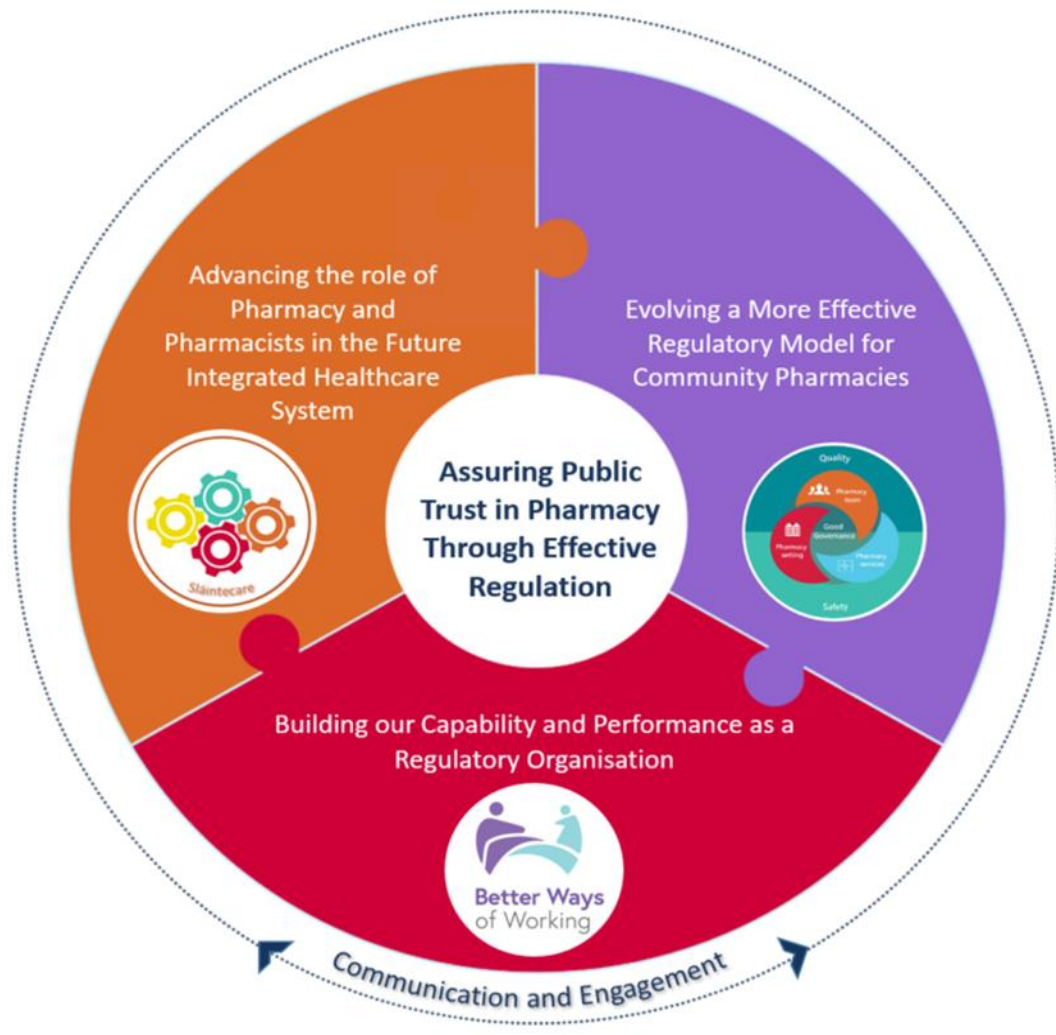
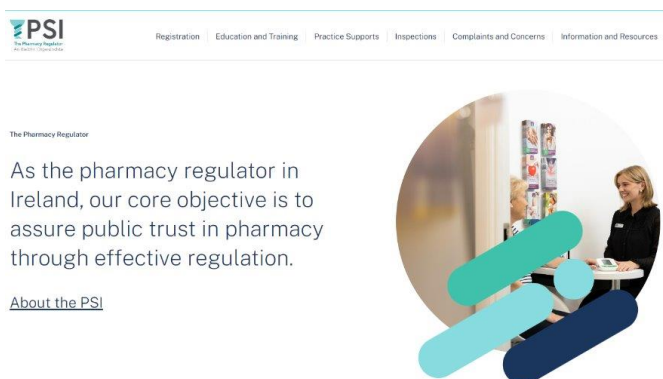


Report of the Registrar Council Meeting 03.10.2024



Highlights from the Registrar

Launch of the new PSI website



In July, we launched our new website, which can be visited at www.psi.ie. Delivered as part of our Corporate Strategy 2021-2024, the new website supports the PSI's commitment to engage more effectively and accessibly with patients, the public and registrants and to communicate clearly and consistently with stakeholders that include the Department of Health, HSE, other public bodies, regulators and the media. The project supports our commitment as a public body to becoming a digital-first regulator.

The new website is mobile responsive and user-friendly with significantly improved design, searchability, multi-media, and accessibility for users. It features imagery from pharmacies across Ireland and from within the PSI offices, which were specially commissioned to give an accurate and authentic representation of modern pharmacy services and pharmacy regulation in Ireland. We remain grateful to all those who volunteered to participate in the photo project. The website continues to provide access to the registers for pharmacies, pharmacists, pharmaceutical assistants and the Internet Supply List which are searchable from the homepage.

