support pharmacy in embedding open disclosure, including the requirement to submit an annual report to the Minister around work in this area.

The PSI has had ongoing meetings with other regulators to ensure a shared understanding of our obligations and expectations under the Framework and have further engaged with the National Patient Safety Office (NPSO) in this regard. The PSI completed our submission and received confirmation from the NPSO of our fulfilment of the Framework's annual report requirement on 31 March 2025.

To help further support pharmacists with their obligations under the Framework, an <u>Open Disclosure Training Programme</u>, specifically designed around open disclosure in pharmacy settings, <u>went live on the IIOP website on 10 April</u>. The PSI will continue to engage with registrants, the NPSO, and other regulators as work around open disclosure evolves.

# Recommendations of the Expert Taskforce to support the Expansion of the Role of Pharmacy

The PSI continues to contribute to the work of the Community Pharmacy Expansion Implementation Oversight Group (IOG), established to oversee the introduction of a Common Conditions Service in community pharmacies, as well as the continuation of prescriptions for contraception.

While the PSI contributes to all six of the workstreams overseen by the IOG, we are the lead for the second workstream, 'Education and training for pharmacists and regulatory matters,' which includes oversight of the delivery of training for the Common Conditions Service and continuation of prescriptions for contraception.

We continue to engage with the IOG and the Irish Institute of Pharmacy (IIOP) regarding the training approach for these services. Work is also underway to progress the development of regulatory supports for pharmacists, including guidance and the drafting of PSI Council rules to enable common conditions training for pharmacists. The delivery of training and other regulatory supports are ultimately dependent on the finalisation of the clinical protocols that will underpin service delivery, secondary legislation and other operational elements.

The PSI has continued to actively develop the training approach to support pharmacists in delivering both the Common Conditions Service (CCS) and the continuation of contraception prescribing. A detailed training specification has been prepared and was presented at the most recent meeting of the IOG. Preparations are underway to begin the development of this training.

### Future of the Pharmacy Workforce

At the recent launch of the <u>PSI Corporate Strategy 2025-2028</u>, wherein the PSI makes a strategic commitment to examine the issues facing the professional workforce, we took the opportunity also to highlight the <u>Pharmacy Workforce Working Group 2024 Summary Report</u>, which discusses the outputs from the working group's inaugural year.

Particular strides have been made in areas such as data collection and analysis to facilitate workforce modelling (like our most recent <u>survey of the register</u>), reduction in administrative burden, guidance around <u>governance roles within pharmacy</u>, and improving overall working conditions.

Further insights on the working group will be contained in an article submitted by the PSI for an upcoming edition of the *IPU Review* magazine.

#### Accreditation

Our accreditation panels are drafting evaluation reports on their recent accreditation visits to the existing accredited MPharm programmes in the State. These reports are due to be circulated to the respective universities over the coming weeks for their comments before being presented at the June Council meeting for consideration.

#### Implement a Delineated Pharmacy Model

Draft guidance and proposed amendments to the Regulation of Retail Pharmacy Business Regulations to facilitate a delineated pharmacy model were considered by PSI Council on 25 April 2024.

PSI is currently drafting and reviewing the required amendments to the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495/2008)

that are required to facilitate a delineated model. These proposed amended rules will be issued for public consultation in due course. A principles-based guidance document that will provide support for practitioners implementing this model is also being considered and prepared.



## **Objective 2**

Evolve our Regulatory Approach to Drive Safe Patient Outcomes in the Delivery of Pharmacy Care

#### Stakeholder Engagement in patient safety and quality initiatives

Year to date, the Quality and Safety team has carried out a total of 47 inspections. The team conduct pharmacy registration inspections where we have registration applications for new pharmacy openings, changes of ownership and relocations of pharmacy premises.

At present, 5 onsite registration-related inspections have been conducted to assess compliance with the Retail Pharmacy Business Regulations and PSI Guidelines.

A total of 42 risk-based pharmacy inspections have been conducted to date. Risk-based inspections are undertaken following a review of information available to the PSI. These inspections are focused on a particular area or the general operation of the pharmacy, including inspection/compliance history or where a member of the public or an external body has raised a concern.

