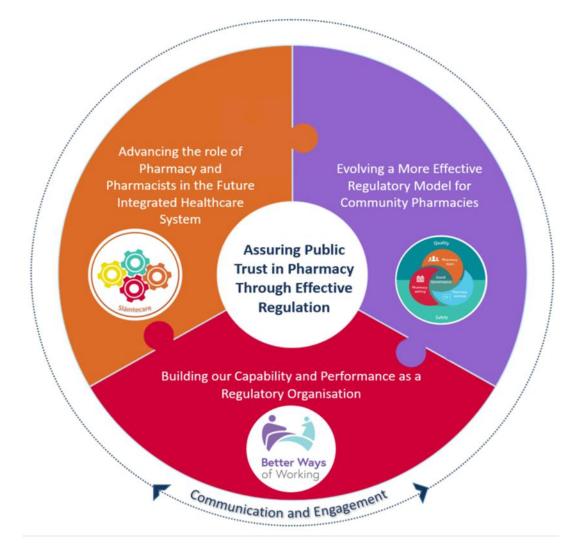


# Report of the Registrar Council Meeting 20.06.2024



# Highlights from the Registrar

# Ongoing Regulatory Work Programmes in 2024

Activity	Outputs	Update
Operationalise the revised Third Country Qualification Recognition (TCQR) route process leading to registration as a pharmacist.	All applications coming through the former TCQR route will have been processed, and the route closed by Q4 of 2024. The revised TCQR route under SI 452/2023 has been in effect since 10 July 2023, and the processing of applications received under the new route will be fully operationalised.	Due to a number of factors, in 2024, PSI sought legal advice regarding the operationalisation of the revised TCQR route and removing the mandatory adaptation period from the recognition process. The issue of whether further legislative amendment is required was also considered. A revised proposal was presented to the Regulatory and Professional Policy Committee at their meeting on 6 June, outlining the advice received, a comparative analysis of other healthcare regulators in Ireland and the proposed solutions to give effect to the new TCQR route with a particular emphasis on the proposed examination at Stage 3. The proposed amendment to the revised TCQR route will be considered by Council on 20 June.
Review of the regulation of retail pharmacy businesses within a hospital setting.	Report on the Review of the Regulation of retail pharmacy businesses in hospital settings to be submitted to the Department of Health by the end of Q4.	The draft Position Paper on Hospital Pharmacy Regulation was presented to the Regulatory and Professional Policy Committee for discussion at its meeting on June 6, 2024. At present, PSI is cognisant that we have committed to progressing work on the regulation of Hospital Pharmacies on the PSI service plan for 2024. However, we are mindful of the ongoing work of the Pharmacy Taskforce and its recommendations, particularly the expanded role of

		pharmacists working in both hospital and community pharmacies. Further work will be undertaken on this paper over the coming months, and a further draft will be presented to the RPP at their meeting in September.
Take steps to ensure PSI is meeting our Public Sector Equality and Human Rights Duty.	Assessment of human rights and equality issues relevant to the functions and purpose of PSI. Action plan to address issues raised in the equality and human rights assessment. Information on developments and achievements regarding equality and human rights issues and actions is included in the Annual Report.	We have secured the services of an external consultant to support the assessment of human rights and equality issues relevant to the work and functions of the PSI. This work will commence in Q3.
Development of PSI's next Corporate Strategy and underpinning Service Plans over the period of the strategy.	Strategy approved by Council by year end with a clear focus on the PSI's development and future direction.	<ul> <li>As part of the strategic planning process, a significant amount of work has been undertaken since the last Council meeting in April, including: <ul> <li>A roundtable workshop session was held with key stakeholders on 9 May which was well attended.</li> <li>The Council Strategy Sub-Group met on two occasions to discuss the draft strategy and proposed strategic objectives.</li> <li>A session was held with Council on 21 May to review the proposed strategic objectives. Sessions were held with ELT and separately with all PSI staff to review the proposed strategic objectives.</li> </ul> </li> </ul>

		Following these stakeholder engagements, the draft corporate strategy for public consultation is tabled for Council's consideration today.
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 our April newsletter, we highlighted information and resources on antimicrobial resistance for pharmacists and the public that are now available on the PSI website.