Ensuring that there is ease of access to frequently used webpages and documents, the Communication and Engagement team have ensured redirects from the old to the new website are in place. We have so far gained positive feedback on the new website and continue to welcome feedback from all users to ensure we continue to meet their needs.

Publication of the final report from the Expert Taskforce to Support the Expansion of Pharmacy

In August, we welcomed the announcement by the Minister for Health Stephen Donnelly T.D. to progress the phase two recommendations by the Expert Taskforce on expanding the scope of practice for pharmacists.

Speaking at the launch of the [final report from the Expert Taskforce to Support the Expansion of the Role of Pharmacy](#), the Minister outlined the intent of strategic recommendations contained within the report to introduce full pharmacist prescribing authority in a phased manner over the coming years.

This will initially focus on the limited prescribing of prescription-only medicines by pharmacists under a common conditions service. Through this service, pharmacists will offer advice and treatment for

common, often self-limiting conditions within community pharmacies. They will be authorised to prescribe and dispense prescription-only medicines for an approved list of common conditions that they are trained to diagnose and manage, enhancing access to timely care and reducing the burden on other healthcare providers, aligned to the principles of Slaintecare. To begin with, patients will have access to care for eight conditions, which can be extended over time as the service evolves in community pharmacies.

In the report, the Expert Taskforce has also provided other evidence-based policy recommendations to the Minister, including the development of independent autonomous prescribing by pharmacists. This recommendation is proposed to be implemented in a step-wise manner and will be dependent on several enablers, including a legislative and regulatory framework and the development of dedicated post-graduate training.

Supporting pharmacist involvement in the upcoming Autumn/Winter vaccination campaign

On 11 September, the Registrar approved the NIO training in respect of Comirnaty® JN.1 30mcg, Comirnaty® JN.1 10mcg (For children aged 5-11 years) and Comirnaty JN.1 3mcg (for Children Aged 6 Months to 4 Years), as training for the purposes of Regulation 4F(b) of the [Medicinal Products \(Prescription and Control of Supply\) \(Amendment\)\(No.4\) Regulations 2024 \(S.I. No. 458 of 2024\)](#) to facilitate pharmacist vaccinators in supplying and administering these vaccines, as part of the COVID-19 national vaccination programme. These vaccines will be the main COVID-19 booster vaccines used in the upcoming Autumn/Winter Vaccination campaign, based on recent recommendations from the National Immunisation Advisory Committee (NIAC).

Additionally, as part of this updated legislation, amendments were made to reduce administrative burden for pharmacists and streamline record-keeping requirements. These amendments include:

- Removal of the requirement to notify a patient's GP that a vaccine has been supplied or administered.
- The record of vaccination is now to be retained for two years post-administration instead of eight years.
- Records of vaccination must be recorded electronically and should be readily available for inspection. Paper records for vaccination are no longer required.
- Aligning the consent requirements for all vaccines and emergency medicines.

PSI joins the Regulators Advisory Group of the International Pharmaceutical Federation (FIP)

Following discussions with representatives from FIP, we submitted an application for membership as an observer organisation over the summer, enabling us to join the Regulators Advisory Group at FIP. This group comprises pharmacy regulators from France, Portugal, the USA, Canada, New Zealand and Australia. We attended our first meeting of the group in September.

Ongoing Regulatory Work Programmes in 2024

| Activity | Outputs | Update |
|---|---|---|
| Continued Operationalisation of 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. | <p>The removal of a mandatory adaptation period from the revised TCQR route was approved by PSI Council on 20 June 2024.</p> <p>An internal TCQR working group has been established including representatives from Registrant & Customer Relations, Quality & Safety and Fitness to Practise & Legal Affairs (FTPLA), who will have an holistic perspective in analysing, advising, and steering the process to completion. .</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 Q4. | <p>The draft Position Paper on Hospital Pharmacy Regulation was presented to the Regulatory and Professional Policy Committee for discussion at its meeting on 6 June 2024.</p> <p>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.</p> <p>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 November.</p> |
| Take steps to ensure PSI is meeting our Public Sector Equality and Human Rights Duty. | <ul style="list-style-type: none"> • 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. | The process to assess the human rights and equality issues related to the functions and purpose of the PSI has begun with the appointed external consultants. The external consultants have facilitated two sessions with the Equality, Diversity and Inclusion (EDI) |

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| | <ul style="list-style-type: none"> Information on developments and achievements regarding equality and human rights issues and actions is included in the Annual Report. | Working Group to date, with the process due for completion in November. |
| 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. | <p>Since the last Council meeting in June, the draft Corporate Strategy was issued for public consultation in July. The consultation was open from 3-25 July 2024.</p> <p>The Council Strategy Sub-Group met on 11 September to discuss the public consultation report and the updates made to the draft strategy further to the feedback received through the public consultation.</p> <p>The public consultation report and the updated draft strategy are tabled for Council's consideration at their meeting on 3 October.</p> |
| Advance our actions to contribute to Ireland's second National Action Plan on Antimicrobial Resistance 2021-2025 (known as iNAP2) to address antimicrobial resistance (AMR) and help advance Ireland's response to AMR by improving awareness and knowledge of AMR amongst the pharmacy profession, including pharmacy students, to ensure that it is an integral part of the delivery of pharmacy services. | Participation of pharmacists in continuing professional development (CPD) and education on AMR, infection prevention and control (IPC) and antimicrobial stewardship (AMS) is encouraged by the promotion of resources and increased awareness of the importance of these areas for practice. | <p>As Council will be aware, PSI has obligations to take a number of actions under iNAP2, which is the national action plan to combat antimicrobial resistance across both human and animal health.</p> <p>In response to a request from the National Patient Safety Office in August, PSI provided a progress update on our actions under iNAP2. The purpose of the update is to inform the development of iNAP3.</p> <p>PSI had previously submitted a mid-term review in 2022 summarising our progress under iNAP2 for 2021-2022 and setting out the actions we would take under iNAP2 during 2023-2024.</p> |

