

Report of the Registrar Council Meeting 25th April 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.	<p>In July 2023, PSI conducted a market-sounding exercise on the provision of an adaptation placement service for the revised TCQR route, as provided for under SI 452/2023, and this exercise has now concluded. Following consultation, no suitable providers were identified, and as such, outsourcing the adaptation period is currently not a viable option.</p> <p>Due to a number of factors, in 2024, PSI sought further 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 memo was issued to the Regulatory and Professional Policy Committee for their meeting on 11 April, outlining the advice and the proposed solutions to give effect to the new TCQR route. Upon discussion with the Committee, a revised memo will be prepared for the 6th June RPP meeting, detailing further information on operational aspects and pharmacy implementation of the proposed revised route.</p>
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 Q2.	Work is continuing on the review of the regulation of retail pharmacy businesses in a hospital setting and is on track to be submitted to the DoH by the end of Q2 2024.

EOI to appoint Expert Pharmacist Witnesses to a Panel to support Committees of Inquiry in Fitness to Practise complaints.	The EOI concluded with 47 applications received. Following the assessment of all applications, 14 individuals were selected for appointment.	Formal induction training for all successful applicants will take place towards the end of May.
Take steps to ensure PSI is meeting our Public Sector Equality and Human Rights Duty.	<p>Assessment of human rights and equality issues relevant to the functions and purpose of PSI.</p> <p>Action plan to address issues raised in the equality and human rights assessment.</p> <p>Information on developments and achievements regarding equality and human rights issues and actions is included in the Annual Report.</p>	The specification is being finalised for an external expert who will assist with assessing human rights and equality issues relevant to the functions and purpose of PSI.
Implementation of the PSI's Climate Action Plan/ Sustainability programmes of work.	<p>Training of staff</p> <p>Recommendations implemented with clear targets and a roadmap to ensure the PSI remains engaged on climate issues.</p>	<p>The Health, Safety and Sustainability Committee continue to keep under review the implementation of the recommendations.</p> <p>A training course has been identified for senior management.</p>
Development of PSI's next Corporate Strategy and underpinning Service Plans over the period of the strategy.	Strategy approved by Council by yearend with a clear focus on the PSI's development and future direction.	<p>As part of the strategic planning process, a number of facilitated meetings have taken place since the last meeting of Council, including;</p> <ul style="list-style-type: none"> • The Council Strategy Subgroup • Council Training and Development Day <p>Mazars have been appointed following a procurement exercise to support PSI in the strategic planning and development process.</p> <p>We have issued a survey to a number of relevant stakeholders of the PSI and will</p>

		hold a stakeholder engagement event in May to discuss the survey findings.
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.	We highlighted the new landing pages for pharmacists and the public on the topic of AMR and AMS on our social media platforms and in our April newsletter.

Communication & Stakeholder Engagement Updates

Overview of meetings attended by the Registrar and PSI staff	
February 28 th 2024	PSI Staff attended a Registration Managers Forum with the other healthcare regulators. Discussion centred around the EU Commission paper from November 2023 regarding the recognition of third-country qualifications. There was also discussion regarding language proficiency requirements and the approach of each of the regulators.
March – April 2024	We continue to attend meetings of the Expert Taskforce to Support the Expansion of the Role of Pharmacy. PSI also chaired meetings of the Taskforce Implementation subgroup that supports the implementation of the first Taskforce recommendation on prescription extension by pharmacists. We also continued to attend fortnightly meetings of the Taskforce Research Sub-Committee.
March 7 th 2024	We attended an International Collaborative seminar on <i>‘Measuring Patient Safety Performance – International Insights to Support Healthcare Reform’</i> . The event was hosted by the National Patient Safety Office in the Department of Health, in association with the International Society for Quality in Healthcare and the Health Service Executive.
March 12 th 2024	We held the first meeting of the PSI Continuing Professional Development (CPD) Review Working Group established to support, inform and advise on the development of an evidence-based proposal to inform the Council’s consideration of the revised scope of the CPD Model for Pharmacists.
March 12 th 2024	We met with representatives from the Irish Pharmacy Union (IPU) to discuss a range of matters of relevance to both organisations.
March 14 th 2024	We held a second exploratory workshop with the Irish Institute of Pharmacy to gather their insight and expertise as part of the development of an evidence-based proposal to inform the Council’s consideration of the revised scope of the CPD Model for Pharmacists.
March 14 th 2024	We attended a meeting of the Pharmaceutical Strategy Working Group. The purpose of the group is to support and inform Ireland’s contribution to the development and implementation of the EU Pharmaceutical Strategy and the formulation of EU Pharmaceutical Regulations.
March 14 th 2024	We attended a meeting of the Overprescribing Working Group. This group is coordinated by the Irish Medical Council, and its focus is on tackling the

