

Report of the Registrar

Council Meeting 14th December 2023



Highlights from the Registrar

PSI Pharmacist Workforce Survey 2023

On 22 November, we launched our second annual pharmacist workforce survey. This survey will allow us to continue to monitor trends relating to the patient-facing pharmacist workforce following the publication of the [PSI Pharmacy Workforce Intelligence Report](#), which was launched on the 25 September. The survey will remain open until 21 December 2023, and we are encouraging all PSI-registered pharmacists and 5th-year pharmacy students to respond to this important survey.

Regional Roadshow Events

In October, we ran a series of regional roadshows, marking another significant milestone in our ongoing commitment to engaging with registrants. The roadshows were the first in-person events held by the PSI following the pandemic and were an opportunity to discuss several important topics, including pharmacy governance roles, pharmacist workforce planning and fitness to practise.

The events took place in Sligo, Limerick, Cork, and Dublin. Attendees from across the country commended the events for providing useful insights into the ongoing work of the PSI and affording pharmacists from all sectors the opportunity to raise any queries they had with PSI staff.

As an important element of our engagement with those we regulate, the regional roadshows aimed to connect with registrants and to listen to insights and reflections from those in attendance. The roadshows allowed us to inform registrants of the latest sectoral developments and capture feedback and insights on various PSI projects and initiatives. For those who were unable to attend the roadshow events, recordings of the presentations are being made available on the PSI website.

Ongoing Regulatory Work Programmes in 2023

Activity	Outputs	Update
Implement the revised Core Competency Framework (CCF) for pharmacists.	Roadmap in place for the implementation of the revised CCF for pharmacists in 2023	Engagement with the Irish Institute of Pharmacy (IIOF) regarding the implementation of the revised CCF continued. The IIOF delivered a series of roadshows covering topics such as how to self-assess against the revised framework using objective evidence, feedback, and reflective practice. The conclusion of these roadshows brings this piece of regulatory work to an end. An implementation plan was

		agreed with the Schools of Pharmacy in Q2 of 2023 and PSI will continue to liaise with the Schools of Pharmacy in this regard.
Operationalise the revised Third Country Qualification Recognition (TCQR) route process leading to registration as a pharmacist.	Revised route commenced in 2024	<p>The PSI project team is in the process of implementing the revised TCQR route, with the current focus being on developing the adaptation placement component of the new route.</p> <p>PSI conducted a market-sounding exercise on the provision of an adaptation placement service for the revised TCQR route, and this exercise has now concluded. We are currently seeking external legal advice in relation to matters concerning the adaptation placement.</p>
Operationalise our Regulatory Risk Statement as a key tool in managing incoming information, intelligence, and strategic learning to help identify and respond to risks to patient safety and/or serious concerns as to the quality of community pharmacy services.	<ul style="list-style-type: none"> • New risk reporting mechanisms developed and operating by year-end. • Continued development of the joined-up approach to identifying and addressing regulatory risk. 	Work concerning developing processes for identifying and assessing regulatory risk is progressing within the Community Pharmacy Assurance Business Area.
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	<ul style="list-style-type: none"> • Participation of pharmacists in continuing professional development (CPD) and education on AMR, infection prevention and control (IPC) and antimicrobial stewardship (AMS) encouraged by the promotion of resources and increased awareness of the importance of these areas for practice. 	<p>AMR Engagement Initiative</p> <p>In October, we attended a conference on 'Collaborating Across Borders: a multidisciplinary approach to AMS'. The conference brought together multidisciplinary participants from around the Republic and Northern Ireland working on AMS/AMR who shared research and recent developments in this area.</p>

amongst the pharmacy profession, including pharmacy students, to ensure that it is an integral part of the delivery of pharmacy services.	<ul style="list-style-type: none"> • Accreditation standards review and relevant guidance documents for RPBs (Retail Pharmacy Business) to be reviewed in 2023 will be informed by HSE's Antimicrobial Stewardship: Guidance for all healthcare settings. 	Disseminating global initiatives in AMR There are a number of established global AMR awareness campaigns that take place annually, such as European Antibiotic Awareness Day and World Antimicrobial Awareness Week. We promoted these through our social media channels.
---	--	---