Communication & Stakeholder Engagement Updates

| Overview of meetings attended by the Registrar and PSI staff | |
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| June 27 th 2024 | We held the second meeting of the Pharmacy Workforce Working Group. |
| July 2024 | We continued 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. |
| July 11 th 2024 | We attended a meeting of the Pharmaceutical Strategy Working Group. The purpose of this multi-stakeholder group, which was established by the Department of Health, is to discuss Ireland's position in response to the EU Commission's legislative package relating to the revision of the General Pharmaceutical Legislation. |
| July-September | We continue to attend fortnightly meetings of the National COVID-19 Vaccination Programme Pharmacy Workstream Working Group. |
| July 25 th 2024 | We held our third quarterly operations meeting of the year with the Irish Institute of Pharmacy (IIOF). |
| 1 August | We met with HIQA to discuss a revised Memorandum of Understanding and the impact of the upcoming Patient Safety Act. |
| August 7 th & 27 th 2024 | <p>We met with the IIOF to discuss draft changes to the PSI (CPD) and PSI (Registration) Rules needed to operationalise the approved changes to the Continuing Professional Development (CPD) Model for Pharmacists and for the development and implementation of a CPD model for pharmaceutical assistants.</p> <p>The purpose of these meetings was to identify any substantive feedback that key stakeholders may have on the draft rules and to incorporate this feedback, where appropriate, in advance of a wider public consultation on the draft rules.</p> |
| August 8 th 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). The group is currently working to agree on new Terms of Reference and will have their next meeting in October. |
| August 12 th 2024 | We participated in a recording of a Q&A session with representatives from Boots Ireland on the topic of prescription extension to support an upcoming |

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| | meeting with pharmacists and store managers from across the Boots network of pharmacies. |
| August 13 th 2024 | We attended the launch in the Department of Health of the final report from the Expert Taskforce to Support the Expansion of the Role of Pharmacy. |
| August 29 th 2024 | We met with the Irish Pharmacy Union (IPU) to discuss draft changes to the PSI (CPD) and PSI (Registration) Rules in advance of a wider public consultation on the draft rules. |
| August 29 th 2024 | We met with the Hospital Pharmacists Association of Ireland (HPAI) to discuss draft changes to the PSI (CPD) and PSI (Registration) Rules in advance of a wider public consultation on the draft rules. |
| August 30 th 2024 | We met with the Practising Pharmacist Representative from the PSI CPD Review Working Group to discuss draft changes to the PSI (CPD) and PSI (Registration) Rules in advance of a wider public consultation on the draft rules. |
| September 4 th 2024 | We met with the Pharmaceutical Assistants Association (PAA) to discuss progress on the development and implementation of a CPD model for pharmaceutical assistants and to discuss draft changes to the PSI (CPD) and PSI (Registration) Rules in advance of a wider public consultation on the draft rules. |
| September 5 th 2024 | We attended a meeting with the IMVO, DoH, and HPRA to discuss the FMD aspects of the Windsor Framework, including the planned communications activity to prepare end-users and MAHs. |
| September 10 th 2024 | We attended a Safety Features Oversight Group, where the IMVO updated us on scanning, decommissioning, and alert rates, other operational updates, European activity and Brexit/Windsor Framework. |
| September 10 th 2024 | We attended the Smart Health Summit in Croke Park. |
| September 11 th 2024 | The ELT met with representatives from the DoH for the second governance meeting of the year. Topics discussed were progress on the implementation of the 2024 service plan, the Performance Delivery Agreement, delineation, Reform of the Pharmacy Act and FMD. The minutes of the April 2024 meeting are available on the Council iPad. |
| September 12 th 2024 | We attended the first meeting of the Community Pharmacy Expansion Implementation Oversight Group (IOG), established by the Minister and |

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| | chaired by the Department of Health to oversee the introduction of a common conditions service. |
| September 13 th 2024 | PSI staff met with the Irish Pharmacy Union (IPU) to discuss the National Patient Safety Office/Department of Health's new <i>Open Disclosure Framework</i> and upcoming plans to support community pharmacists with the rollout and implementation. |
| September 17 th 2024 | Two teams from Professional Standards presented at CLEAR's Annual Education Conference 2024 in Baltimore, Maryland. The conference sessions provided information on our actions and activities on the Workforce Intelligence Report and implementation project and the reforms to our Continuing Professional Development System for pharmacists. |
| September 17 th 2024 | On World Patient Safety Day, we attended the National Patient Safety Office Conference, themed 'Think Global, Act Local', where developments in patient safety were discussed. The event also highlighted the new Patient Safety Rights Charter, introduced by WHO earlier this year, as well as a resource to improve communications between patients and their healthcare provider- '#MyHealthMyVoice'. |
| September 19 th 2024 | 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. |
| September 25 th 2024 | We attended a meeting of the Sodium Valproate Stakeholder group, which includes representatives from the HPRA, DoH, Epilepsy Ireland and OACS Ireland. |
| September 25 th 2024 | We attended the launch of the IPU White Paper: " <i>Key Enablers for a Sustainable Pharmacy Model.</i> " |
| September 26 th 2024 | We held the third meeting of the Pharmacy Workforce Working Group. |

