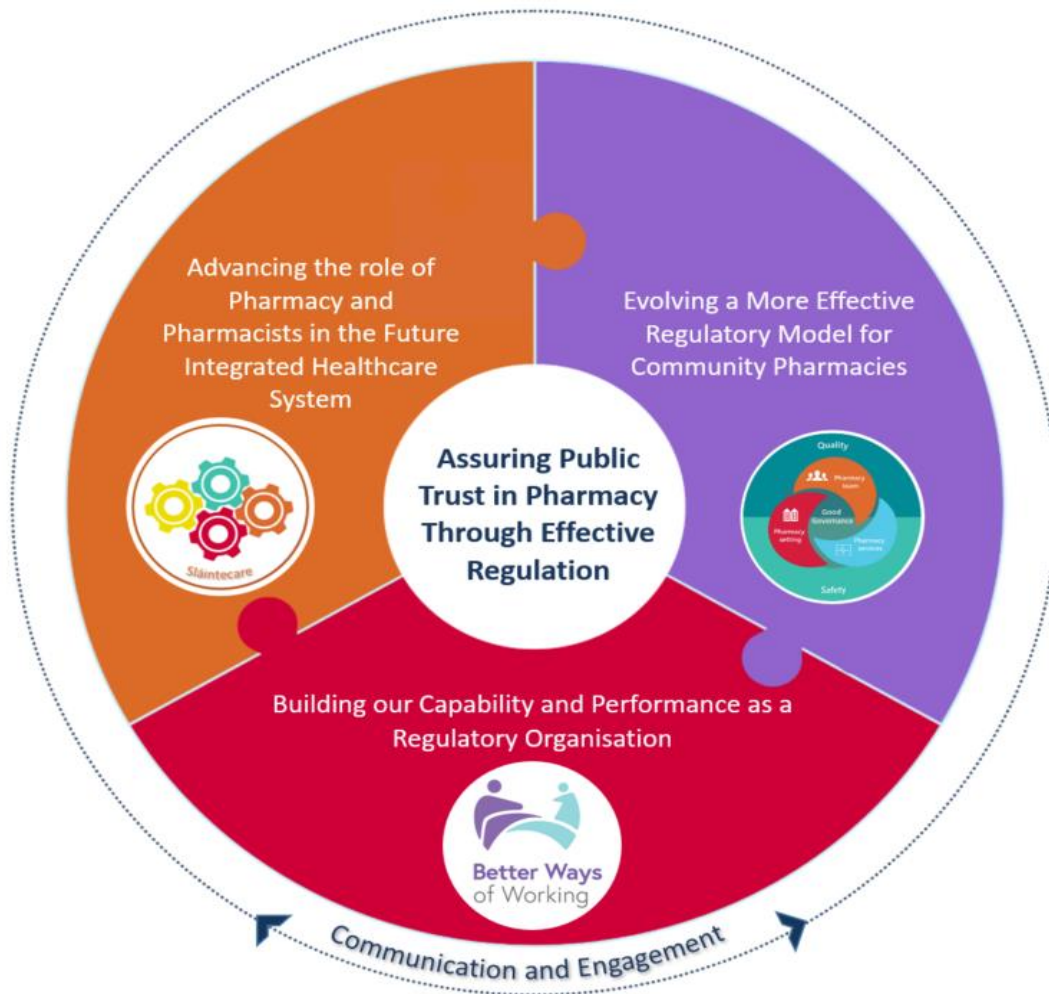




The Pharmacy Regulator
An Rialtóir Cógaisíochta

Report of the Registrar



Report to Council Meeting of 7 October 2021

Highlights from the Registrar

Governance Meeting with Department of Health

A periodic governance meeting with the Department of Health was held on 29 September (one of three scheduled each year). We are in the process of agreeing the annual Performance Delivery Agreement with the Department, as required under the Code of Governance for State Bodies – this was delayed this year due to the pandemic. Once agreed, this will be uploaded to Council iPads.

As part of the meeting, the Department raised the issue of compliance by pharmacies with the requirements of the Falsified Medicines Directive (see further on page 5 of this Report). This matter will be further discussed with the Department on 13 October.

Planning for Service Plan 2022

At the Council Development Day on 21 October, I will present the proposed Service Plan priorities for 2022 for discussion with Council. As 2022 is the second year of the current 3-year corporate planning cycle, it is an important year in PSI making real progress on the Council's strategic priorities.