# Communication & Stakeholder Engagement Updates

Overview of meetings attended by the Registrar and PSI staff		
April – June 2024	We continue to attend meetings of the Expert Taskforce to Support the Expansion of the Role of Pharmacy. PSI also continues to chair the Taskforce Implementation subgroup that supports the implementation of the first Taskforce recommendation on prescription extension by pharmacists and to attend fortnightly meetings of the Taskforce Research Sub-Committee.	
April- June 2024	We continue to contribute to the National COVID-19 Vaccination Programme – Pharmacy Workstream Working Group.	
April 20 <sup>th</sup> 2024	The President and Vice President of Council attended the HPAI Conference.	
April 23 <sup>rd</sup> 2024	We held our second quarterly operations meeting of the year with the Irish Institute of Pharmacy (IIOP).	
April 25 <sup>th</sup> & 26 <sup>th</sup> 2024	We attended the Health Services Research and Pharmacy Practice (HSRPP) Conference at UCC, which had the theme of 'Sustainable Development in Healthcare' and showcased some current research in pharmacy practice.	
April 26 <sup>th</sup>	We attended a meeting in the Department of Health with the Chief Pharmaceutical Officer (CPO) from Singapore and her team, where developments in the pharmacy sectors in jurisdictions were discussed, along with the responsibilities of the office of the CPO in Singapore.	
April 28 <sup>th</sup> 2024	We attended the IPU Conference in Athlone. The Registrar presented on the topic of 'Regulating for Patient Safety at a Time of Change' and was a member of the panel in the afternoon discussion.	
May 1 <sup>st</sup> 2024	We attended a meeting of the Regulator's Forum, where we received an update on Connecting for Life: Ireland's National Strategy to Reduce Suicide 2015 – 2024 and an update from the Professional Regulation Unit in the Department concerning the development of a framework to guide regulation policy into the future.	
May 2 <sup>nd</sup> 2024	We attended a Safety Features Oversight Group, where the IMVO updated us on scanning, decommissioning, and alert rates. The Windsor Framework (WF) and the actions required to prepare end-users and MAHs, including communications activity, were also discussed.	
May 2 <sup>nd</sup> & 16 <sup>th</sup> 2024	We participated in a meeting of the Medicines Criticality Assessment Group (MCAG) regarding a potential high-impact medicine shortage.	

May and 2024	The President Degistrar and Lload of Strategie Deliay and Communication
May 2 <sup>nd</sup> 2024	The President, Registrar and Head of Strategic Policy and Communication
	participated in a meeting with Deloitte, which is supporting the IPU with the
	conclusion of a Whitepaper on the Key Enablers for a Sustainable Pharmacy
	Model, to provide PSI's perspective on the paper.
May 7 <sup>th</sup> 2024	We met with the Medicines, Controlled Drugs, and Pharmacy Legislation Unit
	to discuss upcoming and anticipated legislative changes required by PSI over
	the remainder of 2024 and in the next strategic cycle.
May 8 <sup>th</sup> 2024	We met with Brid Ryan, Clinical Lead ePharmacy, HSE who provided us with an
	overview of the national ePrescribing Project.
May 9 <sup>th</sup> 2024	We held a strategy workshop session with a selection of PSI's key stakeholders
	at the Hyatt Regency Hotel.
May 9 <sup>th</sup> 2024	We attended a meeting of the Pharmacy eHealth Group in the Department of
	Health.
May 10 <sup>th</sup> 2024	We held our first biannual strategy meeting of the year with the IIOP and RCSI.
May 14 <sup>th</sup> 2024	We met with the other Irish health and social care regulators as part of the
	interprofessional learning group, now renamed the Interprofessional
	Collaborative Practice Group (IPCP). Evolving from an education/student
	priority, the group will now focus on discussions and actions to improve
	interprofessional collaboration both at a university level and in the workforce.
May 15 <sup>th</sup> 2024	We attended a meeting at the offices of the NMBI, with delegates from the
	HPRA, to gain understanding, assist the NMBI with medicines management
	queries and share insights on common regulatory medicines management
	concerns and issues spanning the sectors.
May 15 <sup>th</sup> 2024	As part of the public consultation process, we conducted a Focus Group
	meeting with 20 members of the PSI Pharmacist Panel to gather feedback on
	the draft Guidelines to Support Medicines Therapy Review and Prescription
	Extension.
May 16 <sup>th</sup> 2024	We met with Dr Fran Lloyd from the Northern Ireland Centre for Pharmacy
	Learning and Development (NICPLD) to discuss pharmacist prescribing in
	Northern Ireland.
May 16 <sup>th</sup> 2024	We attended a meeting with the Department of Health, where we received an
	update on the European Health Data Space and eHealth/ePrescribing.
May 27 <sup>th</sup> 2024	On 27/05/24, PSI hosted the second quarterly meeting of the HealthCare
	Regulators, which focused on Fitness to Practise. A number of agenda items