We are currently preparing our next set of inspection findings from the PSI Quality and Safety Team to disseminate inspection insights and support a culture of continuous improvement and learning across the community pharmacy sector. This initiative aims to uphold the delivery of safe and quality services to patients and the public from retail pharmacy businesses.

#### Patient and Public involvement in our work

As part of our commitment to ensuring that the voices of patients and the public are central to the development of pharmacy services in Ireland, the PSI continues to progress its work under the Patient and Public Involvement workstream. This initiative seeks to create opportunities for meaningful engagement with patients to inform and enhance regulatory and policy developments in pharmacy.

In March, we were delighted to host a meeting of the HPRA Patient Forum in PSI House, with thanks to the Patient Forum members and the HPRA for facilitating the opportunity. The highly informative session provided the opportunity to engage directly with members of the Forum on a number of ongoing projects. These included discussions on the evolving role of the pharmacist, particularly in relation to training requirements for vaccinations and the Common Conditions Service. The group also considered the proposed delineated pharmacy operating model, which would support the provision of protected breaks for pharmacists during the working day. We sought feedback on how best to communicate these initiatives to the public, and the Forum provided valuable insights on both content and approach. The

meeting also included an introductory overview of the PSI's role and statutory functions to provide context for participants.

In parallel, we have progressed work on a research application for an HRB Applied Partnership Award designed to explore effective methods of patient engagement. This research aims to support the development of practical approaches to involving patients and the public in our regulatory work. Interim feedback on the application from Health Research Board (HRB) reviewers was received recently, and we have worked with our research partners to respond to the comments and questions raised.



## **Objective 3**

Enhance and Align our Organisation and People to Successfully Achieve our Strategic Priorities and Core Responsibilities

## Strategic HR Update

A new performance management system has been introduced to support alignment across the organisation and to strengthen the delivery of PSI's strategic priorities and core responsibilities. As part of this initiative, all staff participated in performance management training delivered by the Institute of Public Administration (IPA). This training aimed to ensure a consistent understanding of the new system and to support staff in engaging meaningfully with the performance management process. The implementation of this new system represents a further step in embedding a culture of continuous improvement and organisational alignment across PSI.

## Workforce Planning and Recruitment

We continue to focus on workforce planning and recruitment. We are currently progressing with the following recruitment:

| Role  |                                | Contract Type                                  |
|---|--------------------------------|--|
| Pharmacy Practice and Policy Manager (formerly Advanced Practice Manager) | Assistant Principal<br>Officer | Fixed Term Contract – 3 Years (Contract stage) |
| HR Officer  | Higher Executive<br>Officer    | Permanent (Post interview checks are underway) |
| Head of Registration and Education  | Chief I Pharmacist             | Permanent                                      |
| Finance and Support Services Clerical Officer                             | Clerical Officer               | Permanent                                      |

The following posts are sanctioned, and recruitment will commence shortly:

| Role   | Grade                       | Contract Type                 |
|--|-----------------------------|-------------------------------|
| Pharmacy Practice Coordinator (formerly Advanced Practice Coordinator) | Higher Executive<br>Officer | Fixed Term Contract - 3 Years |
| Corporate Governance Manager   | Grade VIII                  | Permanent                     |
| Authorised Officer (Eng III) x 2                                       | Engineer Grade III          | Permanent                     |

## Implementing the Public Sector Equality and Human Rights Duty

The PSI's Public Sector Duty Action Plan was approved by the Executive Leadership Team (ELT) and will be published on the PSI website. This action plan sets out PSI's commitment for 2025 in relation to implementing our public sector duty. A presentation was made to the PSI Council at its training and development day on 27 March on our public sector duty and the steps the PSI has taken in relation to implementing our duty and the PSI Council's role in this regard.

## **ICT Strategy**

The trial of Co-pilot (Microsoft's AI tool) is nearing completion, and the ICT team has been analysing its performance and implications. Based on the findings, the team will be making recommendations to the Executive Leadership Team (ELT) regarding the integration and potential benefits of Co-pilot within our organisation. This trial has provided valuable insights that will shape our future strategies and enhance operational efficiency.