	overprescribing of benzodiazepines and gabapentinoids (gabapentin and pregabalin).
March 19 th 2024	We attended the Controlled Drugs National Group, led by the Care Quality Commission. This group is comprised of key regulators and agencies across Ireland and the UK with a remit for controlled drugs.
March 21 st 2024	We attended a meeting of the Pharmacy eHealth Group.
March 22 nd 2024	We attended an IMVO strategy roundtable meeting to inform the development of their new strategy.
March 25 th 2024	We participated in a meeting of the Medicines Criticality Assessment Group (MCAG) in relation to a potential high-impact medicine shortage.
April 3 rd 2024	We held the second meeting of the PSI Continuing Professional Development (CPD) Review Working Group established to support, inform and advise on the development of an evidence-based proposal to inform the Council's consideration of the revised scope of the CPD Model for Pharmacists.
April 11 th 2024	We invited Mr Niall Sinnott, Head of eHealth and Information Policy, to PSI House to present to the Strategy Sub-group and PSI colleagues on eHealth developments across the health system, with a focus on those most likely to impact the pharmacy sector over the lifetime of the next Corporate Strategy.
April 15 th 2024	We met with the Department of Public Expenditure, National Development Plan Delivery, and Reform's Open Data Unit to be briefed on the progress of the Public Sector Data Strategy and the Open Data Communications Plan.
April 16 th 2024	The ELT met with representatives from the DoH for the first governance meeting of the year. Topics discussed were progress on the implementation of the 2024 service plan, workforce matters, delineation, and superannuation. Minutes from the December 2023 meeting are available on your iPad.
April 18 th 2024	We held the first meeting of the Department of Health and PSI Pharmacy Workforce Working Group. The group has been established to facilitate the recommendations and actions in the Workforce Intelligence Report to be progressed. The group will also be a forum for the Department of Health and others to obtain agile and expert contributions to strategic workforce planning for the wider health system.

Recent communication/collaboration with other regulatory and public authorities

On 10 April we issued a survey to a number of PSI's key stakeholders as part of our engagement with them to help inform the development of the next Corporate Strategy. The main objective of the survey is to gather feedback on the current strategy as well as seek views on the direction of our next Corporate Strategy.

We have invited these stakeholders to discuss the survey findings at an in-person event on 9 May 2024.

Public consultations and other submissions

In April we submitted a response to the National Medicinal Product Catalogue project's consultation aimed at standardising medicinal product information at a national level. The consultation sought feedback on the data points to be included in the NMPC.

Other external communication

[News release](#)

1 March 2024: Legal validity of prescriptions has been extended from six to 12 months.



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

Key updates

Review of the CPD Model for Pharmacists

Work continues on this multi-annual project. Significant research and engagement have been undertaken in recent weeks to develop 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'). The draft proposal is intended to inform and elaborate on the Council's consideration of the scope of the revised CPD model for pharmacists. The draft proposal was discussed and considered by the Regulatory and Professional Policy Committee at its meeting on 11 April and is being recommended to Council for approval at its meeting of 25 April.

Future Pharmacy Workforce

Following on from the Emerging Risks to the Future Pharmacy Workforce project undertaken in 2023, the annual workforce survey for 2023/2024 was circulated to all pharmacists registered with the PSI and to 5th year pharmacy students across the three Schools of Pharmacy in late November. The draft Workforce Survey Analysis Report was discussed and considered by the Regulatory and Professional Policy Committee at its meeting of 11 April and is being recommended to Council for approval at its meeting of 25 April.