Overview of External Communications (20 June 2024 – Present)

| Date Issued | Communication Type | Target Audience | Subject | Channel |
|--------------------------|---------------------------------|--|---|------------------------|
| Thursday, 20 June 2024 | Public Consultation | Pharmaceutical Assistants/ Registrants | CPD Themes for Pharmaceutical Assistants & Reminder on Expanding Pharmacists' Roles | Email, Website |
| Thursday, 27 June 2024 | Press Release | Trade Press, Health Correspondents | PSI Council Re-elected Ms. Katherine Morrow as President for a Second Term; Dr. Denis O'Driscoll Elected as Vice-President | Media Outlets, Website |
| Tuesday, 2 July 2024 | Press Release | National News Desks, Health, Broadcast, Regional | PSI Annual Report Published | Media Outlets, Website |
| Wednesday, 3 July 2024 | Corporate Strategy Consultation | Stakeholders | Corporate Strategy Consultation June 2024 | Email, Website |
| Wednesday, 3 July 2024 | Corporate Strategy Consultation | All Registrants | Corporate Strategy Consultation June 2024 | Email, Website |
| Thursday, 4 July 2024 | Public Consultation/Update | All Registrants | Naloxone Training Requirements and Public Consultation on CPD Themes | Email, Website |
| Monday, 15 July 2024 | Update/Reminder | All Registrants | Helping you prepare for prescription extension & Reminder: PSI Public Consultations | Email, Website |
| Monday, 22 July 2024 | Newsletter | All Registrants, General Audience | PSI Newsletter: Issue 2 - Summer 2024 | Email, Website |
| Tuesday, 6 August 2024 | Update/Guidance | All Registrants | Learn from Pharmacy Inspections New European Economic Area (EEA) Prescription Guidance | Email, Website |
| Thursday, 13 August 2024 | Press Release | Health Sector Stakeholders, Pharmacists, Media Outlets (Health and National) | PSI Welcomes the Minister for Health's Publication of the Final Report of the Expert Taskforce to Support the Expansion of the Role of Pharmacy | Media Outlets, Website |

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|------------------------------|-----------------|-------------------------|--|----------------|
| Thursday, 29 August 2024 | Reminder | All Registrants | Prescription Extension takes effect 1 September: reminder of changes and resources | Email, Website |
| Wednesday, 4 September 2024 | Survey | Pharmacists | State of the Register Survey | Email, Website |
| Friday, 20 September 2024 | Update | All Registrants | Updates for the Autumn/Winter Vaccination Campaign Practice Update: Administration of Injectable Medicines | Email, Website |
| Wednesday, 25 September 2024 | Survey Reminder | Supervising Pharmacists | Supervising Pharmacists: Share Your Insights in the State of the Register Survey | Email, Website |
| Wednesday, 25 September 2024 | Survey Reminder | Pharmacists | Pharmacists: Share Your Insights in the State of the Register Survey | Email, Website |



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

Key updates

Review of the CPD Model for Pharmacists

Work has continued on drafting proposed changes 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 (S.I. No. 494 of 2008)(as amended), to give effect to and support the introduction of the approved changes to the CPD model for pharmacists, and to support the development and implementation of a CPD model for pharmaceutical assistants.

During August, we shared the draft rules with a number of key stakeholders, with the rationale provided for each proposed change. The purpose of this exercise was to identify any substantive feedback that key stakeholders may have on the draft rules and to incorporate this feedback, where appropriate, in advance of a wider public consultation. We then held engagement meetings with these key stakeholders to collate their feedback on the draft rules with a view to preparing a final draft for consideration by the Regulatory and Professional Policy Committee.

The procurement specification for the next iteration of the Irish Institute of Pharmacy (IIOP) was published on eTenders on 12 August and was live until 10 September.

Future Pharmacy Workforce

The Future Pharmacy Workforce Working Group continues to meet quarterly and had its second meeting on 27 June 2024, and included new membership from an early-career pharmacist. The remaining meetings of 2024 will take place in September and December.

We remain focused on ensuring pharmacy can continue to meet the needs of the sector and wider health system in Ireland in both the short and longer term. A necessary next step involved undertaking workforce modelling to help inform future practice. During September, the PSI issued a state of the register survey to all pharmacists to assess the national picture of pharmacy through clear calculations and projections on the number of pharmacists required to meet current and future needs of the pharmacy sector and wider health system in Ireland. Information collected from the survey will foster understanding of current workforce dynamics and better enable modelling of what future pharmacy workforce needs will be.

Continuing Professional Development (CPD) Model for Pharmaceutical Assistants

We concluded our public consultation over the summer months on the proposed CPD themes to underpin the model of continuing professional development for Pharmaceutical Assistants.

Master of Pharmacy (MPharm) Degree

We have received an application for first-time accreditation of a new MPharm programme from a higher education institution (HEI). This is a first-time application, and the accreditation visit will take place in quarter four of this year.