## **Cyber Security**

There were two significant upgrades to the security on the PSI Registration Portal implemented last year, and we engaged with a third party to validate the impact. We recently received a report from that third-party organisation, which specialises in portal security and deep and dark web intelligence. The review made recommendations to improve the security of our portal, which have been passed on to our portal provider for implementation. The report also highlighted the statistics available to show the positive impact of the current security setup. This report will be used to fortify our portal security and ensure the integrity of our online presence.

## **Core Funding Review**

We have concluded the tender process for a service provider to carry out a Core Funding Review to ensure we maintain a sustainable financial position and appropriate funding model to enable the PSI to continue to carry out its statutory functions and to deliver on its strategic and operational mandate to the requisite standard. We are currently contracting with the successful tenderer and progressing plans with regard to the start date of the project. The outputs of this project will provide Council with the necessary contextual analysis and environmental appraisal to support evidence-based decision-making as to the appropriate future resourcing requirements for the PSI.

## Implementation of the 2024 Climate Action Roadmap

Implementation of the 2024 Climate Action Roadmap, as approved by Council in June 2024, is ongoing. Progress under each of the mandate categories is as follows:

#### **Our Targets:**

The publication of the Government's Climate Action Plan 2025 has been delayed due to governmental changes. It is now estimated that the Plan will be published in April. Upon receipt, PSI will proceed with the development of its 2025 Climate Action Roadmap.

#### **Our People:**

PSI completed the Reduce Your Use campaign, which ran from October 2024 to March 2025, with regular communications to staff to improve staff awareness of energy use and management. There has been a notable decrease in energy use compared to the same period over 2023/24, and once the March 2025 energy bills have been received and the results from the close-out survey to staff have been received, a full assessment of the campaign's success can be made.

Two members of the Health, Safety, and Sustainability Committee (HSSC) have completed their Green Team National Programme Training. Additionally, one member of the HSSC has completed training for the current SEAI Monitoring and Reporting (M&R) cycle, which has a deadline of 16 May.

| Services/goods to be procured                              | Current status   |
|--|--|
| Establishment of a panel of Legal Assessors & Mediators    | Completed March 2025, Panel established  |
| TCQR route - provider of examination for new TCQR route    | Dynamic Purchasing System (DPS) for the examination under the new TCQR route published 10/03/25, live and open to responses.   |
| IIOP   | Current contract is being extended, under the same terms and conditions with the RCSI, for 8 months, until 31 December 2025, in line with our procurement policy and with reference to the provisions of the public procurement rules (Art. 72 of Directive 2014/24/EU), in which public bodies may modify contracts, in certain limited circumstances. The limited extension to the existing contract is required while the final stages of the reform of the CPD model are ongoing. The procurement process is ongoing (negotiated procedure) with the current provider with a view to having a new contract in place under the revised model for CPD in 2026, subject to the legislative provisions being signed. |
| Facilities management                                      | Tender specification in development with the assistance of PSI's procurement advisors. Stage one (PQQ) to be published by April 2025.  |
| Digital Skills Training                                    | RFT developed and under review.  |
| Core Funding Review  | Tender published 19 February 2025 utilising OGP framework agreement for Business, Management and ICT Consultancy Services. Evaluation of submissions complete and outcome letters issued, contracting in progress with the successful tenderer.  |
| Investment<br>Management                                   | Tender documents in development and under review by PSI's procurement advisors.  |
| Phone Systems  | Request for quotes circulated 24 February 2025. Evaluation of submissions complete and outcome letters issued, contracting ongoing with successful tenderer.   |
| Cloud-based system for<br>Council Meeting<br>Documentation | Tender documents developed and published on 25 March 2025 on etenders with the assistance of our procurement advisors.   |

## Appendix 1 – Statistical Summary

## Complaints and Fitness to Practise (figures as at 11/4/2025)

| Complaints for Screening Committee (Preliminary Proceedings Committee – PPC) | Total Year to<br>Date | 2024 year-to-date equivalent |
|--|-----------------------|------------------------------|
| Total new complaints received year to date                                   | 10                    | 17                           |
| New complaints received since last report date                               | 6                     | 6                            |
| Total open, active complaints*   | 62*                   | 42                           |
| Complaints considered by PPC since last report date                          | 10**                  | 5                            |

<sup>\*8</sup> of which are before Council at its next meeting, and a further 7, at least, which will be ready for the June meeting