On 18 April, we held the first meeting of the Department of Health and PSI Pharmacy Workforce Working Group. The group has been established to facilitate the recommendations and actions in the Workforce Intelligence Report published in 2023 to be progressed. The group will also be a forum for the Department of Health and others to obtain agile and expert contributions to strategic workforce planning for the wider health system.

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

PSI continues to contribute to the work of the [Expert Taskforce to support the expansion of the role of pharmacy](#). 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.

We committed to developing Guidelines to support pharmacists to give effect to the first recommendation of the Expert Taskforce: empowering pharmacists to extend prescriptions.

Draft updated guidelines

As Regulation 9A of the Regulation of Retail Pharmacy Businesses (Amendment) Regulations 2024 ([S.I. No. 74/2024 - Regulation of Retail Pharmacy Businesses \(Amendment\) Regulations 2024 \(irishstatutebook.ie\)](#)) provides the legislative basis for this change; it was decided to update the existing Guidelines on the Counselling and Medicines Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business. The updated draft guidelines:

- reflect the legislative change in March 2024, giving pharmacists the authority to extend the validity of certain prescriptions and
- provide a principles-based framework, which is intended to be supportive and enabling rather than prescriptive.

Public consultation

The draft updated guidelines were approved by the Regulatory and Professional Policy Committee for public consultation at its meeting on 11 April 2024.

Over the coming weeks, we will invite stakeholders to engage in our public consultation to gather feedback and insights to ensure that the updated principle-based guidelines are effective and responsive to support pharmacists in the consistent delivery of safe and high-quality person-centred care regarding medicine therapy review, counselling, and prescription extension.

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

The Expert Taskforce continues to progress its second phase: considering the approaches to be taken on how to empower pharmacists to prescribe within their scope of practice. In support of this initiative, the Minister for Health, Stephen Donnelly, has received government approval to proceed with the drafting of a further amendment to the Health (Miscellaneous Provisions) Bill 2024. This amendment will lay the groundwork for the introduction of pharmacist prescribing. This amendment will make provision in primary legislation for the further 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 principle-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. Four overarching governance principles have been developed to provide clarity on the differing responsibilities in relation to each governance role, with each principle being supported by concise, outcomes-focused indicators. The guidance also provides clarity to registrants on the legislative interpretation of 'whole time charge' with respect to the role of supervising pharmacists. The guidance was approved by Council at its meeting on 7 March and will be circulated to all registrants before the end of April.

We have drafted guidance on the Operation of a Retail Pharmacy Business using a Delineated Model and sought extensive legal advice on the required amendments to the Regulation of Retail Pharmacy Business Regulations and Registration Rules needed to give effect to such a pharmacy model and whether this can be permitted under the Pharmacy Act 2007. The draft guidance and proposed amendments to the Regulation of Retail Pharmacy Business Regulations were considered by the Regulatory and Professional Policy Committee at its meeting on 11 April. The Committee is recommending to Council that the proposed amendments be submitted to the Department of Health for their consideration and approval, along with the guidance document to support the proposed amendments.

We are currently establishing a quarterly 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 the coming weeks.

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 we are finalising the guidance documents and any required updates to our website. We will publish and circulate these to registrants before the end of April.

Codeine Specialist Surveyor Exercise

Following the specialist surveyor exercise conducted in 2022, we are conducting 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 results of this exercise will be shared with Council in the coming months.

Falsified Medicines Directive update

Compliance with the Falsified Medicines Directive

We are observing an improvement in Falsified Medicines Directive (FMD) compliance rates. According to the IMVO, the decommissioning rate for the week commencing 25 March 2024 was 72.3%.

PSI Monitoring Compliance

The PSI monitors the performance of pharmacies according to FMD requirements. Since January, PSI has conducted a number of focused inspections to assess compliance with FMD requirements, particularly where there were low levels of scanning and decommissioning. We also engage directly with pharmacies and pharmacists where there is a concern as to their compliance.