	were tabled, including Disciplinary Committee management, PPC Case Officer training, Council/Board sanctions hearings, and a proposed conference for regulators of the healthcare professions.
May 30 <sup>th</sup> 2024	We attended a meeting with the IMVO, DoH, and HPRA to discuss the FMD aspects of the Windsor Framework.
June 4 <sup>th</sup> 2024	We attended the RCSI Clinical Partner Evening, which showcased examples of pharmacy practice innovation and practice-based research.
June 4 <sup>th</sup> & 5 <sup>th</sup> 2024	We attended the biannual meeting of EDQM's Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) as guests to hear about the changes in pharmacy practices in countries throughout Europe.

## **Other external communication**

- In our April newsletter, we issued an Expression of Interest to pharmacists and pharmacy owners to participate in a photo shoot. The purpose of the photo shoot, which will take place across three pharmacies in June, is to create a bank of photography that is representative of community pharmacy in Ireland, conveying the range of services provided by pharmacists and highlighting diversity in the profession. The visuals will be used across all PSI communications channels and, in particular, will be used on the new PSI website (launching Q3 2024).
- On 25 April, we issued an expression of interest seeking applications from suitably qualified individuals interested in joining the Disciplinary Committees of the PSI, i.e. the Health Committee, the Preliminary Proceedings Committee and the Professional Conduct Committee. It is intended to establish a panel from which vacancies that arise on the various committees over the coming years can be filled.
- On 14 May, PSI issued an expression of interest for early career community pharmacists (i.e. any pharmacist registered for < 5 years) to join the Pharmacy Workforce Working Group, with a view to providing the perspective of a patient-facing pharmacist in this stage of their career.
- On 15 May, we issued an expression of interest for suitably qualified individuals who would be
  interested in participating in the work of accreditation teams tasked with reviewing and making
  recommendations for accreditation in respect of the national MPharm programmes. It is
  intended to establish a panel from which particular teams will be constituted in accordance
  with the Accreditation Policy.

 On 16 May, we issued a Press Release welcoming the announcement of a public consultation on the expansion of the role of pharmacists by Minister for Health Stephen Donnelly TD. The public consultation, which runs until 28 June, offers an opportunity for the public and interested parties to provide views on further expansion of services provided by pharmacists that could offer additional benefits to public health and patient engagement.



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

Key updates

#### **Review of the CPD Model for Pharmacists**

The Council, at its meeting of 25 April 2024, approved an evidence-based proposal to implement the recommendations contained within the Review of the CPD Model for Pharmacists in Ireland (2023) Report ('The Mazars Report').

Preliminary work has commenced on drafting proposed amendments to the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 (S.I. No. 553 of 2015) and the Pharmaceutical Society of Ireland (Registration) Rules 2008 (S.I. No. 494 of 2008) (as amended), to give effect to and support the introduction of the revisions to the CPD system for pharmacists. A public consultation on the draft rules will be held later in the year.

A market engagement exercise in respect of the Irish Institute of Pharmacy (IIOP) is in train, which will inform the drafting of a procurement specification for the next iteration of the IIOP.

#### **Future Pharmacy Workforce**

The Pharmacy Workforce Survey Analysis Report 2024 was approved by the PSI Council at its meeting on 25 April 2024 and is now available on our website. This report is based on the survey circulated to all pharmacists registered with PSI and 5th-year pharmacy students across the three Schools of Pharmacy on 22 November 2023.