Practice reviews

Having been suspended during 2020/2021 due to the impact of the pandemic, the Royal College of Surgeons has confirmed that it will be in a position to safely facilitate practice reviews (as a component of PSI's system of continuing professional development for pharmacists) as from April 2022. We are proceeding to put in place the necessary arrangements for this, including the giving of timely notification to patient-facing pharmacists who will be selected to participate in practice review.



Update on managing our response to COVID-19

COVID-19 vaccination programme

The level of COVID-19 vaccinations in pharmacies has slowed in recent weeks as the vaccination programme moves through the population of people seeking vaccination via community pharmacies. A total of **286,860** vaccines have been administered to date via pharmacies. The below table gives the breakdown of the age profile of the people attending pharmacies for vaccines. The PSI continue to meet

| Age-Range | Vaccines administered |
|-----------|-----------------------|
| a. < 12 | 65 |
| b. 12-15 | 29842 |
| c. 16-19 | 42835 |
| d. 20-29 | 128696 |
| e. 30-39 | 57967 |
| f. 40-49 | 10271 |
| g. 50-59 | 11420 |
| h. 60-69 | 7193 |
| i. 70-79 | 1005 |
| j. 80-89 | 208 |
| k. 90+ | 70 |

PSI continues to participate in the weekly meetings of the HSE’s vaccination programme subgroup, which has been meeting since January this year) to coordinate the safe roll-out of the vaccination service in community pharmacies.

COVID-19 internal PSI response group

The PSI COVID-19 internal response group, which had been meeting since the onset of the pandemic, will no longer continue to meet and PSI will manage COVID-19 related matters as business as usual via the executive leadership team.



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

Key updates

Core Competency Framework (CCF)

The Steering Group, established to oversee and assist in the review and development of a revised CCF, has met five times to date. Following on from the Expression of Interest process to establish a Working Group to support the delivery of the project, the PSI has hosted three workshops to date. The purpose of the workshops was to gather feedback from Working Group members on the current CCF. The topics considered at each workshop included: a needs analysis; a gap analysis; and feedback on specific competencies and domains included in the CCF. The workshops were well attended with between 15-18 Working Group members attending each workshop, representing all sectors, including community, hospital, industry and role emerging practice.

Review of the CPD Model for Pharmacists

The PSI invited stakeholder organisations to participate in semi-structured interviews and complete a SWOT survey on the current CPD model. Two representative bodies, the Irish Pharmacy Union (IPU) and Pharmacists in Industry, Education and Regulation (PIER) accepted the opportunity to provide feedback. This feedback, along with the feedback received from the survey conducted with registered pharmacists in April 2021, was reviewed and will inform a draft scope for the review which will be considered by Council at its meeting on 16 December 2021.

Department of Health-funded training for community pharmacists

The PSI met with the Department of Health on 30 September to discuss potential training for community pharmacists to be provided via the Irish Institute of Pharmacy, funded through the €600,000 of exchequer funding which is provided by the Department to PSI each year for this purpose.



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

Published Overview Report on COVID-19 Operational Standards for Pharmacies:

The PSI published its first overview report on 21 July 2021 on the implementation of the COVID-19 Operational Standards for Pharmacies, which were introduced in mid-2020. The report highlights a range of good practices found in pharmacies as well as noting some areas requiring improvement.

We continue to conduct exploratory COVID-19 Operational Standards visits through an extended “use and learn” process which will conclude at the end of 2021.



Falsified Medicines Directive:

The Head of Regulation attended a number of meetings of the National Safety Features Oversight Group comprising the Irish Medicines Verification Organisation (IMVO), the Department of Health, the Health Products Regulatory Authority (HPRA), the Pharmaceutical Society of Ireland (PSI), the Health Service Executive (HSE) and the Private Hospitals Association (PHA).

The Safety Features Oversight Group, following consultation with all relevant stakeholders, has now agreed a plan for ending use and learn on a phased basis concluding at the end of Q1 2022.

As part of encouraging registrants with FMD compliance during the use and learn period, the PSI has contacted 100 Retail Pharmacy Businesses (RPB) regarding FMD scanning activity during a two-week period in August 2021.

UK and Ireland Controlled Drugs National Group

The UK Care Quality Commission invited the PSI to attend joint UK and Irish national meetings to discuss concerns relating to the issue of controlled drugs across health and social care sectors. The PSI shared

the results from a study from UCC which had been published in the European Journal of Public Health in May 2021 on how the Irish Pharmacy Regulator impacted on intentional drug overdoses after implementing Guidance for Pharmacists for safe supply to patients of non-prescription medicinal products containing Codeine in 2010.