Communication and Stakeholder Engagement Updates

Overview of meetings attended by the Registrar and PSI staff	
October-December 2023	We continue to contribute to the National COVID-19 Vaccination Programme – Pharmacy Workstream Working Group.
October-November 2023	We delivered presentations to 1 st year MPharm students in the Royal College of Surgeons of Ireland (RCSI), Trinity College Dublin (TCD) and University College Cork (UCC). For the first year, we also delivered presentations to 4 th and 5 th -year MPharm students across all three institutions. Topics included the role of PSI and our regulatory functions, updates on recent developments in pharmacy practice, experiential learning placements, complaints, and concerns, continuing professional development (CPD), and practising in community pharmacy.
October-December 2023	We attended fortnightly meetings of the Expert Taskforce to Support the Expansion of the Role of Pharmacy.
October-December 2023	We participated in regular meetings of the Medicines Criticality Assessment Group, a multi-agency group convened by the HSE/HPRA/DoH to discuss and respond to medicine shortages.
3 October 2023	We attended a conference on ‘Collaborating Across Borders: a multidisciplinary approach to AMS’.
6 October 2023	We attended a roundtable workshop to support the development of the Medical Council’s Statement of Strategy for 2024-2028.
6 October 2023	We held our quarterly operations meeting with the Irish Institute of Pharmacy (IIOP).
11-24 October 2023	We delivered a series of five regional roadshows in various locations across Ireland in October. The aim of the roadshows was to provide clarity for registrants on topical issues such as pharmacy governance roles, the Workforce Intelligence Report, and Fitness to Practise matters.
12 October 2023	We attended the HSE Patient & Public Partnership conference online. The theme of the conference was ‘Creating Tomorrow, Together’ and featured discussions around approaches to partnership with patients.
17 October 2023	We attended the launch of a new information campaign in the Department of Health on the safe sales of paracetamol. The campaign aims to promote the safe sales of paracetamol from a self-harm and suicide prevention perspective – and to reduce the incidence of paracetamol-related intentional drug overdose in Ireland.
18 October 2023	We met with the Department of Health to discuss a number of policy-related matters.
18 October 2023	We met with colleagues from the HPRA to discuss ongoing topics of mutual relevance.

19 October 2023	<p>We attended the National Patient Safety Conference. The theme of the conference was 'Nurturing a positive culture of patient safety: listening, learning, responding.'</p> <p>The National Open Disclosure Framework was also officially launched at the conference. This framework aims to promote a clear and consistent approach to open communication with patients and service users following a patient safety incident or an adverse event.</p>
20 October 2023	We attended the APPEL Future of PharmacIE event hosted at RCSI. PSI colleagues and our two APPEL students exhibited at the event and engaged with students from the three Schools of Pharmacy. The Registrar participated in a panel discussion at the event.
21 October 2023	We attended the IPU Annual Conference. The Registrar participated in a panel discussion at the conference.
23 October 2023	<p>We met with colleagues from the Department of Health and the Central Statistics Office to be briefed on progress regarding ongoing health data initiatives, including the alignment of the legislative and non-legislative frameworks, which will:</p> <ul style="list-style-type: none"> (a) underpin the use of big data, data collection, coding schemes, and data analytics in the health information system (HIS), (b) drive future resource allocation within the integrated healthcare system (Sláintecare), and, (c) provide an evidence base for health policy development.
23 October 2023	We attended a symposium on the development of a roadmap for pharmacist prescribing in Ireland. This event, hosted jointly by NCCP, RCSI and TCD, brought together a range of stakeholders to facilitate the sharing of current evidence for pharmacist prescribing, hear examples from the UK in respect of Pharmacist prescriber education and Pharmacist prescribing in cancer care, and provide a forum for discussion around a future roadmap for pharmacists prescribing nationally.
26 October 2023	We met with the Pharmaceutical Assistants Association (PAA) regarding the Report to support the Development of a Continuous Professional Development Model (CPD) for Pharmaceutical Assistants and to discuss onward engagement with this project.
October/November 2023	As part of the development and review of the draft IOP workplan for 2024, we held engagement meetings with the Department of Health (DOH), the Pharmacy eHealth Group and representatives from the Health Service Executive (HSE), including representatives from the Primary Care Reimbursement Services (PCRS), Antimicrobial Resistance and Infection Control (AMRIC), National Immunisation Office (NIO), Addiction Services, ePharmacy and Acute Hospitals Drugs Management Programme and the