As part of the accreditation process, we published an Expression of Interest (EOI) inviting applications from suitably qualified individuals to participate on this and future accreditation teams. Subsequently, a panel was established and will remain in place for a period of five years. Within that time, members of the panel will be invited to participate as accreditation team members for future accreditation visits.

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

As Council will be aware, the final recommendations of the [Expert Taskforce to support the expansion of the role of pharmacy](#) were published on 13 August. The purpose of the Taskforce, which first met on 29 August 2023 was 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. The final report involved considerable work by Taskforce members, supported by the Department of Health and contributions from colleagues within PSI.

The final report recommends that pharmacists should be enabled to prescribe for a range of common conditions, starting with an initial list of eight conditions which can be extended over time as the service evolves. The Taskforce also recommended the introduction of independent pharmacist prescribing in Ireland and that independent pharmacist prescriber roles be developed across the health service.

The Minister for Health has established the *Community Pharmacy Expansion Implementation Oversight Group* (IOG) to oversee the introduction of a common conditions service, including contraceptive prescribing by pharmacists to extend or continue a prescription for contraception. The Implementation Oversight Group will be chaired by the Department of Health.

The PSI will continue to support the implementation of policy decisions made on the back of the Expert Taskforce recommendations through membership of the IOG and also internally within PSI through the Expansion of Pharmacy Services Working Group, which continues to meet weekly. We will continue to update Council regularly on this progress.

Empowering Pharmacists to Extend Prescriptions (Phase 1 update)

Legislative changes that were introduced on 1 March this year permit pharmacists to extend prescriptions written on or after 1 March from six months up to a maximum of 12 months where appropriate. As a result of these changes, pharmacists have been enabled to extend certain prescriptions since 1 September, where it is safe and appropriate for the patient.

To support pharmacists with this change in their practice, PSI amended our *Guidelines on Counselling and Medicine Therapy Review* to support pharmacists with introducing this change into their practice through a principles-based framework. We also developed a number of frequently asked questions for pharmacists and the public.

In addition, we have been working with the IOP to develop additional resources for pharmacists to support them with this change. IOP has so far delivered a webinar for pharmacists on 28 August entitled '*Prescription Extension – What you need to know to get started*' as well as the first of three online workshops on the topic. They are also providing additional information for pharmacists through the IOP Resource hub.

Evolving a More Effective Regulatory Model for Community Pharmacies



Key updates

Stakeholder Engagement in patient safety and quality initiatives

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, and we await the Department's feedback and final approval. The Department of Health included a question concerning the provision of a delineated pharmacy model in their public consultation on the expansion of the role of pharmacists; this public consultation closed on 28 June. Feedback received in relation to a delineated pharmacy model was positive, and the majority of respondents were in favour of delineation.

PSI are now in the process of reviewing the required amendments to the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495/2008) that are required to facilitate a delineated model. A principles-based guidance document that will provide support for practitioners implementing this model is also being considered.

We issued our first 'Learning from Inspection' communication from the PSI Quality and Safety Team to registrants, providing an overview of inspection findings from January to June 2024. This initiative aims to uphold the delivery of safe and quality services to patients and the public from pharmacies by highlighting areas of concern identified by PSI Quality Assessors.

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 during March and April of 2024. The expected outcome of this exercise was that a pharmacy, acting in compliance with PSI guidance, would not sell a codeine medicine to the specialist surveyor. Of the 250 pharmacies surveyed, 100 (40%) did not sell a codeine medicine, and 150 pharmacies (60%) did sell a codeine medicine.

A report on the specialist surveyor exercise was presented to the Regulatory and Professional Policy Committee at their meeting on 12 September 2024. The report will be shared with PSI Council at its October meeting. Following this meeting, the report will be made available on the PSI website.

PSI Vaccination Guidance

The PSI Vaccination guidance documents have been updated for the 2024/2025 vaccination season. The revised guidance has been published on the PSI website and circulated to registrants to support pharmacists in providing a safe vaccination service. The revised guidance reflects recent legislative amendments, which will streamline record-keeping requirements for pharmacies and reduce the associated administrative burden. This includes removing the requirement to retain paper vaccination records, which now need to be retained for two years as opposed to eight years.

Guidance on Dispensing Prescriptions Issued in another EEA Member State

In August 2024, we published new principles-based guidance for dispensing EEA prescriptions issued in other EEA Member States. This guidance is designed to support pharmacists with dispensing EEA prescriptions, with a focus on prioritising patient-centred safety and care.

Falsified Medicines Directive update

FMD compliance in Ireland continues to show a positive upward trend.

To monitor and enhance FMD compliance, we have undertaken the following initiatives:

- Our Quality Assessors have conducted 162 Falsified Medicines Directive (FMD)-themed inspections in community pharmacies to evaluate FMD compliance. Additionally, FMD compliance is a component of routine pharmacy inspections and is highlighted during new opening inspections.
- We also engage directly with pharmacies and pharmacists where there are concerns about their FMD compliance.
- In August, we shared important [findings](#) from our FMD-themed inspection visits from January to June 2024, reflecting our commitment to transparency and supporting quality improvement in pharmacy.

Pharmacy Practice Update on Administration of Injectable Medicines by Pharmacists

Based on reports from stakeholders and our surveillance activity, it came to light that some pharmacies were offering medicines administration services for medicines supplied on foot of a prescription (i.e., medicines other than those included in the 8th and 12th schedules of Medicines Products Regs). This includes ad hoc services for patients who need support administering injectable medicines, for example, due to dexterity issues, as well as more developed services, such as the administration of travel vaccines that have been prescribed by a doctor. In response to this, an internal cross-functional working group was set up to consider the matter and the appropriate regulatory response.

