

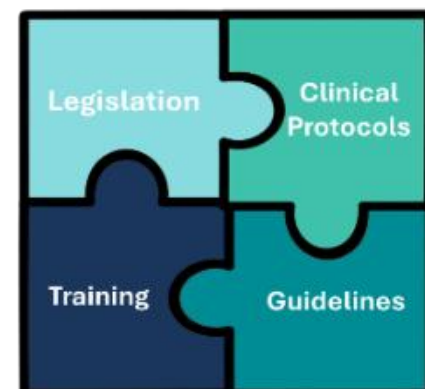
Report of the Registrar Council Meeting 11 December 2025



Highlights from the Registrar

Key enablers for the Common Conditions Service are now available

The Common Conditions Services enables pharmacists to manage and treat patients for an initial eight common conditions, including allowing pharmacists to prescribe where this is the most appropriate option. Development of each of the enablers for the service have been overseen by the multi-stakeholder Department of Health-led Community Pharmacy Expansion Implementation Oversight Group. As of mid-November, the four key enablers are now available:



1. **Legislative amendments** to authorise pharmacists to provide this service.
2. **HSE clinical protocols for each condition.** When providing the service, pharmacists must adhere to the [clinical protocols](#) developed by the HSE and approved by the Minister for Health.
3. **PSI Guidelines.** The PSI has published new [guidelines](#) to facilitate compliance with the legislative framework for the provision of this service. These guidelines provide a principles-based framework, promoting consistency and patient safety, while enabling pharmacists the flexibility to use their professional judgement.
4. **Training for pharmacists.** Pharmacists who wish to provide the service must complete the online training available via the [IIOP website](#).

On 6 November, the Irish Institute of Pharmacy (IIOP) hosted a [webinar](#) that provided an introduction and overview of the Common Conditions Service. The session featured presentations from the Department of Health, HSE, PSI and the IIOP.

Our website has been updated with all of this information (www.psi.ie/information-and-resources/common-conditions-service). We communicated with all registrants via email on 13th November and will continue to keep registrants and others informed as more information becomes available. Aligned with the announcement of the Minister for Health, and marking the availability of the training and our guidelines, we issued a press release on 14 November welcoming these developments (www.psi.ie/news).

In mid-January 2026, the Department of Health intends to launch a public information campaign about the service.

Pricing Transparency Guidance published

Following a request from the Minister for Health, on 22 October, the PSI published the Council-approved guidance to support transparency of medicines pricing and fees for pharmacy services in community pharmacies. The guidance evolves existing expectations, in line with the Code of Conduct, regarding pharmacists' responsibilities to provide clear, accurate, and accessible pricing information to patients and the public when charging for medicines, medical devices or fees for pharmacy services.

The guidance contains one primary principle, which is that patients have a right to transparent and accurate information on the price of medicines and health services they access in pharmacies. Transparency of fees and pricing maintains and enhances public confidence in pharmacists and enables patients to make informed decisions about their health and treatment.

The guidance sets out two minimum requirements for pharmacies and a timeline for implementation that has been communicated to those registered with the PSI:

- By **1 December 2025**, pharmacies must clearly display information about the cost of all professional services (e.g., vaccinations, blood pressure checks) and the range of dispensing fees.
- From **January 2026**, pharmacies must offer detailed receipts for each transaction, itemising product costs and any service or dispensing fees. The PSI is working with relevant stakeholders to ensure this is enabled.

From 1 December, PSI will commence monitoring the implementation of the pricing transparency guidance.

The Minister for Health welcomed the publication of this new guidance with a press release on 23 October 2025.

PSI Pharmacy Workforce Survey Report 2025

This annual survey, now in its fourth year, continues to inform workforce planning and policy development for the pharmacy profession in Ireland. The 2025 survey, commissioned by the PSI and conducted by Grant Thornton, was distributed to all pharmacists registered as of 1 September 2025, with 812 responses to the demographic and work-practice section and 609 responses to the sentiment section. While the response rate was lower than in previous years, the data offers valuable insights into the composition of the workforce, practice settings, and emerging challenges.

The draft survey report was discussed at the November meeting of the Regulatory and Professional Policy Committee, the December meeting of the Workforce Working Group, and is before Council for noting at its meeting on 2 October. It will be published on the PSI website in early 2026.

Autumn/Winter 2025/2026 Vaccination Campaign

The current vaccination programme continues to see significant contributions by pharmacies and pharmacists. As of 23 November, c 139K COVID-19 booster vaccines and c 344K flu vaccines had been administered by community pharmacies as part of the Autumn/Winter 2025/2026 vaccination campaign. This includes more than 114K children's flu vaccines administered by pharmacists – representing 58% of the total vaccines delivered to this age group to date. During this period, 1,122 pharmacies have administered a COVID-19 vaccine, and 1,432 pharmacies have administered a flu vaccine.