	National Cancer Control Programme (NCCP). The purpose of the engagement meetings was to anticipate training needs for pharmacists for 2024.
6-7 November 2023	We attended the 10 th All Ireland Pharmacy Conference. The theme of the conference was 'Creating Momentum & Building Capacity'. The Registrar delivered the opening address at the conference.
8 November 2023	We met with colleagues in the DoH to discuss the substitution of biosimilars by pharmacists.
8 November 2023	We met with colleagues in the IPU (Irish Pharmacy Union) to have a collaborative discussion on pharmacy practice matters.
14 November 2023	We attended the 2023 Professional Standards Authority Research Conference: 'How can regulation research contribute to safer care for all?', which explored topics such as engaging the public in regulatory decision-making, how should regulators respond to the workforce crisis and regulating the future: AI and regulation.
14 November 2023	We attended the Policy Forum for Ireland keynote seminar 'Next steps for Sláintecare reform'. The seminar focused on the next steps for the delivery of Sláintecare reform, including the implementation of new health regions and a shift to more community-based care.
14 November 2023	We met with the Irish Medicines Verification Organisation (IMVO) regarding progress on FMD scanning rates.
14 November 2023	We met with representatives from the Hospital Pharmacists Association of Ireland (HPAI) to discuss, among other matters, the Workforce Intelligence Report, the implementation of the new Hospital Pharmacy Career Structure, and the expansion of the role of pharmacists.
28 November 2023	We attended the online launch of Ireland's first World Breastfeeding Trends Initiative assessment report, which aims to report on key policy and practice indicators relating to breastfeeding in Ireland. PSI also provided comments to support the development of the assessment report, which is detailed in the public consultations section below.
20 November 2023	We met with the IIOF to discuss the first recommendation of the Expert Taskforce established by the Minister for Health to support the expansion of the scope of pharmacists' practice. The purpose of the meeting was to discuss potential training and resources to support pharmacists with this practice change.
22 November 2023	We attended a Medical Council Overprescribing Working Group meeting. The group is currently working on a submission to the Department of Health examining the impact of the overprescribing of benzodiazepines, Z drugs and pregabalin in Ireland. This stakeholder group includes representatives from the Medical Council, HSE, HPRA, Department of Health, the PSI and ICGP.

23 November 2023	We attended a Pharmacy eHealth Group (PeHG) meeting. The PeHG is a special advisory committee established by the Department of Health intended to be a forum for cooperation and engagement, aligned with the implementation of the eHealth Strategy for Ireland.
23 November 2023	We attended an online conference, 'Next Steps for Professional Healthcare Regulation', which discussed progress in the reform of professional healthcare regulation in the UK, including the approach for legislative reform being progressed by the General Medical Council (GMC).
23 November 2023	PSI staff 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.
24 November 2023	We met with the IPU to discuss the implementation of the first recommendation of the Expert Taskforce on prescription extension by pharmacists.
24 November 2023	We attended the annual Irish Medication Safety Network (IMSN) conference at UCC. The theme of the event was 'Smarter Technology for a Safer Tomorrow'.
1 December 2023	We attended the National Digital Health Conference (online): Better Together for Digital HealthCare 2023, which explored the positive impacts of digital health development in our health service, the need for access to accurate and reliable data and the importance of a digitally capable workforce.
5 December 2023	We held our second biannual meeting between PSI, the Schools of Pharmacy and APPEL as part of our ongoing communication and engagement.
5 December 2023	As part of Quality and Qualifications Ireland (QQI) <i>Common Ground</i> series of events, we attended a conference on academic & professional integrity, work-integrated learning, and professional, statutory, and regulatory body (PSRB) and higher education institute (HEI) collaboration. This event was attended by representatives from HEIs and PSRBs.
6 December 2023	We attended a meeting of the Regulators' Forum at the Department of Health.
6-7 December 2023	We participated in a two-day online meeting of the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care. This Committee is part of the European Directorate for the quality of Medicines and Healthcare (EDQM), which is a Directorate of the Council of Europe.
8 December 2023	We held our second biannual strategic meeting between the PSI, IIOP and RCSI.