Surveys were carried out to gather more information on some of the services that patients and the public are using in pharmacies. Legal advice and an expert educational opinion were also sought.

Having considered all the information gathered, we have published a Pharmacy Practice Update on the PSI website, which sets out the expectations of pharmacists and those in governance roles in the delivery of these services. An email was also issued to all registrants signposting to this update.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Business Transformation Programme (BTP Update)

Phase 2 of the Business Transformation Project was delivered and went live in August 2024. This phase introduced functionality for the public to submit Complaints, Concerns, and Queries. Together with the new PSI website, Phase 2 aims to improve the experience for members of the public interacting with the regulator by making the process of submitting Complaints more intuitive. This project was delivered on schedule, on budget, and per the quality criteria agreed upon with our technology partners. Work is ongoing to finalise our preparations for Phase 3 of the Business Transformation Programme whilst ensuring business benefits delivered in earlier phases continue to be availed of.

Strategic HR Update

We continue to focus on workforce planning and recruitment. We have recently completed recruitment for:

- Acting Head of Governance and Programme Delivery (Grade VIII, Fixed Term Contract)
- Head of Community Pharmacy Assurance (Principal Officer Grade, Permanent)

We are currently progressing with the recruitment of:

- People and Organisational Development Manager (Assistant Principal Officer, Permanent)
- Regulatory Executive (Executive Officer, Permanent)
- Acting Head of Practitioner Assurance (Chief I Pharmacist, Fixed Term Contract)
- Finance and Support Services Executive (Executive Officer, Permanent)
- Advanced Practice Manager (Assistant Principal Officer, Fixed Term Contract)

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

- Authorised Officer (Engineer II, Fixed Term Contract)
- Investigations Officer (Engineer II, Permanent)
- Advance Practice Co-Ordinator (Higher Executive Officer, Fixed Term Contract)
- Business Support Services Assistant (Clerical Officer, Permanent)
- Authorised Officer (Engineer III, Permanent)

Learning and Organisational Development

Training and Development Programmes

The following training has been completed.

- **Waste Reduction** – In line with the Climate Action Roadmap, VOICE Ireland provided training to all staff on waste reduction and recycling.
- **Team Building** – Following feedback from the employee engagement survey and recognising the large number of new employees to the organisation, team building activities were completed in July. This initiative was positively received by staff.

Learning and Organisational Development Initiatives

The following initiatives have been launched.

- **Wider Management Team (WMT) Training** – The WMT has been established as a separate entity to ELT. The WMT consists of people managers at AP/Grade VIII level and people managers not at that grade in teams where those grades do not exist. A 3-day training programme facilitated by the IPA has commenced to support the WMT team. The programme focuses on.
 - The role of the WMT within the context of PSI and the wider public sector change, performance and innovation agenda.
 - The impact of their leadership style on others and their approach to delivering results.
 - The behaviours and practices necessary to lead, develop and manage others effectively.
 - The dynamics of change and how best to lead and deliver change.
 - Enhanced individual resilience to follow through on expectations and commitments to manage high-performance teams.
 - Taking a proactive approach to development.
- **Academic and Professional Qualification Funding** – A third-level academic and professional qualification funding campaign was opened, and three applications were received and approved.

Employee Engagement

Employee Feedback and Surveys

We are continuing our focus on employee engagement. Following the results from the employee engagement survey, we held an Anchor Day in June for all staff to discuss some of the feedback further. The focus of the session was on communication, culture, employee engagement, performance management, learning and development and blended working/work-life balance. The findings from the session will be used to drive HR activity.

Employee Wellbeing

Employee Wellbeing Committee

Following the launch of the Wellbeing Strategy, the Workplace Wellbeing Committee has launched with nine members sourced from an internal expression of interest. The Committee is guided by the strategy and its four pillars. Currently, a September Step Challenge under the physical health pillar and social pillar is running amongst staff. The committee will be focusing on mental health for the month of October, with talks being organised by mental health ambassadors.

ICT Update

We have fully moved to SharePoint for our file management system. Moving to SharePoint offers numerous benefits for the PSI. It enhances collaboration and communication by providing a centralised platform where teams can work together on documents in real time. Improved document management features like version control, and secure access ensure that the latest information is always available and protected. SharePoint will also increase productivity through automated workflows and integration with Microsoft 365 tools, and it offers robust security features and compliance management to safeguard data and meet regulatory requirements. It will also reduce IT costs by scaling down the need for on-premises infrastructure and offering scalability.

Security Operations Centre

We have increased our cyber protection through our planned implementation of a 24-hour Managed Security Operations Centre (SOC) service. The benefit of the SOC is that when a security incident is detected, investigation and escalation are performed by security analysts and incident responders, who specialise in root cause analysis and provide on-the-spot recommendations for remediation using pre-described actions. The implementation has been completed for all our devices and servers, and the next phase will include our websites.

Climate Action Updates

The new Climate Action Roadmap, as approved by Council in June, was submitted to the Sustainable Energy Authority of Ireland (SEAI) and the Department of Health. An Environmental Impact Audit examining our work on climate action and sustainability was undertaken by our Internal Auditors. The draft report is under review by management and will be reported at the next Audit and Risk Committee meeting. Key actions under the road map include:

- Upgrade to the general lighting system in PSI House, including replacement of faulty LED lights.
- Brown and glass bins implemented in PSI house
- Staff workshop on sustainable practices and waste reduction held for all staff in August.