The Irish Medicines Verification Organisation (IMVO)

The IMVO continue to support pharmacies that are verifying but not decommissioning medicines successfully and also offers support in the following areas: scanning queries, scanner configurations, IMVS/IMVO account queries and alert queries.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Business Transformation Project (BTP Update)

Phase 2 will deliver functionality to allow members of the public to submit Complaints, Concerns, and Queries. Phase 2 aims to improve the experience for members of the public interacting with the regulator in the notification of Complaints, Concerns and Queries and to streamline the handling processes themselves so as to improve efficiency and reporting. This project is on track for delivery on schedule, within budget and as per the quality criteria agreed with our technology partners.

Strategic HR Matters

We continue to make progress in aligning human resource management and organisational development with PSI's "Building our Capability and Performance as a Regulatory Organisation" objective. Since the last report, key activities have focused on finalising the Employee Wellbeing Strategy and sustaining the ongoing recruitment drive.

Strategic Workforce Planning

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

- Strategic Policy Officer - (Senior Pharmacist - 6 Month FTC)
- Pharmacy Practice Officer - (Engineer II -Permanent)

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

- Head of Community Pharmacy Assurance - (Principal Officer- Permanent) – Interview stage
- Head of Governance and Programme Delivery - (Grade VIII-6 Month FTC) -Offer Stage
- Investigations Manager (Assistant Principal Officer Grade-Permanent) – Offer Stage
- Finance and Support Services Executive (Executive Officer Grade-Permanent) – To be re-advertised with an updated role profile.
- Associate Inspector (Authorised Officer) – Engineer III-Permanent-To be advertised.
- Business Support Services Assistant (Clerical Officer Grade-Permanent)- To be advertised with an updated role profile.

Workshops and Training

Staff completed a SharePoint training session in March as part of the Digital Skills Training Programme. The training, which was delivered during the March Anchor Day, was facilitated by the International Academy of Computer Training (IACT).

Other HR activities

The ELT approved a Wellbeing Strategy for 2024-2027 focusing on four pillars: Physical, Mental & Emotional, Work-Life Balance, and Social Wellbeing. This will be presented to staff on the anchor day scheduled for the end of April.

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

Service/Goods to be Procured	Current Status
Establishment of a panel of Legal Assessors & Mediators	Specifications have been developed by the project team, and documents drafted. Tender documents are being progressed with the assistance of external procurement advisers.
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 has been sought regarding the operationalisation of the revised TCQR route and removing the requirement for an adaptation period. The requirement for the adaption period under the revised route was considered by the Regulatory and Professional Policy Committee at its meeting on 11 April 2024 and will be considered further at their meeting on 6 June 2024.
TCQR new route - provider of new examination for revised TCQR route** (plus additional wash out of the current route to be scoped for equivalence exam)	<p>Following ongoing discussions with our external procurement experts on procurement planning, approach, etc., tender documents are being progressed to establish a Dynamic Purchasing System (DPS) to be published in Q2 2024.</p> <p>** 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 exam versus the cost to be paid directly by the applicant remains to be confirmed by the market.</p>
Registration-related printing and fulfilment services (e.g. registration certificates) and other non-standard print needs. The scope has expanded due to Revenue printing services no longer being available and now also incorporating Design requirements.	Specification for registration-related requirements and all other PSI printing and design requirements is complete, and draft SRFT and documents will be sent at the end of March 2024 to OGP for review. Timeframe to complete is to be confirmed with OGP but could take up to 20 weeks.
Corporate Strategy	Tender completed utilising OGP framework Agreement. Contract was signed on 13 March 2024, with a commencement date of 25 March 2024.

IIOP	Service delivery requirements are to be finalised at the end of Q1, with a view to the tender specification document being developed thereafter. Market engagement process in development with procurement experts.
Review of Target Operating Model and Organisation Structure & Strategic Workforce plan.	Utilising existing OGP FWA, SFRT is being drafted.