Recent communication/collaboration with other regulatory and public authorities

Communication to registrants on Reports of falsified packs of Ozempic™ (semaglutide, 1mg Solution for Injection)

Following engagement with the HPRA and IMVO in relation to reports of falsified packs of Ozempic, PSI wrote to registrants in October. The [communication](#) reminded pharmacists of their role in upholding high standards of patient safety by only sourcing Ozempic™ products from appropriately authorised suppliers and adhering to [FMD requirements](#).

Communication to registrants on medicine shortages and supply of key medicines

Through our membership in the Medicines Criticality Assessment Group (MCAG), we supported the development of a joint message for healthcare professionals and the public on steps being taken to manage medicine shortages. The messages also provided reassurance that analysis from the pharmaceutical industry indicates that the supply of key medicines used during the winter season will meet the anticipated demand. The message was issued to all registrants via email.

Public consultations and other submissions

Ireland's first World Breastfeeding Trends Initiative assessment report

In November, PSI provided comments to support the development of Ireland's first World Breastfeeding Trends Initiative (WBTi) assessment report, which was developed by the Core Group for WBTi Ireland. The final report was published on 28 November and aims to report on key policy and practice indicators relating to breastfeeding in Ireland. The report finds that while Ireland is performing well on some policy and programme indicators, this is not translating into positive scores for indicators relating to infant feeding practices.

Department of Health request to review statutory instruments.

Between October and November, at the request of the Department of Health, we reviewed and provided feedback on two statutory instruments, which were drafted to amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003.

Observations to the CJEU - advertisement and discounting of medicinal products

The PSI was invited as the statutory regulator of pharmacists and pharmacies in Ireland, to submit observations to the European Court of Justice (CJEU) in relation to three questions stated by them following a referral to it by a German court. The referral centred around the interpretation of certain provisions of EU Directive 2001/83 related to the advertisement and discounting of medicinal products and the roles and obligations of pharmacies in EU territories in this respect. The PSI took the opportunity to make observations, which amongst other points, restated the obligations on pharmacists and pharmacies as set out in the [PSI's Guidance](#) on the advertising, promotion and sale of medicinal products, (published on the PSI website). In particular it pointed out to the Court the PSI's position

namely, that the advertising or promotion of medicinal products on the basis of a percentage or other discount, or on any similar basis, could be regarded as the commodification of medicinal products and could have the effect of distracting patients from making an objective evaluation of their normative needs. The observations further stated that such advertising may inadvertently encourage the stockpiling of medicines in the home, with resultant safety risks and potential loss from efficacy from inappropriate storage conditions.

We would like to point out that the Guidance is currently being updated and expected to be published in early 2024.

Other external communication

Eolas Magazine

“Building pharmacy capacity as part of a future integrated healthcare system.” Article due for publication in January 2024.

This feature focuses on the Registrar, reflecting on her first year in the role and profiling PSI work that is “underway, aligned to strategic organisational commitments, to ensure pharmacy is equipped to play a full role as part of a future integrated healthcare system.”

Irish Pharmacy News (IPN)

Two features on PSI were submitted for the December edition of the IPN:

1. Reflecting on the PSI Roadshows across Ireland in October 2023.
2. End of Year Review by PSI Registrar and Chief Officer Joanne Kissane.



Advancing the Role of Pharmacy and Pharmacists in the Future Integrated Healthcare System

Key updates

Expert Taskforce to support the expansion of the role of pharmacists in Ireland.

In October, the Minister for Health accepted the first recommendation of the Expert Taskforce, which will empower pharmacists to extend the validity period of certain prescriptions for up to a maximum of 12 months, in accordance with defined criteria, and when in the pharmacist's professional opinion it is safe and appropriate to do so. The decision to extend will be subject to person-centred criteria such as the current stability of the patient's clinical regime, continuity of care and lack of relevant change. This change is due to take effect from 1 March 2024.

As part of preparing to implement the first recommendation, PSI is engaging with several key stakeholders, including pharmacists. All registered pharmacists were invited to join a PSI panel via expression of interest (EOI). The pharmacist panel will enlighten our regulatory work in a number of ways, beginning with an interactive workshop to inform the implementation of the first recommendation of the Taskforce. We received 104 expressions of interest for the panel.