Following the discussion at the workforce group's inaugural meeting on 18 April, work has been carried out to invite additional members to the group, including seeking a representative from the HSE Primary Care Reimbursement Service (PRCS). Additionally, following an Expression of Interest process, we have invited an early-career pharmacist to join the group. Work has continued on the development of a shared progress reporting tool, which will be reviewed at the next meeting of the group on 27 June 2024.

#### **Entry to MPharm Programme**

We have recently engaged with legal advisors, the Department of Health, and the EU Commission in relation to the possibility of permitting advanced entry to Year 2 of the MPharm programmes, where an applicant holds relevant learning recognised by the programme provider. The outcome of this engagement has allowed us to communicate with the Schools of Pharmacy to confirm that this mechanism is facilitated under the legislation and can be considered by the PSI in the context of the

ongoing accreditation of the programmes. This development has the potential to support improved access to existing pharmacy programmes and known workforce concerns.

#### **Continuing Professional Development Model for Pharmaceutical Assistants**

Last year, the Council approved Mazars <u>Report to Support the Development of a Continuous</u> <u>Professional Development (CPD) Model for Pharmaceutical Assistants.</u> The report makes recommendations for a proposed CPD model for Pharmaceutical Assistants, including the development of 'themes' to provide direction and guidance for Pharmaceutical Assistants to conduct and manage their CPD learning activities within the new model. We have been engaging with the Pharmaceutical Assistants Association (PAA) over the last number of months and are preparing to issue a public consultation over the summer on a set of proposed 'themes' to underpin the model.

# Registrar Approval of HSELand training programme: 'Opioid Overdose Awareness and Naloxone Administration Training (Module 1).

The PSI recently convened an assessment panel of relevant experts to consider the newly available online HSELand training programme: 'Opioid Overdose Awareness and Naloxone Administration Training (Module 1)'.

Further to consideration of the assessment panel's report, the Registrar has approved this training programme, as part of the training requirements for pharmacists, to supply and administer naloxone for the purpose of saving life or reducing severe distress in emergency situations as set out under Regulation 4B of the Medicinal Products (Prescription and Control of Supply) Regulations. The training requirements for pharmacists to supply and administer naloxone in these circumstances have now been updated to include the following:

- CPR,
- Responding to an Emergency Situation and Management of Anaphylaxis (RESMA) and
- Medicines Administration (Parenteral) (PAMT) training programmes
- HSELand 'Opioid Overdose Awareness and Naloxone Administration Training (Module 1).

This means that pharmacists can build on the existing skills they have developed through the delivery of vaccinations and no longer have to undertake specific face-to-face training to supply and administer naloxone in emergencies. It is hoped that this will facilitate pharmacists to upskill in this important area.

#### Expert Taskforce to support the expansion of the role of pharmacy in Ireland

We continue to contribute to the work of the <u>Expert Taskforce to support the expansion of the role of</u> <u>pharmacy</u>. The remit of the Taskforce is to identify and support the delivery of specific objectives which will serve to align services and practices that can be delivered by pharmacists and pharmacies with the needs of the health service and patients.

#### **Phase 1: Empowering Pharmacists to Extend Prescriptions**

PSI has amended the existing <u>Guidelines on Counselling and Medicine Therapy Review</u> to support pharmacists in safely implementing recent legislative changes and enabling pharmacists to extend the validity of certain prescriptions. The Guidelines were updated and amended to reflect the new legislative amendments, provide a principles-based framework, and remove unrelated information.

The updated guidelines underwent public consultation from 24 April to 15 May. We received 169 usable responses to the online survey and three additional responses by email. A focus group meeting was also conducted on 15 May 2024 with members from the recently established PSI Pharmacist Panel. The aim of this focus group was to gather additional insight into the draft guidelines from pharmacists across a range of roles and levels of experience.

Feedback from the consultation was incorporated into the revised guidelines. The Regulatory and Professional Policy Committee decided to recommend these guidelines to Council for approval at its meeting on 20 June 2024.

In addition to the revised guidelines, a number of other supports are being developed for pharmacists including frequently asked questions on prescription extension.