Appendix 1 – Statistical Summary

Complaints and Fitness to Practise (figures as of 18.04.2024)

Complaints for Screening Committee (Preliminary Proceedings Committee – PPC)

Total new complaints received year to date	17
New complaints received since last report date	6
Total open, active complaints*	42
Complaints considered by PPC since last report date **	5

* This figure may include complaints received prior to 2024 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 the complaint to the date of the final PPC decision.

Fitness to Practise (figures as of 18.04.2024)

Inquiries

Total heard or commenced year-to-date *	10
Heard or commenced since last report **	5
Complaints being investigated/prepared for hearing	44
Adjourned pending hearing	2

*54 % meet the KPI of the inquiry being heard within 18 months from the date of referral by the PPC to a Committee of Inquiry. Of those that didn't, 3 involved prosecutions, and 2 involved health matters, both of which delayed the scheduling of inquiries beyond the PSI's control.

** 7 took place before the PCC & 3 took place before the HC

Mediation

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

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

Heard since last report*	3
Heard year to date*	7
Sanction hearings/undertakings being prepared for Council	9

*per respondent

High Court Sanction Confirmation Hearings*

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

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

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

Interim Suspension Applications

Applications heard by Council year to date	0
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Prosecutions

Cases being prepared for District Court Prosecution	0
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Professional Registration (figures as of 11.04.2024)

Route/Application Type	Applications Received 2024 to date.	Applications in Process (including applications received in previous years)
Third Country Qualification Recognition (TCQR) – excluding UK.	53	335
Route/Application Type	Registrations/ Actions Completed as of....	
National Route	4	
EU Route	45	
Non-National Route (Third Country) – UK only	19	
Non-National Route (Third Country) (excl. UK)	16	
European Professional Card – Establishment of Service (Qualification Recognition)	2	
European Professional Card – Temporary & Occasional Provision of Service	1	
Voluntary Cancellations from Register	38	
Involuntary Cancellations from Register	17	
Restorations to Register following Voluntary Cancellation	7	
Restorations to Register following Involuntary Cancellation	1	
Certificates of Current Professional Status issued	28	
IMI Alerts (Internal Market Information) issued by PSI	3	

Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses 2024 (as of 15.04.2024)	
Number of Registered Retail Pharmacy Businesses	1982
Retail Pharmacy Business Openings by Type	New Opening: 4 Permanent Relocation: 3 Change of Ownership: 16
Retail Pharmacy Business Cancellations by Type	Voluntary Cancellations (Closure): 7 Voluntary Cancellations (Permanent Relocations): 3 Voluntary Cancellations (Changes of Ownership): 16 Involuntary Cancellations: 0
Number of Changes in Supervising and Superintendent Pharmacists.	Supervising pharmacist changes: 138 Superintendent Pharmacist changes: 39

Internet Supply Figures as of 15/04/2024	
Number of Pharmacies on Part A	131
Number of Non-Pharmacies on Part B	165

Regulation of Retail Pharmacy Businesses (figures as of 09.04.2024)

Pharmacy Inspections 2024		PSI 2024 Service Plan Pharmacy Inspection Key Performance Indicator (KPI)
Total number of on-site Pharmacy inspection visits to date.	93	200
Total number of registration-related inspections to date.	3	25
Number of pharmacy re-inspections – including re-inspections following Registrar’s decision under Section 71(1)(d) to date.	0	0

Concerns (figures as of 15.04.2024)

Total new concerns received year to date	24
New concerns received since last report date	13
Concerns reviewed since last report date	11
Open concerns	3

Investigation Activity 2024 (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	0
Investigation Activity 2024 (Section 67) – e.g., <i>Interviews / Statements / Pharmacy Visits / Professional Witness</i>		4

Information Governance

Freedom of Information (as of 17 April 2024)

No. of FOI requests received	Granted	Handled outside of FOI	Refused	Currently being processed
5	2	3	0	0

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	
0	0	0	
Data Transfer Requests	Category: Research Purposes	Category: Patient Safety Alert/Product Recall	Category: IIOP
7	2	1	4