The pharmacist workshop will take place on Tuesday, 12 December. It will explore the regulatory tools or supportive information, such as guidance, that may be needed to support pharmacists in their decision-making when extending prescriptions for patients.

As numbers for the first workshop were limited, those pharmacists who were not selected to participate will form part of the PSI Pharmacist Panel and will be consulted as part of future engagement activities to support our work.

Developing a CPD Model for Pharmaceutical Assistants

Work on implementing a continuing professional development (CPD) model for pharmaceutical assistants has continued. Mazars, who provided external support on this project, presented a report recommending a proposed CPD model, which Council approved at its meeting on 22 June 2023. Subsequently, we met with the Pharmaceutical Assistants Association (PAA) on 26 October 2023. An implementation plan has been developed, and updates on its implementation will be delivered to Council during 2024.

Review of the CPD Model for Pharmacists

Work continues on this multi-annual project, with external support provided by Mazars. The Council will be presented with the final draft report at this meeting and will be asked to consider the report with a view to its acceptance and approval of the recommendations contained therein. This report will be instrumental in enabling the continued implementation and evolution of a CPD model for pharmacists that is fit for purpose and informed by national and international best practice. A revised CPD model should ensure that it supports future pharmacist practice in all settings and that it is agile, adaptive, and sustainable, and that it delivers value for money.

Working Group to implement the recommendations of the Workforce Intelligence Report.

One of the actions under Recommendation One of the Workforce Intelligence Report, i.e. “A national strategy for pharmacy workforce planning in Ireland should be designed to align with national and international best practice, taking a multi-agency, data-driven approach as part of an integrated healthcare system” is the establishment of a multi-agency group focused on national strategic workforce planning for pharmacy. This group is to operate under the stewardship of the PSI and the DoH, and draft Terms of Reference are currently under consideration.



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

Falsified Medicines Directive

Throughout 2023, compliance with the Falsified Medicines Directive has continued to grow in an upward trend. Compliance has been consistent in the busier weeks (first and last week) of the month, and for the week beginning 27 November 2023, 69% of medicines packs in the market were successfully decommissioned. This was the highest rate of decommissioning in the year to date. PSI continues to conduct FMD-based focus inspections to assess compliance in pharmacies.

The Irish Medicines Verification Organisation (IMVO) continues to support pharmacies that are verifying but not decommissioning medicines successfully; this support will be extended to those pharmacies that are verifying but have low decommissioning rates.

Autumn Roadshows

As highlighted earlier in this report, we successfully delivered a series of regional roadshows in October, demonstrating our ongoing commitment to engaging with registrants. PSI staff presented on topical issues such as pharmacy governance roles, the Workforce Intelligence Report and Fitness to Practise matters.

The roadshows were well received, and positive feedback was provided by those who attended the events.

Stakeholder Engagement in patient safety and quality initiatives

We are currently developing guidance to help, support, and assist pharmacists on the roles and responsibilities of those in governance roles. We aim to provide clarity to registrants on the legislative interpretation of 'wholetime charge' with respect to the role of supervising pharmacist. Work on the development of this guidance is progressing well, and we aim to have it delivered by Q1 of 2024.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Disciplinary Committees

Following the conclusion of an Expression of Interest, the Council of the PSI recently appointed new members to the Professional Conduct and Health Committees, a Chair to the Health Committee, and new Acting Chairs to the Professional Conduct and Health Committees.

In keeping with the commitment by PSI to ensure that all office holders and Committee members are appropriately supported in the execution of their duties, formal Induction Training to include training on Professional Regulation was carried out for new Committee members at PSI House on 15 November 2023. Annual Chairs and Acting Chairs training also took place on 15 November, focusing on good chairing skills and exercising those skills during statutory complaint hearings.

On 16 November 2023, members of the Professional Conduct and Health Committees attended PSI House for training, which included reviewing reports on statutory complaints and inquiries, reviewing Committee written procedures, and discussing remote and inquiry hearings generally and the effective use of the Legal Assessor at hearings. Updates were also given on the PSI's corporate governance, data protection and expense-claiming policies at the PSI. The afternoon was devoted to professional training on the Deliberations Stage of inquiry hearings, which focused on assessing allegations in complaints, making findings, and recommending sanctions.