#### Phase 2: Empowering Pharmacists to Prescribe within their Scope of Practice.

We also continue to support the Expert Taskforce in progressing its second phase in considering the approaches to be taken on how to empower pharmacists to prescribe within their scope of practice.

The Department of Health is carrying out a public consultation on the expansion of services in pharmacy settings. The Department of Health is seeking the views of medical practitioners, allied health and social care professionals, organisations and interested members of the public, and the survey will remain open until Friday, 28 June 2024.

We have also provided observations on draft amendments to the Health (Miscellaneous Provisions) Bill 2024 that intend to lay the groundwork for the introduction of pharmacist prescribing by making provisions in primary legislation for the expansion of the role of pharmacists.

#### **Evolving a More Effective Regulatory Model for Community Pharmacies**



#### Key updates

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

We have developed guidance on **Pharmacy Governance Roles**, which provides a principles-based outline of the governance responsibilities of the pharmacy owner, superintendent pharmacists, supervising pharmacists, and all pharmacists involved in the operation of a retail pharmacy business. The guidance was approved by the Council at its meeting on 7 March, which was communicated to all registrants and published on the PSI website on 3 May.

Draft delineation 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. Council approved the submission of the proposed legislative amendments to the Department of Health for their consideration. The Department of Health has included a question concerning the provision of a delineated pharmacy model in their current public consultation on the expansion of the role of pharmacists; this public consultation is due to close on 28 June.

We are currently developing what will become a regular communication from the PSI Quality and Safety Team to disseminate inspection insights and findings and support a strong culture of safety 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. The first communication to registrants will be published in June.

# Review of PSI Guidance to support the provision of controlled drugs on an emergency basis.

A number of PSI guidance documents have been updated following the amendment of the Medicinal Products (Prescription and Control of Supply) Regulations to facilitate the emergency supply of Schedule 2, 3 & 4 Controlled Drugs. We have updated our website in relation to the revised provisions, and the revised guidance documents were circulated to all registrants on 3 May.

#### **Codeine Specialist Surveyor Exercise**

Following the specialist surveyor exercise conducted in 2022, we have conducted a further exercise to gain insight into the compliance of community pharmacies with the published PSI guidance on the safe supply of non-prescription medicinal products containing codeine to patients. The specialist surveyor exercise was conducted in 250 pharmacies randomly selected from the PSI Register of Retail Pharmacy

Businesses. A report is currently being prepared and will be shared with the Regulatory and Professional Policy Committee in September and with Council at its meeting on 3 October.

#### **Falsified Medicines Directive update**

The PSI is responsible for supervising pharmacies' compliance with the Commission Delegated Regulation on Safety Features (EU) 2016/161. To monitor compliance with the legislation, the PSI periodically requests reports from the IMVO <u>Irish Medicines Verification Organisation (IMVO)</u> on the number of scans and decommissioning for dispense actions carried out in individual pharmacies.

To evaluate compliance with the Falsified Medicines Directive (FMD), we carry out FMD focus inspections in pharmacies and assess FMD compliance during full systems inspections. Furthermore, we directly engage with pharmacies and pharmacists where there are concerns about their FMD compliance.

FMD compliance is showing a positive upward trend. For the week starting 29 April 2024, the decommissioning rate was at 78%, marking one of the highest transaction rates so far.



## Building our Capability and Performance as a Regulatory Organisation

#### **Key updates**

# of specialist training.

Following an Expression of Interest process, the PSI has established a new panel of 14 pharmacists who may be instructed to act as expert witnesses before Committees of Inquiry in relation to fitness to practise complaints. The role of an expert witness is to provide an independent expert report to the Committees of Inquiry to assist the Committee in deciding whether the conduct alleged amounts to professional misconduct and/or poor professional performance within the meaning of the Pharmacy Act 2007.

We held a specialist training day for the new Expert Witnesses on May 22, 2024. This training comprised the following: (i) an overview of the role by Caroline Murphy, the Fitness-to-Practise and Legal Affairs Manager; (ii) external training from La Touche on the function and role of an expert witness; and (iii) a presentation from Zoe Richardson in Fieldfisher on the practical aspects of briefing an expert witness and giving evidence. This panel will remain in place for an initial period of four years, with the option to be re-appointed for a further two years.