Department of Health Electronic Record-Keeping Implementation Group

The Department of Health has recently established a multi-stakeholder Electronic Record-Keeping Implementation Group to progress legislative changes to allow for records to be maintained electronically in pharmacies. This follows commitments made by the Department of Health in the [Community Pharmacy Agreement 2025 \(www.hse.ie\)](https://www.hse.ie) to reduce administrative burden in pharmacies and introduce reforms to prescription management and record-keeping.

The group is chaired by the Department of Health and comprises representatives from the Irish Pharmacy Union Pharmacy Practice Working Group, HSE, PSI and a patient representative. Five members of the PSI Executive have been appointed to the group across PSI's business areas of Pharmacy Practice, Policy and Engagement, Community Pharmacy Assurance and Registration and Education. An internal cross-organisational group has also been established within PSI to deliver a coordinated regulatory response arising from the proposed legislative changes.

HRB funding for partner research project designed to support our public and patient involvement

At the end of 2024, the PSI partnered with Professor Michelle Flood at Royal College of Surgeons Ireland (RCSI) to submit an application to the Health Research Board for Applied Partnership funding to undertake research to further identify and develop evidence-based practical strategies to incorporate the patient and public voice into our regulatory approach. The application has been successful, and funding of €200,000 has been granted, with initial work on the project commencing in 2025. The research is being undertaken to further our strategic commitment to embed meaningful and beneficial public involvement in our work. The PSI is the principal case-study for the research, and the work over two years will be collaborative, gaining the public and patient perspective, involving experienced academics and researchers, and delving into national and international experiences. When completed, the work has the potential to benefit other healthcare regulatory bodies in Ireland and globally.

Core Funding Review: Public consultation on revised Fees Rules

The PSI conducted a public consultation process over four weeks in November on the proposed PSI Fees Rules 2026, as part of its Core Funding Review Project. We received 728 responses to the consultation, and the results of the public consultation process have been shared with Council.

APPEL 4th Year MPharm Students

In September, we welcomed three 4th-year MPharm students who selected PSI to complete their mandatory four-month experiential learning placement. The students completed work on various strategic projects and gained experience across the organisation, including with our Community Pharmacy Assurance, Education and Professional Standards, and Pharmacy Practice and Policy teams. They also assisted at presentations across the Schools of Pharmacy, delivering insights on their placement experience. Their contribution is very much appreciated, and we have really enjoyed the enthusiasm they have brought to their work in PSI.

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.	<p>The report with recommendations for updates to the training requirements for pharmacists was approved by Council at its meeting on 26 June 2025.</p> <p>The report and recommendations are published on the PSI website and have been communicated to pharmacists.</p>
Continue implementation of the reform of the Continuing Professional Development (CPD) process for pharmacists.	<p>Proposed legislative amendments provided to the Minister for consideration in Q1 2025.</p> <p>Implementation Pathway Plan developed in conjunction with the IOP by Q4 2025.</p>	<p>The proposed legislative amendments to give effect to the revised CPD model for pharmacists, and the new CPD model for pharmaceutical assistants, were approved by the PSI Council at its meeting of 6 March. These were consented to by the Minister for Health on 22 October.</p> <p>PSI and IOP are meeting regularly to progress the necessary changes from an operational and IT perspective, and with a view to developing an Implementation Pathway Plan.</p>
Implementation of CPD system for Pharmaceutical Assistants	<p>Proposed legislative amendments provided to the Minister for consideration regarding the new CPD system in Q1 2025.</p> <p>Implementation Pathway Plan developed, in conjunction with the IOP by Q4 2025.</p>	<p>Section 53 of the Regulated Professions (Health and Social Care) (Amendment) Act 2020, commenced on 6 May, following which pharmaceutical assistants are required to declare at the point of continued registration that they are engaging in CPD. The proposed legislative amendments to give effect to the new CPD model for pharmaceutical assistants were approved by the PSI Council at its meeting of 6 March. These were consented to by the</p>