Business Transformation Project (BTP Update)

PSI completed work with an independent third party, who carried out an assessment of the proposed approach and associated effort estimates for the next phase of work, Phase 2 Complaints, Concerns, and Queries. This independent review also input into the broader review of the PSI/Codec commercial relationship. The Business Transformation Project Programme Board (comprised of three members of the PSI Council and one member external to the PSI) recommendation will be provided at the December 14th Council meeting as to the proposed continuation of the PSI/Codec commercial relationship in 2024.

In 2024, PSI intends to deliver Phase 2 and commence work on Phase 3, Pharmacy Compliance and Quality Assessment.

Development of PSI's ICT Strategy 2024-2027

The vision for the ICT Strategy is to have sustainable ICT as an enabler to becoming a digital-first regulator, making data-driven decisions that enhance the services we provide to all our customers, both internal and external.

We have commissioned Auxilion, a business and technology solutions consultant, to assist with the strategy's development, and they are partnering with us as we move through the development process.

Workshops with Council and staff in October and one-to-ones with a cross-section of the Executive Leadership Team and the Wider Management Team have taken place. The November newsletter included a short questionnaire to give our registrants the opportunity to provide feedback on our existing and future digital engagements with them.

Auxilion has completed a review of our current ICT capability and capacity, which was used to map where we are as we look to the future. Auxilion has used its expertise in future technology trends to help the PSI consider what is needed as part of our digital future and with regard to existing public sector ICT strategies.

The PSI's ICT Strategy will be ready for consideration by the Council at its March 2024 meeting.

Strategic HR Matters

Through the ongoing implementation of our HR Strategy 2021-2024, PSI is advancing its commitment to continuous improvement in all areas of human resource management and organisation development. Progress made since the last report includes conducting a number of workshops and training and preparing for the launch of the next Employee Engagement survey to assess employee satisfaction and identify areas for improvement.

Strategic workforce planning

The following positions have closed and are in the final stages of the hiring process, with offers being extended and contracts being finalised:

- Associate Inspectors (Authorised Officer) (Eng III) (3 out of 4 positions)
- Community Pharmacy Quality and Safety Manager (Permanent)
- Community Pharmacy Quality and Safety Manager (FTC acting-up position)
- Head of Corporate Services (Principal Officer) (Permanent)
- Inspector (Authorised Officers) (Engineer II) (Permanent) x 1
- Inspector (Authorised Officers) (Engineer II) (FTC) x 1
- Finance and Support Services Executive (Executive Officer) (Permanent)

The following campaigns are in train or will be commenced:

- Professional Standards Officer (Engineer II Grade) – to be re-advertised.
- Investigations Manager (Assistant Principal Officer Grade)
- Business Support Services Assistant (Clerical Officer Grade)
- Strategic Policy, Research and Projects Coordinator (Higher Executive Officer Grade)

Organisation Development

We are committed to fostering a culture of continuous learning and development. In Q4, we focused on several key training initiatives aligned with our strategic objectives and supported employee growth. These initiatives included:

First Aid Training:

- Our in-house First Aiders were trained and certified as first responders, enabling them to respond to medical emergencies in the workplace.

Belbin Team Roles:

- The workshop provided an insight into team dynamics and collaboration. Belbin's Team Roles is a model identifying nine team roles grouped into action-oriented, people-oriented, and thought-oriented categories. Effective teams have a balance of all nine roles. The model can be used to improve team effectiveness by identifying strengths and weaknesses, developing strategies, and helping members understand their roles.

Climate Action Mandate and PSI's Roadmap:

- To support our commitment to sustainability and deliver as part of the Government's Public Sector Climate Action Plan, a workshop took place with staff during the Anchor Day in October to discuss PSI's contribution to meeting Ireland's climate targets. This workshop raised awareness about our environmental goals and encouraged employees to adopt eco-friendly practices in their daily work.

Autism Awareness:

- In conjunction with PSI's Equality, Diversity and Inclusion Working Group, a session was delivered by AsIAM at our November Anchor Day. AsIAM provide autism awareness training, and it was organised to provide our staff with a comprehensive understanding of autism and how to create a more inclusive and supportive work environment for individuals with autism.