## **Business Transformation Programme (BTP Update)**

PSI plans to implement Phase 2 of the Business Transformation Project in early Q4 2024. This phase will introduce features enabling the public to submit Complaints, Concerns, and Queries. This phase of the project is progressing as planned, within budget and meeting the quality standards agreed upon with our technology partners.

In parallel with Phase 2 progression, we have commenced planning for Phase 3 of the Business Transformation Project, entitled Pharmacy Compliance and Quality Assessment. Functionality will be developed to improve the scheduling and notification of inspections, investigations and downstream reporting.

## Strategic HR Update

Under the PSI's "Building our Capability and Performance as a Regulatory Organisation" objective, we have successfully launched the Employee Wellbeing Strategy to all staff, demonstrating our commitment to a positive work environment. Additionally, we continue to be actively engaged in recruitment activities.

Completed competitions since the last report, one competitions have been successfully completed:

• Investigations Manager (Assistant Principal Officer Grade-Permanent)

We currently have the following campaigns in train for open recruitment:

• Head of Governance and Programme Delivery - (Grade VIII-6 Month FTC) - Contract stage

- Head of Community Pharmacy Assurance (Principal Officer- Permanent) 2<sup>nd</sup> Interview stage
- Finance and Support Services Executive (Executive Officer Grade-Permanent).
- Associate Inspector (Authorised Officer) Engineer III-Permanent
- Business Support Services Assistant (Clerical Officer Grade-Permanent)
- Investigations Officer (Engineer II Permanent)
- Regulatory Executive (Executive Officer Permanent)

The following three posts have recently been sanctioned by the DoH:

- Advanced Practice Manager (APO 3-Year FTC)
- Advanced Practice Co-ordinator (HEO 3-Year FTC)
- HR, People and Organisational Development Manager (APO Permanent)

The following post is under consideration for regrading by the DoH:

Quality Assessor (Authorised Officer) – (Sanctioned at Senior Pharmacist Grade, request to regrade to Engineer II, which is an equivalent grade on the Civil Service Pay Scales -Permanent)

Other Training and Development Initiatives

We continue to focus on improving employee skills in several areas. An online driver training programme was launched for all staff who drive for work. Additionally, the Executive Leadership Team (ELT) and Wider Management Team (WMT) are participating in Climate Action Leadership training offered by the Institute of Public Administration (IPA). The ELT are also furthering their leadership development through the Belbin program, engaging in both individual and group coaching sessions.

#### **Employee Engagement Survey**

We shared the results of our 2024 Employee Engagement Survey with staff during one of our Team Brief sessions and with the Performance and Resources Committee. The survey was well received by staff, with an 80% response rate. Going forward, it will be carried out on an annual basis.

The survey underscored our strong organisational culture, with 81% of employees expressing happiness and contentment working at PSI. Our diversity and inclusion initiatives are making a significant impact, as 83% of staff believe that EDI training and events have positively influenced the PSI work environment, and 85% recognise equality, diversity, and inclusion as a priority for PSI. Compared to the 2019 survey, the most significant improvements are seen in work-life balance, conditions of employment, teamwork, communication, being treated with dignity and respect, and feeling valued.

The biggest unfavourable score increases since 2019 are related to receiving training to keep up to date with developments, performance standards, learning and development, opportunities for promotion and colleagues feeling their work makes a positive difference to the public. Whilst we

celebrate the positive feedback received, we are also focused on areas of improvement highlighted by the survey. Areas of focus for improvement in 2024 are;

**Performance Management**: We are conducting a comprehensive review of our performance management process to ensure fairness and consistency of approach.

**Learning and Development**: Training for the wider management team (AP/Grade VIII specific training) is being scheduled with the Institute of Public Administration (IPA). We also issued an expression of interest call for third-level course funding to all staff, and we are currently reviewing applications. In addition, all employees have access to the DCM Learning Portal, which contains on-demand courses as well as webinars. We aim to continue to provide training for all grades throughout Q3 and Q4 through the IPA while also developing a skills and competency matrix.