National Standards Authority of Ireland

The Head of Regulation met with the National Standards Authority of Ireland (NSAI) to create a line of communication between NSAI Legal metrology and PSI. The meeting discussed legal metrology, the NSAI regulatory role in non-automatic weighing instruments (NAWI) used in pharmacies, EU initiatives and planned legal metrology inspections.

Supervising/Superintendent Pharmacist regulation

We are receiving reports from pharmacy owners and superintendent pharmacists having difficulty in sourcing supervising pharmacists, which is resulting in longer lead times in appointing supervising pharmacists. The situation is being monitored by PSI. We continue to review all applications of Supervising and Superintendent Pharmacists Requirement under sections 27(c), 28(b) and 29(c) which state that at the premises where a retail pharmacy business is carried on, there must be “a registered pharmacist who has a 3 year minimum post-registration experience in whole time charge of the carrying on of the business there” and for a Superintendent Pharmacist under sections 27(b), 28(a) and 29(b) which state that in the carrying on of a retail pharmacy business “the part of the business that consists of the management and administration of the sale and supply of medicinal products is under the personal control of a registered pharmacist who has a 3 year minimum post registration experience”. We perform regular audits of compliance to ensure that pharmacies are complying with this legislation.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Business Transformation Programme:

Phase 1 of the BTP (the new online system for registration) launched on 27 September. This is a significant milestone for PSI on our digital transformation journey, with a new public register, registration portal and backend system now live. The new system moves many of our processes online for the first time, providing an enhanced experience for the public, registrants and applicants. It also streamlines our internal processes for registration and will provide better quality data which will be a key enabler on our journey to become a more risk-based regulator. PSI colleagues are being supported by our technology partner Codec during a 'Hypercare' period to manage the transition to the new system – this runs until 14 October. For registrants and applicants, a range of videos and guides have been created, and a helpline is in place to deal with any queries. The registration section of the website has also been reviewed and updated in line with the new registration portal. Meanwhile, planning is commencing for the next phase of the BTP.

Strategic HR Update:

- **Business continuity and blended working:** Planning has started for a phased introduction of blended working arrangements at PSI. From end October until end January 2022, we will endeavour to have up to 2 days per week to be worked at PSI House, with at least one of the days per week dedicated to team-based meetings and other collaborative work. Further clarity for period beyond that date will follow once the Government's Blended Working Framework has been released.
- **Workforce planning and recruitment:** Two *Quality Assessors – Pharmacy Services* were appointed in August 2021 following an open recruitment competition - one permanent, one fixed-term maternity cover. The following recruitment competitions are in train:
 - *Regulatory Executive*
 - *Quality and Safety Manager*
 - *Customer and Registrant Relations Lead*Sanction from the Department has been received for the backfill of the two-year secondment to the Department of the *Head of Practitioner Assurance (Acting)* and the two-year career break backfill for the *Professional Standards Manager (Acting)*.

Organisation Development Project (ODP) Update:

The Organisation Development Project has completed Phase 1, 'Mobilisation', Phase 2, 'Current State Analysis', Phase 3 'Future Organisation Structure' and Phase 4 'Develop Change Management Plan'. The New Operating Model was approved by the Steering Group and subsequently went live 5 July 2021, and the final Phase 5 'Implementation' continues until October 2022.

The Implementation Plan comprises three workstreams: 1) Governance and Communications, 2) Change the Way we Work and 3) Develop our People.

Under workstream 1) the Steering Group is monitoring progress through Benefits Realisation Management and the Risk Register. These, and the Internal Communications Plan, are reviewed monthly. Under workstream 2), role profiles for all staff are reviewed and agreed and the clarity on roles and responsibilities across the organisation and within teams is furthermore supported by the elaboration of RASCI's. The initial focus in this workstream is on establishing the Programme Delivery Function and implement the new matrix-structured functions. Under workstream 3), the work related to the organisation wide Skills and Competencies Assessment Analysis and Development Plan (training plan) continues. A proposal for Planning of Learning and Development interventions and delivery timeframes will be presented to the Steering Group this autumn. The work on an Internal Communication Strategy and approach has commenced and the plan for sanctions and recruitments is under implementation. Also, the Coaching Programme for the PSI Executive Leadership Team is continuing, and training for all managers on People Management in a hybrid working environment is currently underway.