Finance Matters

The Travel & Subsistence Policy has been updated, reviewed and approved by ELT. A new internal guidance document and process map have also been developed. Training for Council members will be included as part of the October training day. Key updates include:

- Updated information about insurance requirements and staff who drive for work, recouping any additional costs incurred.
- Clarifications drawn from Revenue confirming an employee's 'normal place of work' is PSI House and how this impacts the calculation of allowable mileage and is particularly relevant to staff members who conduct fieldwork or regularly work remotely.
- Enhanced reporting requirements (ERR) for expenses, including travel and subsistence payments, introduced earlier in 2024 and the knock effects on processing time for claims and also on the requirement for existing public sector Council and Committee members undertaking work for PSI to claim expense directly from the employer. The best procedure on how to implement this requirement is ongoing.

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 | Submissions received from tenderers from the first stage of the procurement process. Evaluation ongoing with external procurement partners. |
| TCQR new route - adaptation period support | This procurement activity is no longer required, following the decision by Council at their June 2024 meeting to remove the mandatory adaptation period from the revised TCQR route. |
| TCQR new route - provider of new examination for revised TCQR route (plus additional wash out of current route to be scoped for equivalence exam) | <p>Following on-going discussions with our external procurement experts, tender documents are being progressed to establish a Dynamic Purchasing System (DPS) for the examinations under the new TCQR route.</p> <p>Until such time, in accordance with advice received, PSI awarded further services under the current FWA with UCC to provide for the remaining requirement of Third Country Recognition (TCQR) Equivalence Examinations under the existing route until applications closed or transferred to new route when it opens.</p> |
| Registration-related printing and fulfilment services (e.g. registration certificates) and other non-standard print needs. Scope has expanded due to revenue printing no longer available and also Design requirements | Tender evaluation ongoing with the assistance of OGP, and new contract expected to be in place October 2024. |
| Review of Target Operating Model and Organisation Structure | Publicised SRFT utilising existing OGP FWA with closing date 6 th Sept. Tender evaluation ongoing with assistance of OGP, and contract expected to be in place October 2024. |
| IIOP | Market engagement concluded at the end of June with the assistance of procurement advisors. Based on consolidated views received during the consultation process, tender documents were updated and finalised. Request for Tender published on e-tenders and TED on 14 August using an open procedure. Closing date for submission of tenders was 10th September 2024. Evaluation ongoing with assistance from external procurement partners. |
| Facilities management | Tender specification in development with the assistance of procurement advisors with aim to publish Oct 2024. |
| Digital skills training | Tender documentation developed and under review, expected to be circulated October 2024. |

Appendix 1 – Statistical Summary

Complaints and Fitness to Practise (as of 20 September 2024)

| Complaints for Screening Committee (Preliminary Proceedings Committee – PPC) | Total year-to-date | 2023 year-to-date equivalent |
|--|--------------------|------------------------------|
| New complaints received year-to-date | 50 | 48 |
| New complaints received since last report date | 18 | n/a |
| Open, active complaints* | 77 | n/a |
| Complaints considered by PPC since last report date ** | 8 | n/a |

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

**These complaints were heard over 2 meetings. None 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

| Inquiries | Total year-to-date | 2023 year-to-date equivalent |
|--|--------------------|------------------------------|
| Heard or commenced year-to-date * | 16 | 13 |
| Heard or commenced since the last report | 3 | 5 |
| Complaints being investigated/prepared for hearing | 46 | 42 |

*32% meet the KPI of the inquiry being heard within 18 months from the date of referral by the PPC to a Committee of Inquiry. 12 took place before the PCC & 4 took place before the HC

| Mediation | Total year to date | 2023 year-to-date equivalent |
|--|--------------------|------------------------------|
| Referrals to mediation since the last report | 0 | 1 |
| Referrals pending mediation | 0 | 1 |
| Held year-to-date | 0 | 0 |

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

| | Total year-to-date | 2023 year-to-date equivalent |
|---|--------------------|------------------------------|
| Heard since the last report* | 0 | 2 |
| Heard year to date* | 16 | 9 |
| Sanction hearings/undertakings being prepared for Council | 9 | 9 |

*per respondent

High Court Sanction Confirmation Hearings

| | Total year-to-date | 2023 year-to-date equivalent |
|--|--------------------|------------------------------|
| Heard year-to-date | 9 | 2 |
| Cases being prepared for High Court confirmation | 0 | 1 |

Appeals

| | Total year-to-date | 2023 year-to-date equivalent |
|--|--------------------|------------------------------|
| Heard year-to-date | 0 | 0 |
| Cases being prepared for High Court appeal | 0 | 0 |
| Judgment awaited | 1 | 1 |

Call-overs and Other Applications Before Committees of Inquiry

| | Total year-to-date | 2023 year to date equivalent |
|------------------------------------|--------------------|------------------------------|
| Callovers heard year to date: | | |
| (1) Professional Conduct Committee | 3 | 3 |
| (2) Health Committee | 3 | 3 |
| Held since last report date. | | |
| (1) Professional Conduct Committee | 2 | 2 |
| (2) Health Committee | 2 | 2 |