### Fitness to Practise (figures as of 11 April 2025)

| Inquiries/Hearings                         | Total Year to | 2024 year-to-date |
|--|---------------|-------------------|
|  | Date          | equivalent        |
| Total heard or commenced year-to-date      | 8             | 10                |
| Heard or commenced since the last report * | 3             | 5                 |
| Complaints being investigated/prepared for | 37            | 44                |
| hearing                                    |               |                   |

<sup>\*37.5 %</sup> meet the KPI of the inquiry being heard within 18 months from the date of referral by the PPC to a Committee of Inquiry. 7 took place before the PCC & 1 took place before the HC

#### Mediation

| Mediation  | Total Year to<br>Date | 2024 year-to-date equivalent |
|--|-----------------------|------------------------------|
| Total referrals to mediation since the last report | 0                     | 0                            |
| Total referrals pending mediation                  | 0                     | 1                            |
| Held year-to-date                                  | 0                     | 0                            |

<sup>\*\*2</sup> of these complaints were being considered for the 2<sup>nd</sup> time. 3 complaints were adjourned. None of the 10 cases met the KPI of the PPC decision within six months from the date of receipt of the complaint to the date of the final PPC decision. For the 7 cases where a decision was made, the average time was eight months.

## Sanction hearings/ undertakings/dismissals/applications before Council

| Sanction Hearings/                                   | Total Year | 2024 year-to-date |
|--|------------|-------------------|
| Undertakings/Dismissals/Applications before Council* | to Date    | equivalent        |
| Heard since last report*                             | 3          | 3                 |
| Heard year to date*                                  | 4          | 7                 |
| Sanction hearings/undertakings being prepared for    | 9          | 9                 |
| Council  |            |                   |

<sup>\*</sup>per respondent

| High Court Sanction Confirmation Hearings        | Total Year to<br>Date | 2024 year-to-date equivalent |
|--|-----------------------|------------------------------|
| Held year-to-date                                | 2                     | 3                            |
| Cases being prepared for High Court confirmation | 0                     | 3                            |

| Appeals                                    | Total Year to Date | 2024 year-to-date equivalent |
|--|--------------------|------------------------------|
| Held year-to-date                          | 0                  | 0                            |
| Cases being prepared for High Court appeal | 0                  | 0                            |
| Judgment awaited                           | 1                  | 1                            |

| Callovers                               | Total Year to<br>Date | 2024 year-to-date equivalent |
|---|-----------------------|------------------------------|
| Callovers heard year to date:           |                       |                              |
| Professional Conduct                    | 1                     | 1                            |
| Committee                               | 1                     | 1                            |
| 2. Health Committee                     |                       |                              |
| Callovers heard since last report date: |                       |                              |
| Professional Conduct                    | 1                     | 1                            |
| Committee                               |                       |                              |
| 2. Health Committee                     | 1                     | 1                            |

## The next PCC and HC Callovers are scheduled for 05 June 2025

| Interim Suspension Applications | Total Year to Date | 2024 year-to-date equivalent |
|---------------------------------|--------------------|------------------------------|
| Applications heard by           | 0                  | 0                            |
| Council year to date            |                    |                              |

| Prosecutions               | Total Year to Date | 2024 year-to-date equivalent |
|----------------------------|--------------------|------------------------------|
| Cases being prepared for   | 0                  | 0                            |
| District Court Prosecution |                    |                              |

## Professional Registration (figures as at 9/4/2025)

| Route/application type  | Registrations/ actions completed as of 9/4/2025 | 2024 year-to-<br>date equivalent |
|---|---|----------------------------------|
| National route  | 4   | 5                                |
| EU route  | 14  | 46                               |
| Non-national route (Third Country) – UK only                                      | 12  | 19                               |
| Non-national route (Third Country) – excluding UK                                 | 17  | 17                               |
|   |   |                                  |
| European Professional Card – establishment of service (qualification recognition) | 1   | 3                                |
| European Professional Card – temporary and occasional provision of service        | 0   | 1                                |
|   |   |                                  |
| Voluntary cancellations from Register   | 44  | 38                               |
| Involuntary cancellations from Register   | 39  | 17                               |
|   |   |                                  |
| Restorations to Register following voluntary cancellation                         | 12  | 7                                |
| Restorations to Register following involuntary cancellation                       | 0   | 1                                |
|   |   |                                  |
| Certificates of Current Professional Status issued.                               | 31  | 28                               |
|   |   |                                  |
| IMI Alerts (internal market information) issued by PSI                            | 1   | 3                                |