		<p>Minister for Health on 22 October.</p> <p>In November, a communication was issued to the PA Association and to all Pharmaceutical Assistants on the Register notifying them of the commencement of Section 53 of the Regulated Professions (Health and Social Care) (Amendment) Act 2020.</p>
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 was approved by the Council on 24 April. The 2025 activity plan has been progressed by the Communications and Engagement team, supporting significant external communication on key project developments throughout 2025, publications, consultations, elections, and pharmacist and patient engagement. The website has been enhanced with content updates and some improved functionality, and our social media activity has been consistent and enhanced with new brand templates
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.	<p>PSI are a key stakeholder in the delivery of Ireland's National Action Plan on Antimicrobial Resistance. We attended the One Health Conference, which was jointly hosted by the Department of Health and the Department of Agriculture, Food and the Marine on 17 November. The event marked the launch of Ireland's Third National Action Plan on Antimicrobial Resistance (iNAP3) 2026-2030.</p> <p>In our autumn newsletter, we highlighted the AMS microlearning videos for community pharmacists, developed by HSE-AMRIC in collaboration with McCauley's</p>

		pharmacy group. The videos aim to provide bite-sized learning about antimicrobial stewardship that can be easily incorporated into community pharmacists' working day.
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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

Recommendations of the Expert Taskforce to Support the Expansion of the Role of Pharmacy

One of the main priorities for PSI is its contribution to the implementation of the Department of Health's Expert Taskforce to Support the Expansion of the Role of Pharmacy. The recommendations of the Taskforce align services and practices that can be delivered by pharmacists and pharmacies, providing an enhanced role for pharmacy within an integrated healthcare system. As highlighted above, as of mid-November, the four key enablers are now available, authorising community pharmacists to provide the Common Conditions Service. Work on introducing a continuation of Contraception service in pharmacies was commenced in 2025 and is expected to be made available in community pharmacies in 2026. [PSI also welcomed the HRB report on pharmacist prescribing](#), which was commissioned as part of the work on the expansion of the role of pharmacy.

Propose and Implement Policy Changes Agreed with DOH

The PSI have engaged with the DoH on a number of policy initiatives in pharmacy across 2025, including;

- **Pricing Transparency Guidelines**, which were published on 22 October and circulated by email to all registrants on the same date.
- Work has commenced on a new workstream being led by the Department of Health on **Electronic Record-Keeping** practices in pharmacies. The first meeting of the group took place on 17 November. This work arises from the Community Pharmacy Agreement 2025.

PSI have also been invited to attend a new **Strategic Medicines Access and Availability Group** that will investigate, examine and pursue all appropriate measures that could improve the availability of medicines in Ireland by strategically addressing medicines shortages and gaps in availability, encourage an increase in the number of authorised and marketed medicinal products in Ireland and reduce our national reliance on EMPs. The first meeting took place on 28 November.

Regulatory Response to Digital Health Initiatives

Our strategy makes a strong commitment to support pharmacy to embrace digital technologies to support the delivery of safe, effective pharmacy services and to enhance patient outcomes. Chief among the initiatives is the National Shared Care Record and ePrescribing, both initiatives which have the potential to significantly enhance the delivery of services, increase efficiency, and streamline processes. The strategy also highlights an organisational commitment to modernise our regulatory approach and to embrace digital technologies, to enhance service delivery and communications to all stakeholders. PSI are represented on the ePrescribing project board overseeing the procurement and implementation of ePrescribing in Ireland. PSI have also been invited to sit on the Digital for Care advisory Board to advise on the implementation of the HSE eHealth Strategy Digital for Care.

Development of PSI Safe Staffing Guidance

The PSI [Workforce Intelligence Report](#), published in September 2023, provided a baseline view of the pharmacy workforce in Ireland. The Report provided recommendations to ensure the sustainability of the future pharmacy workforce. One of the short-term recommendations (1-2 years) proposed publishing guidance on the expectations of pharmacy owners, superintendent pharmacists and supervising pharmacists in ensuring safe staffing levels, adequate staffing mix and appropriate rest periods in community pharmacy.

As a result, the PSI has developed proposed 'Safe Staffing Guidance' which sets out the key responsibilities of pharmacists and those in pharmacy governance roles to support compliance with the Regulation of Retail Pharmacy Business Regulations 2008 (as amended). The guidance outlines the regulatory expectations for pharmacy owners, superintendent pharmacists, and supervising pharmacists regarding staffing levels, skill mix, and appropriate rest periods, aligned with statutory obligations, with the paramount aim of ensuring patient and public safety.

The guidance set out an overarching principle, with four indicators to support the provision of safe staffing in pharmacies, with an accompanying self-assessment checklist for those in governance roles to consider in conjunction with the guidelines. They are intended to be supportive, offering flexibility for implementation, as the pharmacist(s), support staff, staff skill mix, and the services provided will be unique to each pharmacy. Regardless of the specific arrangements, however, the same principle and accompanying indicators apply to every pharmacy.

Council will consider the draft Guidance with a view to issuing for public consultation at this meeting.