Interim Suspension Applications

| | Total year to date | 2023 year to date equivalent |
|--|---------------------------|-------------------------------------|
| Applications heard by Council year to date | 0 | 1 |

| Prosecutions | Total year to date | 2023 year to date equivalent |
|---|---------------------------|-------------------------------------|
| Cases being prepared for District Court Prosecution | 0 | 1 |

Professional Registration

| Route/Application Type - Qualification Recognition | Total year to date (13/09/2024) | 2023 year to date equivalent |
|--|--|---|
| Third Country Qualification Recognition (TCQR) – excluding UK | 135 | 114 |
| Route/Application Type - Registration | Total year to date (13/9/2024) | 2023 year to date equivalent |
| National Route | 8 | 10 |
| EU Route | 101 | 134 |
| Non-National Route (Third Country) – UK only | 48 | 64 |
| Non-National Route (Third Country) (excl. UK) | 32 | 17 |
| | | |
| European Professional Card – Establishment of Service (Qualification Recognition) | 6 | 6 |
| European Professional Card – Temporary & Occasional Provision of Service | 0 | 1 |
| | | |
| Voluntary Cancellations from Register | 78 | 57 |
| Involuntary Cancellations from Register | 28 | 17 |
| | | |
| Restorations to Register following Voluntary Cancellation | 12 | 10 |
| Restorations to Register following Involuntary Cancellation | 4 | 4 |
| | | |
| Certificates of Current Professional Status issued | 69 | 45 |
| | | |
| IMI Alerts (Internal Market Information) issued by PSI | 5 | 3 |

Retail Pharmacy Businesses

| Registration of Retail Pharmacy Businesses | | Total year to date (23/9/2024) | 2023 year to date equivalent |
|---|--|-----------------------------------|---------------------------------|
| Number of Registered Retail Pharmacy Businesses | | 1984 | 1981 |
| Retail Pharmacy Business Openings by Type | New Opening | 11 | 23 |
| | Permanent Relocation | 7 | 1 |
| | Change of Ownership | 44 | 65 |
| Retail Pharmacy Business Cancellations by Type | Voluntary Cancellation – Closure | 12 | 22 |
| | Voluntary Cancellation – Permanent Relocation | 7 | 1 |
| | Voluntary Cancellation – Change of Ownership | 44 | 65 |
| | Involuntary Cancellation | 0 | 1 |
| | Supervising pharmacist changes: | 283 | 392 |
| | Superintendent Pharmacist changes: | 77 | 67 |

| Internet Supply | Total year to date (23/9/2024) | 2023 year-to-date equivalent |
|------------------------------------|-----------------------------------|---------------------------------|
| Number of Pharmacies on Part A | 135 | 145 |
| Number of Non-Pharmacies on Part B | 181 | 166 |

Regulation of Retail Pharmacy Businesses

| Pharmacy Inspections | Total year to date (as of 20 September 2024) | PSI 2024 Service Plan Pharmacy Inspection Key Performance Indicator (KPI) | 2023 year to date equivalent |
|---|--|---|------------------------------|
| Total number of on-site Pharmacy inspection visits to date*. | 257 | 200 | 127 |
| Total number of registration-related inspections to date. | 14 | 25 | 13 virtual & 10 onsite |
| Number of pharmacy re-inspections – including re-inspections following Registrar’s decision under Section 71(1)(d) to date. | 1 | 0 | 3 |

*This figure does not include onsite registration-related inspections.

Concerns

| | Total year to date | 2023 year to date equivalent |
|--|--------------------|------------------------------|
| New concerns received | 66 | 33 |
| New concerns received since last report date | 33 | 11 |
| Concerns reviewed since the last report date | 26 | 12 |
| Open concerns | 7 | 6 |

Investigation Activity (Inspection & Enforcement) year – to - date

| No. of investigations open | No. of investigations initiated since the last Council meeting | No. of investigations closed since the last Council meeting |
|--|--|---|
| 18 | 2 | 1 |
| Investigation Activity 2024 (Section 67) – e.g., <i>Interviews / Statements / Pharmacy Visits / Professional Witness</i> | | 16 |

Investigation Activity (Inspection & Enforcement) 2023 year-to-date equivalent

| No. of investigations open | No. of investigations initiated since the last Council meeting | No. of investigations closed since the last Council meeting |
|--|--|---|
| 16 | 3 | 4 |
| Investigation Activity 2023 (Section 67) – e.g., <i>Interviews / Statements / Pharmacy Visits / Professional Witness</i> | | 10 |

Information Governance

Freedom of Information and Data Protection year to date

| No. of FOI requests received year to date | Granted/Part Granted | Handled outside of FOI | Refused | Currently being processed |
|---|----------------------|------------------------|---------|---------------------------|
| 19 | 7 | 9* | 2 | 1 |

*reasons including: records publicly available/PSI did not hold records/foi did not progress/3rd party consultation

Data Protection

| No. of Subject Access Requests received year to date | Granted | | Refused |
|--|--|---|--|
| 5 | 5 | | 0 |
| No. of Data Breaches year to date | Reported to the Data Protection Commissioner (DPC) | | Not meeting the threshold for reporting to DPC |
| 1 | 1 | | |
| Data Transfer Requests year to date | Category: Research Purposes | Category: Patient Safety Alert/Product Recall | Category: IIOB |
| 20 | 10 | 1 | 9 |