## Retail pharmacy businesses

| Registration of Retail Pharmacy<br>Businesses 2025 (figures as of<br>09/04/2025) | Registrations/ actions completed as of 09/04/2025   | 2024 year-to-<br>date equivalent |
|--|---|----------------------------------|
| Number of Registered Retail<br>Pharmacy Businesses                               | 1985  | 1982                             |
| Retail Pharmacy Business openings by type  | New opening: 0 Permanent relocation: 2 Change of ownership: 12  | 4<br>3<br>16                     |
| Retail Pharmacy Business cancellations by type                                   | Voluntary cancellations (closure): 4 Voluntary cancellations (permanent relocations): 2 Voluntary cancellations (changes of | 7<br>3                           |
|  | ownership): 12<br>Involuntary cancellations: 0  | 0                                |
| Number of changes in supervising and superintendent pharmacists                  | Supervising pharmacist changes: 96 Superintendent pharmacist changes: 339   | 39                               |

| Internet supply                            | Figures as of 09/04/2025 | 2024 year-to-date equivalent |
|--|--------------------------|------------------------------|
| Number of pharmacies on Part A             | 132                      | 131                          |
| Number of non-pharmacy retailers on Part B | 197                      | 165                          |

## Regulation of Retail Pharmacy Businesses (figures as of 11/4/2025)

| Pharmacy Inspections 2025   |    | PSI 2025 Service Plan Pharmacy Inspection Key Performance Indicator (KPI) | 2024 year-to-date<br>equivalent |  |
|---|----|---|---------------------------------|--|
| Total number of onsite Pharmacy inspection visits to date   | 42 | 300   | 80                              |  |
| Total number of registration-related inspections to date  | 5  | 15  | 3                               |  |
| Number of pharmacy re-inspections – including re-inspections following Registrar's decision under Section 71(1)(d) to date. | 0  | 0   | 1                               |  |

| Concerns (figures as of 11/4/2025)           | Total Year to<br>Date | 2024 year-to-date equivalent |
|--|-----------------------|------------------------------|
| Total new concerns received year to date     | 49                    | 24                           |
| New concerns received since last report date | 26                    | 13                           |
| Concerns reviewed since the last report date | 25                    | 11                           |
| Open concerns                                | 17                    | 3                            |

| Investigation activity 2025 - Part 7 of the Pharmacy Act / Inspection & Enforcement) |                                  |                          |
|--|----------------------------------|--------------------------|
| Number of investigations   | Number of investigations         | Number of investigations |
| open   | initiated since the last Council | closed since the last    |
|  | meeting                          | Council meeting          |
| 18   | 1                                | 0                        |
| Investigation Activity 2025 (Section 67) – e.g. Interviews /                         |                                  | 6                        |
| Statements / Pharmacy Visits / Professional Witness                                  |                                  |                          |

| Investigation activity 2024 – year to date equivalent - Part 7 of the Pharmacy Act / Inspection & Enforcement) |                                  |                          |  |
|--|----------------------------------|--------------------------|--|
| Number of investigations   | Number of investigations         | Number of investigations |  |
| open   | initiated since the last Council | closed since the last    |  |
|  | meeting                          | Council meeting          |  |
| 15   | 0                                | 2                        |  |
| Investigation Activity 2024 (Se  | 1                                |                          |  |
| Statements / Pharmacy Visits / Professional Witness  |                                  |                          |  |

## Information Governance (as of 16/04/2025)

## Freedom of Information

| Number of FOI requests received | Granted | Handled<br>outside of FOI | Refused | Currently being processed |
|---------------------------------|---------|---------------------------|---------|---------------------------|
| 5                               | 5       | 0                         | 0       | 0                         |