The external consultants from BearingPoint have a more advisory role in Phase 5, and the Executive Leadership Team is in charge of the implementation process. A Stage Gate is planned for early October, where the initiatives to date will be reviewed and a more detailed plan for Q4 of 2021 will be agreed.

Communication and engagement

Procurement has been advanced on both the tender for website redevelopment and for PR consultancy services. Both of these processes will conclude in the next number of weeks.

There has been significant communications support as part of the Registration Portal go-live with the creation of user resources including videos to support registrant use of the portal, website material, emails and social media content

Communications planning and research activities are underway to underpin the Corporate and Communications Strategy objectives for the remainder of the year, and into next year in support of service planning activities.

Social Media: We continue to promote the work of PSI and share relevant public health and safety content via digital communications, through Twitter and LinkedIn. In September we shared content on World Patient Safety Day on 17th September and, World Pharmacists’ Day on 25th September. We have 1,625 followers on Twitter and 2,136 followers on LinkedIn

Disciplinary Committee - Appointments and Training Update

Following an Expression of Interest held earlier in the year, 5 new pharmacist pharmacy owners were appointed to the Professional Conduct (4) and Health (1) Committees respectively, and a further 8 new members were appointed to the Professional Conduct Committee from a Reserve Panel which was established following an Expression of Interest held in 2019. A further appointment (1) was also made from the Council of the PSI to the Professional Conduct Committee. The 14 appointments in total therefore, were either in response to vacancies created following the end of the terms of serving Committee members, or to ensure that the composition of the Committees remained in compliance with the provisions of section 34 of the Pharmacy Act 2007, as amended. Induction Training regarding fitness to practise and professional discipline regulation in the context of the PSI and the Pharmacy Act 2007 was also held for new Committee members (see below).

In accordance with the PSI’s ongoing commitment to support the Disciplinary Committees in the execution of its statutory responsibilities, four training sessions for Disciplinary Committees (including new members Induction Training) have taken place since the last Council Meeting, as follows:

| | |
|-------------------------------------|------------------------------|
| Preliminary Proceedings Committee | 8 September 2021 (half day) |
| Induction for new Committee Members | 10 September 2021 (full day) |
| Professional Conduct Committee | 14 September (half day) |
| Health Committee | 15 September (half day) |

All sessions were delivered by La Touche training with input from the Legal Affairs Unit and in the case of the PPC, PCC and Health Committee training, these involved refresher training and updates on fitness to practise and professional discipline proceedings, fair procedures and recent legislation and case-law.

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

| Services / Goods to be Procured | Current Status |
|---|---|
| Website Re-Design Development, Hosting and Support Services | This competition is at the final stages of evaluation. |
| Merchant Acquiring Services and Payment Gateway Services | OGP Single Supplier Frameworks (Direct Drawdown) being progressed. |
| Legal Services | New OGP Framework drawdown to be activated with tender documentation being finalised with OGP for imminent publication to the framework |
| Stenography and transcription services | Services to be accessed through OGP framework. The Notification to Activate Services Form (NASF) is close to being finalised with new service provider. |
| Public Affairs and Communication Advisors | OGP Framework drawdown: competition at final stage of evaluation |
| External Auditors | OGP Framework drawdown: the tender documentation has been submitted to OGP for publication by end September |

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at Sept 23 2021)

For the purposes of this appendix, please note that references to 'last report date' refers to the Registrar's Report dated 14 June 2021.

Fitness to Practise (FTP) Concerns

| | |
|--|-----|
| Total new concerns received year to date | 102 |
| New concerns received since last report date | 26 |
| Concerns reviewed since last report date | 33 |
| Open concerns with FTP | 7 |

Fitness to Practise Complaints for Screening Committee (PPC)

| | |
|--|------|
| Total new complaints received year to date | 59 |
| New complaints received since last report date | 24 |
| Total open active PPC complaints | 46* |
| Complaints considered by PPC remotely since last report date | 19** |

* This figure may include complaints received prior to 2021 which are still being processed. It excludes complaints recently closed.

**85% of which met the KPI of the PPC decision being made within six months from the date of receipt of complaint to the date of the final PPC decision.

Inquiries

| | |
|--|----|
| Heard remotely year to date | 6* |
| Heard remotely since last report | 1 |
| Complaints being investigated/prepared for hearing | 44 |

*4 inquiries took place before the Professional Conduct Committee and 2 inquiries took place before the Health Committee of which one stands adjourned and is expected to resume in Q3. The 6 inquiries took place over 10 days.