Higher Executive Officer (HEO) Core Skills Training:

- The training, delivered by Public Affairs Ireland (PAI), focused on team leadership, analysis and decision-making, and interpersonal and communication skills.

Overall Impact of Training Initiatives:

Our training initiatives in Q4 will enhance employee skills, promote a positive and inclusive work environment, and align our workforce with our strategic objectives. We are committed to continuing our investment in employee development and ensuring our workforce is equipped to meet the challenges and opportunities that lie ahead.

Innovation and EFQM

An innovation session for staff was facilitated by Alan Doherty (founder and principal of Novara Labs) during the Public Sector Transformation Week. The session involved using design thinking principles to look at some PSI challenges.

We continue to embed EFQM throughout the organisation and a presentation was made to staff to demonstrate how the work that we do is aligned to the EFQM model.

Equality, Diversity, and Inclusion Working Group

The Equality, Diversity and Inclusion Working Group issued an Equality, Diversity, and Inclusion (EDI) survey to all staff in November. The purpose of the survey is to gain high level information on the following areas:

- Staff diversity levels in PSI.
- Staff views on diversity.
- Staff experiences of discrimination.
- Perceived levels of inclusion.
- General EDI feedback.

This is the second EDI survey to be issued to staff. The information will help us identify trends related to equality, diversity, and inclusion in the PSI, and recommend cross-departmental interventions within the organisation.

Finance matters

From 01 January 2024, under Revenue's new Enhanced Reporting Requirements (ERR), PSI will be required to report to Revenue details of certain expenses and benefits made to staff, Council and Committee members (office holders). This information must be submitted on or before the payment is made. The information to be submitted from 01 January includes the date paid and amount of each payment for:

- travel vouched
- travel unvouched
- subsistence vouched

- subsistence unvouched
- value of any small benefit exemption

PSI's Finance and Support Services Team is reviewing PSI's processes with the view to developing the most efficient process to have in place for complying with these requirements and reporting to Revenue via ROS or through our Payroll software.

Procurement activity update for contract values in excess of €25k:

Service/Goods to be Procured	Current Status
Third Country Qualification Recognition – Equivalence Exam (for additional exams under the existing TCQR route and new route)	The procurement planning approach is ongoing with external procurement experts.
TCQR new route - adaptation period support	Discussions are ongoing with external procurement experts on procurement planning and approach. A Preliminary Market Consultation was published and closed on 10 July. Consideration of the outcome of this exercise is ongoing, and the next steps in development. ** As this is a new process operating under a new policy, and as the TCQR application fee will operate on a cost-recovery basis, the cost to PSI of this support versus the cost to be paid directly by the applicant remains to be confirmed by the market.
Establishment of a panel of Legal Assessors (Mediator Panel added)	Specifications have been developed by the project team –Tender documents have been progressed with the assistance of External Procurement Experts.
Registration-related printing and fulfilment services (e.g., registration certificates) and other print needs. *Scope has expanded due to revenue-free printing no longer being available	Specification for registration-related requirements has been progressed. All other PSI print and design requirements are being scoped and specified and will then be sent to OGP for review.
Remote Hearings	Specifications have been developed by the Legal Affairs team. RFQ under development for <€50k requirements following review and advice from procurement expertise.

Appendix 1 – Statistical Summary

Complaints and Fitness to Practise (figures as of 5 December 2023)

For the purposes of this appendix, please note that references to '*last report date*' refers to the Registrar's Report submitted for the Council meeting on 5 October 2023.

The Executive is currently reviewing the KPIs in use for complaints and inquiries and will bring a paper to Council in Q1 2024 for their consideration.

Complaints for Screening Committee (Preliminary Proceedings Committee – PPC)

Total new complaints received year to date	65
New complaints received since last report date	10
Total open, active complaints*	39
Complaints considered by PPC since last report date **	10

* This figure may include complaints received prior to 2023 which are still being processed

**These complaints were heard over 1 meeting. 60% met the KPI of the PPC decision within six months from the date of receipt of complaint to the date of the final PPC decision.

Fitness to Practise (as of 5 December 2023)

Inquiries

Total heard or commenced year to date *	17
Heard or commenced since last report **	3
Complaints being investigated/prepared for hearing	38
Adjourned to 2024	1

38% meet the KPI of the inquiry being heard within 18 months from the date of referral by the PPC to a Committee of Inquiry.