Implement a Delineated Pharmacy Model

At its meeting of 2 October 2025, the Council approved the public consultation report on proposed changes to the RPB Registration Rules to support the operation of a Delineated Operating Model and recommended the proposed RPB Registration Rules for approval and for subsequent submission to the Minister for Health for her consent.

Additional work is currently ongoing to align the legislative framework and ensure that the necessary congruence occurs between PSI and DoH responsibilities.

Implementation of Recommendations from the Workforce Intelligence Report

The fourth and final meeting of the Workforce Working Group for 2025 was hosted in PSI House on 4 December. The group received a presentation on the final report of the Employer and Employee Pharmacist Forum from Mary Rose Burke, who chaired the Forum.

The key findings from the Pharmacy Workforce Survey Analysis Report were presented to the group by Grant Thornton for discussion, along with an update from members on progress made on actions and recommendations for which they are responsible.

MPharm Accreditation

At its meeting on 2 October, the Council approved the sixth MPharm programme in the State, following the accreditation team's recommendation to accredit the proposed MPharm degree programme at South East Technological University (SETU). Following the publication of the accreditation report on our website, we were pleased to highlight the successful accreditation process and issued a press release on 9 October, in coordination with the University, and containing a quote from the Minister for Health.

This concludes the activities against this project for 2025, with annual reporting and compliance visits to take place across 2026.



Objective 2

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

Reform of the Pharmacy Act

Since 2018, the PSI has been engaging with the Department of Health on advancing reform of the Pharmacy Act 2007 in the public interest. Reform of the Act was discussed at the governance meeting with the DoH on 9 October and at a 2026 planning meeting held between PSI and DoH on 21 October with a view to agreeing on an approach to progress this work. PSI met with DoH on 25th November to discuss working on the Reform of the Act project in 2026. It was agreed that PSI would prioritise a gap analysis for the Fitness to Practise (FtP) provisions in the Pharmacy Act in order to define the FtP amendments required. This work is to be completed in Q1 2026.

Patient and Public Involvement in our Work

PSI Pharmacist Panel

We continued to deliver on our commitment to ensure the patient and public perspective informs our regulatory approach. The PSI Pharmacist Panel was created to ensure that regulatory changes and pharmacy initiatives are informed by practical experience and expertise. We were pleased to deepen our engagement with our Pharmacist Panel this year, gaining input on several initiatives, including valuable contributions during the consultation period on the draft rules and guidance concerning the Common Conditions Service and during the development of guidance in support of pricing transparency in pharmacies. We were pleased to have some of the panel members attend the launch of our Corporate Strategy in April, having gained their input during its development in 2024. The panel has been in place for two years, and its membership will be renewed this December/January, with an opportunity provided for new members.

HPRA Patient Forum

The PSI was also pleased to host a HPRA Patient Forum meeting this year, which provided a valuable opportunity to enhance understanding about the role of the PSI, to discuss the expanded scope of practice of pharmacists, including vaccinations, prescribing for common conditions, in addition to a discussion on the delineated operating model. Engagement with both forums provides PSI with valuable insights, expertise and ensures regulatory changes are underpinned by evidence-based informed decision-making. In addition, it further supports building trust in pharmacy regulations.

As highlighted above, at the end of 2024, the PSI partnered with the Royal College of Surgeons Ireland (RCSI) and has been successful in receiving funding of €200,000 from HRB

to undertake research to further identify and develop evidence-based practical strategies to incorporate the patient and public voice into our regulatory approach.

Stakeholder Engagement in patient safety and quality initiatives

Year-to-date, the Quality and Safety team has carried out a total of 303 inspections. The team conduct pharmacy registration inspections where there are registration applications for new pharmacy openings and relocations of pharmacy premises. To date, 28 registration-related inspections have been conducted to assess compliance with the Regulation of Retail Pharmacy Business Regulations 2008 and PSI Guidelines.

A total of 274 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 focus 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. PSI Inspectors are continuing to observe increased instances of non-compliance related to the management and supply of Controlled Drugs (CDs). As a result, 44 inspections focusing on CD compliance have been conducted in 2025.



Objective 3

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

Strategic HR Update

HR Strategy (2025 – 2028)

Utilising the findings of the Culture Audit, Employee Engagement Surveys, Current State Assessments, Operating Model Review, Strategic Workforce Plan and Employee Feedback, the HR Strategy 2025 – 2028 has been developed. This strategy reflects PSI's ambition to remain a modern, responsive regulator in a rapidly evolving healthcare environment, ensuring our people are empowered to deliver on the commitments set out in the Corporate Strategy 2025–2028. Building on the strong foundations of the previous HR Strategy, the new Strategy focuses on strengthening leadership capability, enhancing workforce planning, modernising systems and embedding a culture of openness and inclusion. By investing in capability and fostering collaboration, the HR Strategy will create the conditions for our people to perform at their best and contribute fully to PSI's mission of protecting public health and patient safety through effective regulation.