Mediation

| | |
|---|---|
| Total complaints referred to mediation year to date | 4 |
| Mediations held year to date | 2 |

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

| | |
|---|---|
| Heard year to date | 8 |
| Sanction hearings/undertakings being prepared for Council | 1 |

* This is reported on a per respondent basis. One of the eight matters stands adjourned and has not yet been completed.

High Court Sanction Confirmation Hearings*

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

Appeals against Council Sanction and/or Fitness to Practise Committee Findings

| | |
|--------------------|---|
| Cases under appeal | 1 |
|--------------------|---|

Scheduled Call-Overs Before Committees of Inquiry

| | |
|------------------------------------|-------|
| Callovers heard year to date: | |
| (a) Professional Conduct Committee | (a) 2 |
| (b) Health Committee | (b) 2 |
| Held since last report date | (a) 1 |
| (a) Professional Conduct Committee | (b) 1 |
| (b) Health Committee | |

The next callover is scheduled for 30 September 2021.

Interim Suspension Applications

| | |
|--|---|
| Applications heard by Council year to date | 1 |
|--|---|

Prosecution

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

Professional Registration (figures as of 24 September 2021)

- 1 alert has been issued to date this year under the Internal Market Information system to other EU Competent Authorities responsible for the implementation of the provisions of the Professional Qualifications Directive as it pertains to pharmacists.
- 2 EPC applications for the temporary & occasional provision of service have been received to date in 2021, one of which is in progress while the 2nd one was not a valid application.
- 6 EPCs for establishment of service have been received to date in 2021 (new European route of entry to recognition and registration). 2 completed, 2 in progress, 1 withdrawn and 1 refused.
- 1 EPC application has to date been received and approved for establishment of service in host country (Malta).
- 38 Certificates of Current Professional Status have been issued since 1st January 2021.
- 11 Pharmacist Restoration applications in accordance with S.61 have been processed since 1st January 2021.
- 99 Voluntary Cancellation applications and 52 Involuntary Cancellations have been processed since 1st January 2021.
- Since March 2020 all EU/TCQR Registration meetings have been cancelled in light of Covid-19 outbreak.

- 34 Third Country Qualification Recognition (TCQR other than UK qualified) applications received to date this year, with 128 applications in total in process.
- 45 TCQR (both UK qualified and outside of UK) registration applications processed to date this year.
- 28 EU recognition/registration applications processed to date this year.
- 8 National route applications processed to date this year.

Pharmacists

No. of New Registration, and Restoration Applications, Including Section-77 Restorations, in the context of the COVID-19 pandemic - 9 March 2020 to 23 September 2021.

| No. of new registration applications received which are recorded on applications record db. | Registered | In-process -EU/TCQR (UK qualified) |
|---|------------|------------------------------------|
| - | 372 | 10 |

| No. of New Restoration Applications Received in Accordance with S.61 | Restored | In-process |
|--|----------|------------|
| - | 31 | 3 |

| No of S.77 Registrations Applications Received | Registered | In-process |
|--|------------|------------|
| | 37 | 0 |

Regulation of Retail Pharmacy Businesses (figures as of 21 September 2021)

| Registration of Retail Pharmacy Businesses | |
|---|---|
| Number of Registered Retail Pharmacy Businesses @ 21 September 2021 | 1974 |
| Number of Retail Pharmacy Businesses Registered in 2021 @ 21 September 2021 | New Openings (14); Permanent Relocations (6); Changes of Ownership (65) Total = 85 |
| Number of Retail Pharmacy Businesses Cancelled in 2021 @21 September 2021 | Voluntary Cancellations – Closure (7); |

| | |
|---|---|
| | Permanent Relocations (6); Changes of Ownership (65) Total = 78 |
| Number of Changes in Supervising and Superintendent Pharmacists in 2021 | 367 |

| | |
|------------------------------------|-----|
| Internet Supply | |
| Number of Pharmacies on Part A | 192 |
| Number of Non-Pharmacies on Part B | 157 |

| | |
|--|----|
| Visits to assess against COVID-19 Standards (YTD) | |
| Total Pharmacy Visits | 27 |
| Onsite visits | 1 |
| Virtual visits | 26 |

| | |
|---|----|
| Inspection Activity 2021 | |
| Total number of Inspections | 13 |
| Number of Registration-related Inspections | 2 |
| Number of pharmacy inspections | 9 |
| - Risk-based Inspections | 3 |
| - Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d) | 1 |

| | | |
|--|--|---|
| Investigation Activity (Part 7 / 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 | 2 |
| Investigation Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i> | | 4 |