**Communication and Transparency**: We will continue to focus on improving and fostering open communication by scheduling additional Q&A sessions for all staff as part of Team Briefings with the Registrar and the ELT. We are also developing Internal Communication Guidelines to formally outline the methods of internal communication in use within the PSI and carrying out a review of myPSI.ie (PSI intranet) to ensure all information remains up to date and is easily accessible.

#### Fitness to Practice update

On May 16, a dedicated training day was conducted for members of the Professional Conduct and Health Committees. A guest speaker from the Immigration Council of Ireland delivered a presentation to the Committee members in the morning, addressing topics including discrimination and equality with an emphasis on compliance with the "public sector equality and human rights duty" under section 42 of the Irish Human Rights and Equality Commission Act 2014.

In the afternoon, La Touche delivered a presentation that focused on identifying bias and unconscious bias in decision-making. The presentation covered effective strategies for addressing biases and good decision-making principles.

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

Service/Goods to be Procured	Current Status
Establishment of a panel of Legal	Specifications have been developed by the project team, and
Assessors & Mediators	documents have been drafted. Tender documents are being progressed with the assistance of external procurement partners; the target date to publish - is 24 June.
TCQR new route - adaptation period support	Following discussions with external procurement experts on procurement planning, approach, etc., a Preliminary Market Consultation was published in July 2023, to which there was 1 respondent. Following consultation with the respondent there was no successful outcome that would align with PSI's requirements. Due to the lack of a suitable response to the market consultation, legal advice was sought regarding the operationalisation of the revised TCQR route and potentially removing the requirement for an adaptation period. The requirement for the adaption period under the revised route is being considered by Council on June 20, 2024.
TCQR new route - provider of	Following ongoing discussions with our external procurement
new examination for revised	experts on procurement planning, approach etc., tender
TCQR route** (plus additional	documents are being progressed to establish a Dynamic
wash out of the current route to be scoped for equivalence exam)	Purchasing System (DPS) for the examination under the new TCQR route. **
	Advice received that, under procurement rules, the PSI may award further contracts under the current Framework Agreement with UCC to provide for the remaining requirement of the Third Country Recognition (TCQR) Equivalence Examinations under the existing route until the current route closes or applications are transferred to the new route when it opens.
	** 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 the new exam in the revised route versus the cost to be paid directly by the applicant, remains to be confirmed by the market.
Registration-related printing and fulfilment services (e.g., registration certificates), and	The specification for registration-related requirements and all other PSI requirements is now specified, and the draft SRFT and TRD are

other print needs. *The scope has expanded due to the discontinuation of revenue-free printing.	under review by OGP. The timeframe has been confirmed with OGP and could take up to 20 weeks.
IIOP	Service delivery requirements and specification documents are under development. Market engagement process in progress with procurement advisors.
Review of Target Operating	Utilising Existing OGP FWA - SFRT being drafted at review stage, with
Model and Organisation	the aim to be sent to OGP by early June
Structure & Strategic Workforce	
plan	
Digital Skills Training	RFT under development with aim to be published in June 2024.

#### Appendix 1 – Statistical Summary

## Complaints and Fitness to Practise (figures as of June 11<sup>th</sup>, 2024)

## **Complaints for Screening Committee (Preliminary Proceedings Committee – PPC)**

Total new complaints received year to date	29
New complaints received since last report date	13
Total open, active complaints*	55
Complaints considered by PPC since last report date **	16

\* This figure may include complaints received prior to 2024 which are still being processed

\*\*These complaints were heard over 3 meetings. 56% 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 June 11<sup>th</sup>, 2024)

#### Inquiries

Total heard or commenced year-to-date *	13
Heard or commenced since the last report **	3
Complaints being investigated/prepared for hearing	45
Adjourned pending hearing	0

\* 46% meet the KPI of the inquiry being heard within 18 months from the date of referral by the PPC to a Committee of Inquiry.