The Strategy was shared with the Employee Experience Consultative Forum (EECF), the Wider Management Team (WMT) and the Executive Leadership Team (ELT) to seek feedback. The HR Strategy was considered by the Performance and Resources Committee at its meeting in November and is before Council for approval.

Workforce Planning and Recruitment

We continue to focus on workforce planning and recruitment. Since the last report, the following vacancy was filled.

Role	Grade	Contract Type
Regulatory Executive	EO	Permanent

We are currently progressing with the following recruitment:

Role	Grade	Contract Type
Education and Professional Standards Manager	Grade VIII	Fixed Term Contract

Pharmacy Practice Coordinator	HEO	Fixed Term Contract
Inspector	Engineer III	Permanent
Corporate Governance Manager	AP	Permanent
Fitness to Practise and Legal Affairs Manager	AP	Permanent
Procurement and Customer Relations Lead	HEO	Permanent

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

Role	Grade	Contract Type
Registration and Customer Relations Lead	HEO	Permanent

Business Transformation Project

PSI, having received an effort estimate from our technology delivery partner to digitise mobile inspections and other related functionality for BTP Phase 3, assessed the effort estimate which significantly exceeded available budget and paused related work with our technology delivery partner. PSI have re-framed Phase 3 into 3 components:

1. Management of Inspections/Investigations and associated workflow
2. Mobile inspections
3. Portal aspect

Arising from the delay and in the absence of the delivery of Phase 3, an interim solution for Component 1 has been delivered in-house and was deployed in May. An independent 3rd party has finalised a review into a revised approach to deliver Components 1-3. This review was considered by the Business Transformation Programme Board at their meeting in November, and an update will be provided to Council at its meeting on 11 December.

ICT Strategy

The cloud-based system for Council meeting documentation is in pilot phase, with meetings run through the new system and the old system in parallel. The pilot was completed successfully, with positive feedback received. The December meeting of Council will also be conducted with the new system and the old system in parallel. The new system will replace the current iPad solution used by Council and the Preliminary Proceedings Committee.

Training was completed for Council and PSI administrators. Additional training will be provided in the New Year. Moving to the new solution will help improve the efficiency of meeting preparation and delivery, promote consistency across Council and Committee meetings and reduce the time spent managing the associated hardware. Council and Committee members will use their own devices to access the new system.

The vendor procurement for digital skills training is completed, and the training plan will be finalised in December to schedule ICT training over the coming years.

Core Funding Review

Update on the public consultation on the draft PSI Fees Rules 2026 was included in the highlights of the Registrar section.

Implementation of the 2024/2025 Climate Action Roadmap

Following on from the approval by Council of PSI's Environmental Policy and the 2025 Climate Action Roadmap in September 2025, the following progress under each of the mandate categories is as follows:

Our People:

- The Health, Safety and Sustainability Committee welcomed new members following ELT approval. These new members will be participating in Green Teams training and assisting with the implementation of the PSI's Climate Action Roadmap.
- The Health, Safety and Sustainability Committee issued several communications for Climate Action Week 2025. These included online resources, environmentally conscious recipes, sustainability tips and more, demonstrating our commitment to engaging with staff with sustainability campaigns and resources on a regular basis.

Our Targets:

- The monthly manual meter reading process is continuing in collaboration with Apleona to ensure consistent readings and ongoing review of utilities use, which is reporting a 13% reduction in electricity usage in the last 12 months compared to the previous 12 months.
- Following on from the successful reduction of energy use during the Christmas closure in 2024, it has been confirmed that PSI House will be closing from the 22nd of December 2025 to the 2nd January 2026. During this period, non-essential systems will be shut down to reduce energy consumption in a period of low office attendance.

Our Ways of Working:

- Following on from the approval by Council of the 2025 Climate Action Roadmap in September, a website update has been drafted to update our Climate Action and

Sustainability section, as well as an internal communication to staff. We also intend to include an update in the PSI Newsletter in December.

Our Buildings and Vehicles:

- PSI's project to upgrade the Building Management System (BMS) is progressing, with quotation requests issued. The proposed upgrade aims to enhance energy control, reporting capabilities, and overall system accessibility. PSI preference is for transitioning to an open protocol system, which would allow for more flexible and transparent energy management.
- Work is currently ongoing for the annual Display Energy Certificate audit. This is required to be completed each year to ensure organisations are displaying the most relevant and recently reviewed energy data possible.