## **Data Protection**

| Number of Subject<br>Access Requests<br>received | Granted  | Refused  |                |
|--|--|--|----------------|
| 0  | N/A  | N/A  |                |
| Number of Data breaches                          | Reported to the Data Protection Commissioner (DPC) | Not meeting the threshold for reporting to DPC |                |
| 6  | 0  | 6  |                |
| Data transfer requests                           | Category:<br>Research purposes                     | Category: Patient Safety Alert/Product Recall  | Category: IIOP |
| 4  | 2  | 0  | 2              |

| Appendix 2: Overview   | of meetings attended by the Registrar and PSI staff (since last report)  |
|--|--|
| 4 March, 2025  | We delivered a presentation to 3 <sup>rd</sup> Year pharmacy students at RCSI as part of our continued engagement with pharmacy students on the role and functions of PSI across the three Schools of Pharmacy.  |
| 5 March, 2025  | We attended the launch of a position paper entitled 'Vision and Strategic Approach to Adult Immunisation in Ireland', at the Royal College of Physicians of Ireland (RCPI).  |
| 7 March, 2025  | We attended an international collaborative seminar on patient safety delivered by the National Patient Safety Office at the Department of Health, ISQua and the HSE. The theme of the event was "Running health delivery systems in an era of great challenges: Keeping the orchestra playing while rewriting the symphony." |
| 10 March, 2025   | We coordinated a meeting between Greg Eberhart (former Registrar of the Alberta College of Pharmacists, Canada) and colleagues at the Department of Health to discuss the expanded scope of practice of pharmacists.   |
| We attended a Medicines for Ireland event entitled Digits 2025 Solutions for Greener Industry. |  |
| 13 March, 2025   | We met with HSE Addiction Services as part of our programme of work to review the vaccination and emergency medicines training requirements for pharmacists.   |
| 13 March, 2025   | We met with the other Pharmacy Workforce Working Group members to discuss updates on the recommended actions from the Workforce Intelligence Report.   |
| 14 March, 2025   | We met with Hibernian Healthcare, as part of our programme of work to review the vaccination and emergency medicines training requirements for pharmacists.  |
| 14 March, 2025   | We met with the HSE Enhanced Community Care Programme and Primary Care Contracts, as part of our programme of work to review the vaccination and emergency medicines training requirements for pharmacists.  |
| 18 March, 2025   | We attended the Controlled Drugs National Group, led by the Care Quality Commission. This group is comprised of key regulators and agencies across Ireland and the UK with a remit for controlled drugs.   |

|                | We met with other health and social regulators to discuss our reporting obligations to the Minister for Health under the  |  |  |  |
|----------------|---|--|--|--|
| 19 March, 2025 | National Open Disclosure Framework.   |  |  |  |
| 20 March, 2025 | We met with the Irish Pharmacy Union (IPU), as part of our programme of work to review the vaccination and emergency medicines training requirements for pharmacists.   |  |  |  |
| 20 March, 2025 | We met with the Irish Institute of Pharmacy (IIOP), as part of our programme of work to review the vaccination and emergency medicines training requirements for pharmacists.   |  |  |  |
| 20 March, 2025 | We attended a meeting of the Pharmacy eHealth Group.  |  |  |  |
| 25 March, 2025 | We hosted a meeting of the Health Products Regulatory<br>Authority (HPRA) Patient Forum as part of our ongoing efforts to<br>involve patients and the public in our work.   |  |  |  |
| 31 March, 2025 | We attended a meeting of the Regulatory Advisory Group of the International Pharmaceutical Federation (FIP).  |  |  |  |
| 1 April, 2025  | We met with staff from the National Patient Safety Office to discuss Open Disclosure and our recent submission to the Minister for Health.  |  |  |  |
| 2 April, 2025  | We attended a meeting of the Regulator's Forum in the Department of Health.   |  |  |  |
| 3 April, 2025  | We attended the Pharmaceutical Manager's Institute Conference. The Registrar and Vice President participated in a panel discussion on "Empowering Pharmacists: Tools and Strategies for Thriving Amid Change".  |  |  |  |
| 4 April, 2025  | We met with the IIOP to commence planning and drafting of an Implementation Pathway Plan to continue implementation of the reforms to the CPD process for pharmacists and the development and implementation of a CPD system for pharmaceutical assistants. |  |  |  |
| 5 April, 2025  | The President and Registrar attended the Hospital Pharmacists Association of Ireland Gala Dinner of the annual conference.  |  |  |  |
| 7 April, 2025  | We met with the Northern Ireland Centre for Pharmacy Learning and Development (NICPLD) as part of our programme of work to review the vaccination and emergency medicines training requirements for pharmacists.  |  |  |  |
| 7 April, 2025  | We participated in the first meeting of the Communications Sub-<br>Group of the Community Pharmacy Expansion Implementation<br>Oversight Group (IOG).   |  |  |  |