**2 took place before the PCC & 1 took place before the HC

Mediation

Total referrals to mediation since last report	1
Total referrals pending mediation	1
Held year-to-date	0

Sanction Hearings/ Undertakings/Dismissals/Applications before Council

Heard since last report*	6
Heard year to date*	15
Sanction hearings/undertakings being prepared for Council *	9

*Per registrant

High Court Sanction Confirmation Hearings

Heard year-to-date	3
Cases being prepared for High Court confirmation	2

Appeals

Heard year-to-date	0
Cases being prepared for High Court appeal	0
Judgment awaited	1

Call-overs and Other Applications Before Committees of Inquiry

Callovers heard year to date:	
(1) Professional Conduct Committee	(1) 3
(2) Health Committee	(2) 3
Held since last report date.	
(1) Professional Conduct Committee	(1) 0
(2) Health Committee	(2) 0

The next PCC and HC Callovers are scheduled for 05 December 2023

Interim Suspension Applications

Applications heard by Council year to date	2
--	---

Prosecutions

Cases being prepared for District Court Prosecution	1
---	---

Professional Registration (figures as of 4 December 2023)

Route/Application Type	Applications Received 2023 to date.	Applications in Process (including applications received in previous years)
Third Country Qualification Recognition (TCQR) – excluding UK.	144	339
Route/Application Type	Registrations/ Actions Completed 2023 (to 4/12/2023)	
National Route	181	
EU Route	167	
Non-National Route (Third Country) – UK only	105	
Non-National Route (Third Country) (excl. UK)	25	
European Professional Card – Establishment of Service (Qualification Recognition)	11	
European Professional Card – Temporary & Occasional Provision of Service	0	
Voluntary Cancellations from Register	115	
Involuntary Cancellations from Register	25	
Restorations to Register following Voluntary Cancellation	8	
Restorations to Register following Involuntary Cancellation	2	
Certificates of Current Professional Status issued	52	
IMI Alerts (Internal Market Information) issued by PSI	6	

Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses (as of 4 December 2023)	
Number of Registered Retail Pharmacy Businesses	1984
Retail Pharmacy Business Openings by Type	New Opening: 28 Permanent Relocation: 4 Change of Ownership: 74
Retail Pharmacy Business Cancellations by Type	Voluntary Cancellations (Closure): 24 Voluntary Cancellations (Permanent Relocations): 4 Voluntary Cancellations (Changes of Ownership): 74 Involuntary Cancellations: 1
Number of Changes in Supervising and Superintendent Pharmacists. (Numbers as of 1 December 2023)	Supervising pharmacist changes: 494 Superintendent Pharmacist changes: 83

Internet Supply Figures as of 1 December 2023	
Number of Pharmacies on Part A	143
Number of Non-Pharmacies on Part B	144

Regulation of Retail Pharmacy Businesses (figures as of 1 December 2023)

Pharmacy Inspections 2023		PSI 2023 Service Plan Pharmacy Inspection Key Performance Indicator (KPI)
Total number of on-site Pharmacy inspection visits to date.	149	160
Total number of registration-related Virtual Inspections to date.	13	20
Number of pharmacy re-inspections – including re-inspections following Registrar’s decision under Section 71(1)(d) to date.	3	0

Concerns

Total new concerns received year to date	134
New concerns received since last report date	21
Concerns reviewed since last report date	25
Open concerns	15

Investigation Activity 2023 (Part 7 of the Pharmacy Act / Inspection & Enforcement)		
No. of investigations open	No. of investigations initiated since the last Council meeting	No. of investigations closed since the last Council meeting
17	2	1
Investigation Activity 2023 (Section 67) – e.g., <i>Interviews / Statements / Pharmacy Visits / Professional Witness</i>		15

Information Governance as of 4 December 2023

Freedom of Information

No. of FOI requests received	Granted	Handled outside of FOI	Refused	Currently being processed
9	1	3	4	1

Data Protection

No. of Subject Access Requests Received	Granted	Refused
2	2	0
No. of Data Breaches	Reported to the Data Protection Commissioner (DPC)	Not meeting the threshold for reporting to DPC
6	2	4
Data Transfer Requests	Category: For Research Purposes	Category: IIOP
18	5	13