Procurement Update

Services/goods to be procured	Current Status
Irish Institute of Pharmacy (IIOP)	The procurement process is ongoing (negotiated procedure) with the current provider, with a view to having the new contract in place reflecting the revised model for CPD in early 2026, following the signing of the new rules (S.I No. 508/2025 & S.I No. 509/2025) on 23rd October. A further short extension, to 31 st March 2026, is required to fully align our requirements under the new contract.
Facilities management	Competitive procedure with negotiation (2-stage) is ongoing with Stage one complete, and the full tender specification for Stage two is in development, with the assistance of procurement advisors. Current contract extended until the 31 st of March 2026 to ensure continuity of services and to enable the two-stage procurement process with negotiation to complete.
Digital Skills Training	Tender concluded with contracting ongoing.
Investment Management	Contract awarded and work has commenced on account setup and the development of an Investment Strategy.
Third Country Qualification Route (TCQR)	Following the cancellation of the dynamic purchasing system process, direct negotiation is ongoing with the aim of having a contract awarded in early 2026.
Cloud-based system for Council Meeting Documentation	Tender concluded and contract awarded.
Stenography Services	SRFT published under the OGP framework agreement, evaluation of submissions ongoing.
Consultancy services to conduct an in-depth analysis and provide recommendations on the role as a Competent Authority for NIS 2 and the AI Act.	Request for quotation published on eTenders 19/11/26.

Appendix 1 – Statistical Summary

Complaints and Fitness to Practise (figures as of 1 December)

Complaints for Screening Committee (Preliminary Proceedings Committee – PPC)	Total Year to Date	2024 year-to-date equivalent
Total new complaints received year to date	35	54
New complaints received since last report date	12	10
Total open, active complaints*	31	63
Complaints considered by PPC since last report date **	20	26

*This includes 12 complaints that are ready for Council.

**These complaints were heard over two meetings. 72% 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.

Fitness to Practise (figures as of 1 December)

Inquiries/Hearings	Total Year to Date	2024 year-to-date equivalent
Total heard or commenced year-to-date *	22	19
Heard or commenced since the last report	4	3
Complaints being investigated/prepared for hearing	54	39

* 36% meet the KPI of the inquiry being heard within 18 months from the date of referral by the PPC to a Committee of Inquiry. Nineteen took place before the PCC & three took place before the HC

Mediation

Mediation	Total Year to Date	2024 year-to-date equivalent
Total referrals to mediation since the last report	2	0
Total referrals pending mediation	4	0
Held year-to-date	0	0

Sanction hearings/ undertakings/dismissals/applications before Council

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*	Total Year to Date	2024 year-to-date equivalent
Heard since last report*	15	7
Heard year to date*	30	24
Sanction hearings/undertakings being prepared for Council	8	5

*per respondent

High Court Sanction Confirmation Hearings	Total Year to Date	2024 year-to-date equivalent
Held year-to-date	5	9
Cases being prepared for High Court confirmation	3	2

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 Date	2024 year-to-date equivalent
Callovers heard year to date:		
1. Professional Conduct Committee	4	4
2. Health Committee	4	4
Callovers heard since last report date:		
1. Professional Conduct Committee	1	1
2. Health Committee	1	1

The next PCC and HC Callovers are scheduled for 12 March 2026.

Interim Suspension Applications	Total Year to Date	2024 year-to-date equivalent
Applications heard by Council year to date	0	0
Prosecutions	Total Year to Date	
Cases being prepared for District Court Prosecution	0	0

Professional Registration (figures as of 28/11/2025)

Route/application type	Registrations/ actions completed	2024 year-to-date equivalent
National route	170	165
EU route	53	100
Non-national route (Third Country) – UK only	74	70
Non-national route (Third Country) – excluding UK	49	44
European Professional Card – establishment of service (qualification recognition)	7	13
European Professional Card – temporary and occasional provision of service	0	0
Voluntary cancellations from the Register	148	141
Involuntary cancellations from the Register	59	29
Restorations to Register following voluntary cancellation	27	16
Restorations to Register following involuntary cancellation	1	2
Certificates of Current Professional Status issued.	76	80
IMI Alerts (internal market information) issued by PSI	5	3

Retail pharmacy businesses (as at 28/11/2025)

Registration of Retail Pharmacy Businesses 2025	Registrations/ actions completed	2024 year-to-date equivalent
Number of Registered Retail Pharmacy Businesses	1987	1986
Retail Pharmacy Business openings by type	New opening: 15 Permanent relocation: 8 Change of ownership: 49	16 7 51
Retail Pharmacy Business cancellations by type	Voluntary cancellations (closure): 11 Voluntary cancellations (permanent relocations): 8 Voluntary cancellations (changes of ownership): 49 Involuntary cancellations: 0	14 7 51 0
Number of changes in supervising and superintendent pharmacists	Supervising pharmacist changes: 254 Superintendent pharmacist changes: 331	347 96
Internet supply	Registrations	2024 year-to-date equivalent
Number of pharmacies on Part A	123	136
Number of non-pharmacy retailers on Part B	201	209