| 8 April, 2025    | We attended a meeting of the Community Pharmacy Implementation Oversight Group (IOG).   |  |  |
|------------------|---|--|--|
| 10 April 2025    | Representatives from PSI met with officials from the Department of Health for the first governance meeting of the year.   |  |  |
| 10 April, 2025   | We attended a meeting of the National ePrescribing Project Board.   |  |  |
| 11 April, 2025   | We met with the National Immunisation Office (NIO) as part of our programme of work to review the vaccination and emergency medicines training requirements for pharmacists.          |  |  |
| 15 April, 2025   | We participated in a meeting of the National Working Group on Preventing Paracetamol-Related Intentional Drug Overdose.   |  |  |
| 16 April, 2025   | We met with the Pre-Hospital Emergency Care Council (PHECC) as part of our programme of work to review the vaccination and emergency medicines training requirements for pharmacists. |  |  |
| March-April 2025 | We continue to attend fortnightly meetings of the National COVID-19 Vaccination Programme Pharmacy Workstream Working Group.  |  |  |

Appendix 2

Overview of External Communications (since last report)

| Date issued   | Communication<br>type       | Target<br>audience                               | Subject   | Channel                           |
|---------------|-----------------------------|--|---|-----------------------------------|
| 12 March 2025 | Notice of nomination period | Pharmacists                                      | Reminder - call<br>for nominations<br>for pharmacist<br>members of PSI<br>Council       | Email, website,<br>social media   |
| 24 March 2025 | Event Invitation            | Relevant<br>stakeholders                         | Corporate<br>Strategy launch<br>invite  | Email                             |
| 26 March 2025 | Newsletter                  | All registrants<br>and newsletter<br>subscribers | PSI Newsletter,<br>Issue 1 of 2025  | Email (available on website also) |
| 8 April 2025  | Information                 | Pharmacists                                      | Council election<br>details and<br>summary of<br>Strategy launch                        | Email                             |
| 9 April 2025  | Information                 | Pharmaceutical assistants and pharmacy owners    | Summary of<br>Strategy launch<br>and overview of<br>Council election<br>process ongoing | Email                             |
| 11 April 2025 | Information                 | Pharmacists                                      | Final reminder<br>for return of<br>ballot papers –<br>election                          | Email, social<br>media            |
| 15 April 2025 | Survey consultation         | Pharmacists                                      | Survey about vaccination and emergency medicines training as part of a review           | Email, website                    |

#### Public consultations and other submissions

## Medical Council – Draft Rules for the Establishment of Subcommittees of the Preliminary Proceedings Committee (PPC)

On 7 March 2025, the PSI provided feedback to the Medical Council on their stakeholder consultation regarding draft rules for the establishment of PPC subcommittees. This consultation sought views from healthcare professionals and the public on proposed changes intended to support the operation of the Medical Council's fitness to practise procedures.

## Pharmaceutical Society of Northern Ireland – Consultation on Amendments to the PSNI (General) Regulations (Northern Ireland) 1994

On 11 April 2025, the PSI submitted a response to the Pharmaceutical Society of Northern Ireland's consultation on proposed legislative amendments to support the implementation of the Joint Standards of Initial Education and Training (2021). These amendments relate in particular to the Foundation Training Year (FTY) and aim to contribute to the development of a modern and agile pharmacy workforce in Northern Ireland.

#### Department of Health - Draft Strategy for 2025-2028

The PSI responded to the Department of Health's consultation on its draft strategy on 11 April 2025. The strategy outlines the Department's vision and key priorities for the coming years, guided by the commitments in the Programme for Government, Sláintecare, and other relevant health policies. The PSI's submission focused on ensuring the continued integration of pharmacy within broader health system reforms.