\*\* 10 took place before the PCC & 3 took place before the HC

#### Mediation

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

#### Sanction Hearings/ Undertakings/Dismissals/Applications before Council\*

Heard since the last report*	9
Heard year to date*	16
Sanction hearings/undertakings being prepared for Council	4
*per respondent	

## High Court Sanction Confirmation Hearings\*

Heard year-to-date	5
Cases being prepared for High Court confirmation	1

#### 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		
(2) Health Committee			
Held since last report date.	1		
(1) Professional Conduct Committee			
(2) Health Committee			

The next PCC and HC Callovers are scheduled for June 13, 2024

#### **Interim Suspension Applications**

Applications heard by Council year to date	0
	-

#### Prosecutions

Cases being prepared for District Court Prosecution	0
---	---

# Professional Registration (figures as of 7<sup>th</sup> June 2024)

Route/Application Type	Applications Received 2024 to date.	applications received in previous	
Third Country Qualification Recognition (TCQR) – excluding UK.	84	386	
Route/Application Type		Registrations/ Actions Completed as of 7/6/2024	
National Route		6	
EU Route		77	
Non-National Route (Third Country) – UK onl	У	34	
Non-National Route (Third Country) (excl. UK)		29	
European Professional Card – Establishment of Service		3	
(Qualification Recognition)			
European Professional Card – Temporary & Occasional		0	
Provision of Service			
Voluntary Cancellations from Register		56	
Involuntary Cancellations from Register		17	
Restorations to Register following Voluntary Cancellation		11	
Restorations to Register following Involuntary Cancellation		2	
Certificates of Current Professional Status iss	sued	46	
IMI Alerts (Internal Market Information) issued by PSI		5	

## **Retail Pharmacy Businesses**

Registration of Retail Pharmacy Businesses 2024 (as of 7 <sup>th</sup> June 2024)			
Number of Registered Retail Pharmacy Businesses 1982			
Retail Pharmacy Business Openings by Type	New Opening: 7		
	Permanent Relocation: 4		
	Change of Ownership: 27		
Retail Pharmacy Business Cancellations by Type	Voluntary Cancellations		
	(Closure): 10		
	Voluntary Cancellations		
	(Permanent Relocations): 4		
	Voluntary Cancellations		
	(Changes of Ownership): 27		
	Involuntary Cancellations: 0		
Number of Changes in Supervising and Superintendent	Supervising pharmacist		
Pharmacists (as of June 10, 2024)	changes: 192		
	Superintendent Pharmacist changes: 45		

Internet Supply Figures as of June 10th 2024	
Number of Pharmacies on Part A	134
Number of Non-Pharmacies on Part B	184

## Regulation of Retail Pharmacy Businesses (figures as of June 7th, 2024)

Pharmacy Inspections 2024	4 PSI 2024 Service Plan Pharmacy In Key Performance Indicator (KPI)	
Total number of on-site	140	200
Pharmacy inspection visits to date.		
Total number of registration- related inspections to date.	6	25
Number of pharmacy re- inspections – including re- inspections following	1	0
Registrar's decision under Section 71(1)(d) to date.		

## Concerns (figures as of June 7<sup>th</sup>, 2024)

Total new concerns received year to date	33
New concerns received since last report date	11
Concerns reviewed since the last report date	12
Open concerns	6

Investigation Activity 2024 (Part 7 of the Pharmacy Act / Inspection & Enforcement)			
No. of investigations open	No. of investigations initiated	No. of investigations closed since	
	since the last Council meeting		
17	7 2		
Investigation Activity 2024 (Section 67) – e.g., Interviews /		5	
Statements / Pharmacy Visits / Professional Witness			

#### **Information Governance**

## Freedom of Information and Data Protection (as of June 10<sup>th</sup>, 2024)

No. of FOI requests received	Granted	Handled outside of FOI	Refused	Currently being processed
10	2	5**	1*	2

\* In two cases information provided to the requester when determining the scope and the requester decided to close the request.

\*\*PSI did not hold the records requested, and FOI did not progress

#### **Data Protection**

No. of Subject Access Requests Received	Granted	Refused	
3	2	0	
No. of Data Breaches	Reported to the Data Protection Commissioner (DPC)	Not meeting the threshold for reporting to DPC	
0	0		
Data Transfer Requests	Category: Research Purposes	Category: Patient Safety Alert/Product Recall	Category: IIOP
13	6	1	6