Regulation of Retail Pharmacy Businesses (figures as of 28/11/2025)

Pharmacy Inspections 2025		PSI 2025 Service Plan Pharmacy Inspection Key Performance Indicator (KPI)	2024 year-to-date equivalent
Total number of onsite Pharmacy inspection visits to date.	274	300	348
Total number of registration-related inspections to date.	28	15	18
Number of pharmacy re-inspections – including re-inspections following Registrar’s decision under Section 71(1)(d) to date.	1	0	2

Concerns (figures as of 13 June 2025)	Total Year to Date	2024 year-to-date equivalent
Total new concerns received year to date.	179	134
New concerns received since the last report date.	49	21
Concerns reviewed since the last report date.	50	25
Open concerns.	20	15

*2025 figures similar to 2023 figures. Changes to our website are also providing more info to patients/public about the concerns process vs complaints process, and we believe this will result in more concerns being received over time.

Investigation activity 2025 - Part 7 of the Pharmacy Act / Inspection & Enforcement)		
Number of investigations open.	Number of investigations initiated since the last Council meeting	Number of investigations closed since the last Council meeting.
18	3	3
Investigation Activity 2025 (Section 67) – e.g. Interviews / Statements / Pharmacy Visits / Professional Witness.		25

Investigation activity 2024 – year to date equivalent - Part 7 of the Pharmacy Act / Inspection & Enforcement)		
Number of investigations open.	Number of investigations initiated since the last Council meeting.	Number of investigations closed since the last Council meeting.
16	0	2
Investigation Activity 2024 (Section 67) – e.g. Interviews / Statements / Pharmacy Visits / Professional Witness.		17

Information Governance (as of 28/11/2025)

Freedom of Information

Number of FOI requests received	Granted	Handled outside of FOI	Refused	Currently being processed
13	10	1	0	2

Data Protection

Number of Subject Access Requests 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	
13	1	12	
Data transfer requests	Category: Research purposes	Category: Patient Safety Alert/Product Recall	Category: IIOP
20	14	1	5

Pharmacy practice queries

Number of Pharmacy Practice queries answered that were received from pharmacists, members of the public and other healthcare professionals or organisations	
Total number of pharmacy practice queries answered in period 22 September to 21 November 2025	Total number of pharmacy practice queries answered since 30 June 2025
60	144

Appendix 2: Overview of meetings attended by the Registrar and PSI staff (since last report)

October – December 2025	We continue to attend fortnightly meetings of the National COVID-19 Vaccination Programme Pharmacy Workstream Working Group.
October – December 2025	<p>We continue to attend monthly meetings of the Community Pharmacy Expansion Implementation Oversight Group (IOG), established to oversee the introduction of the Common Conditions Service in community pharmacies.</p> <p>We are also participating in the monthly meetings of the Communications Subgroup of the IOG, planning for the roll-out of the service.</p>
October – November 2025	We visited RCSI, TCD and UCC to present to pharmacy students across different academic years on various topics such as the role and remit of the PSI, expectations while on placement, governance roles in pharmacies and preparing for registration.
3 October 2025	We met with the HSE's Clinical Lead in ePharmacy, who presented an overview of the National ePrescribing Project.
9 October 2025	We had our second governance meeting of 2025 with the Department of Health.
9 October 2025 & 2 Dec 2025	We attended a meeting of the 'Preventing Paracetamol-Related Intentional Drug Overdose' Working Group. The overall aim of the Group is to collaborate on actions to prevent paracetamol-related intentional drug overdose by optimising adherence to existing legislation that limits access to paracetamol.
13 October 2025	We attended a meeting of the Regulators Advisory Group of the International Pharmaceutical Federation, FIP.
15 October 2025	Our Pharmacy Practice and Policy Manager delivered a presentation to students undertaking a Master's in Hospital Pharmacy at Trinity College Dublin. The presentation focused on the recommendations from the Final Report of the Expert Taskforce.
21 October 2025	We held a planning meeting with the Department of Health to discuss key priorities for our draft Service Plan 2026.
5 November 2025	We attended an online session at the Faculty of Pathology International Pathology Day Conference which addressed 'Near Patient Testing and the Future of Diagnostics'.

6 November 2025	We met with the Medical Council to discuss the Safe Prescribing and Dispensing of Controlled Drugs: Medical Council and PSI Joint Guidance , as well as the process for managing any necessary future updates.
12 November 2025	We attended a meeting of the Regulator's Forum in the Department of Health.
14 November 2025	We attended a Department of Health Sláintecare webinar entitled 'Transformation in Ireland's Health and Social Care Services- what it means for the patient and service user' as part of Public Service Transformation Week.
14 November 2025	Head of Pharmacy Practice, Policy and Engagement attended the first meeting of the Digital for Care advisory board
17 November 2025	We attended the One Health Conference, which was jointly hosted by the Department of Health and Department of Agriculture, Food and the Marine. The conference explored the theme of "Innovation and Collaboration in One Health" and also marked the launch of Ireland's Third National Action Plan on Antimicrobial Resistance (iNAP3) 2026-2030.
November/December 2025	We attended the bi-weekly meetings of the Department of Health's Electronic Record-Keeping Implementation Group.
18 November 2025	We attended the Professional Standards Authority's annual research conference in London. The theme of the event was Preventing harm: turning insight into impact.
20 November 2025	We met with the National Standards Authority Ireland (NSAI) Legal Metrology to discuss extemporaneous dispensing equipment used in pharmacies.
21 November 2025	Head of Pharmacy Practice, Policy and Engagement attended the annual conference of the Irish Medication Safety Network (IMSN)
21 November 2025	We attended the inaugural Interprofessional Healthcare Regulatory Symposium in the offices of the Nursing and Midwifery Board of Ireland (NMBI), where areas of common interest, challenge and opportunity were discussed and explored with colleagues from other regulators and the Department of Health.
23 November 2025	The Registrar attended the CommCare AGM, where she participated in a panel with Clare Fitzell of the IPU and Stuart Fitzgerald.

26 November	Head of Pharmacy Practice, Policy and Engagement, attended the HSE ePrescribing project board meeting
27 November 2025	The President and Pharmacy Practice and Policy Manager attended a Department of Health meeting on the development of a new National Drugs Strategy.
28 November 2025	The Registrar and the Head of Pharmacy Practice, Policy and Engagement attended the first meeting of the DoH Strategic Medicines Availability and Access Group
2 and 3 December 2025	We attended the biannual meeting of the European Directorate for the Quality of Medicines and Healthcare (EDQM) Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC).
2 December	We had our third governance meeting of 2025 with the Department of Health.
4 December	The fourth meeting of the Pharmacy Workforce Working Group was held in PSI House.

Appendix 2

Overview of External Communications (since last report)

Date issued	Communication type	Target audience	Subject	Channel
28 September 2025	Survey Reminder	Pharmacists	Last chance to participate in PSI Pharmacist Workforce Survey 2025	Email, social media
22 October 2025	Information	Registrants	New guidance to support pricing transparency for the public in pharmacies – effective dates and key requirements	Email, website, social media
28 October 2025	Information	Registrants/all	Department of Health consultation on proportionality of legislative amendments proposed by Regulated Professions (Health and Social Care) (Amendment) Bill	Website, social media (linked in newsletter on 31 Oct.)
30 October 2025	Public consultation	Registrants, other stakeholders	Public consultation on revised PSI (Fees) Rules, including Core Funding Review report published	Email, website, social media (included also in newsletter on 31 Oct.)
31 October 2025	Newsletter	Registrants and subscribers	PSI Newsletter: Issue 3, October 2025	Email, website, social media
12 November 2025	Information	Pharmaceutical assistants	Update on implementation of CPD Model for Pharmaceutical Assistants	Email

13 November 2025	Information	Registrants	Common Conditions Service – access to training and other enablers	Email, website, social media, press release
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Public consultation and other submissions

Quality and Qualifications Ireland (QQI) - Public Consultation on **their Draft Statutory Quality Assurance Guidelines on Programmes Involving Work-integrated Learning**.

On 17 October, PSI provided feedback to Quality and Qualifications Ireland (QQI) as part of their public consultation on the Draft Statutory Quality Assurance Guidelines on Programmes Involving Work-integrated Learning. The guidelines are intended to support the quality assurance and enhancement of programmes that involve work-integrated learning and thus the provision of appropriate teaching, learning and assessment experiences for learners engaged in these programmes.

Health Information Quality Authority (HIQA) – Public Consultation on revised draft **National Standard for Hospital Discharge Information**

In November, PSI provided feedback to HIQA as part of their public consultation on a revised Draft National Standard for Hospital Discharge Information. The aim of the consultation was to gather feedback to ensure that the relevant and appropriate data elements are included in a hospital discharge dataset so that accurate information about the patient is shared with primary healthcare professionals upon discharge from an acute hospital, ensuring safe continuity of care.