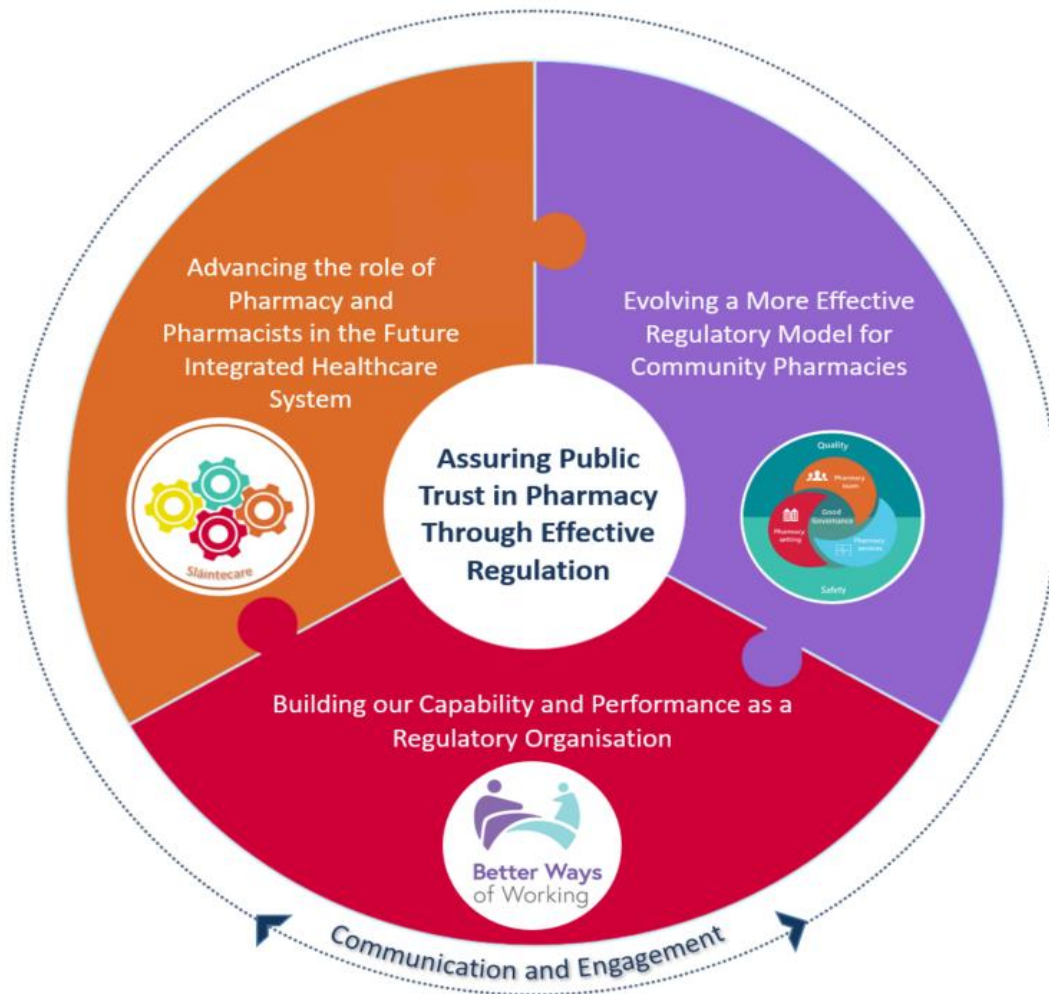




The Pharmacy Regulator
An Rialtóir Cógaisíochta

Report of the Interim Registrar



Report to Council Meeting of 6 October 2022

Highlights and general engagement updates from the Interim Registrar

COVID-19 and Influenza vaccination services in pharmacies

- **Review and approval of HSE NIO training module for new adapted vaccine**

PSI has assessed and approved the HSE's National Immunisation Office (NIO) training module on new mRNA COVID-19 vaccine formulations namely, Comirnaty® Ready to Use 30mcg and adapted COVID-19 booster vaccines Comirnaty® RTU (ready to use) Original/Omicron BA.1 and Comirnaty® RTU (ready to use) Original/Omicron BA. 4-5 and Spikevax® Original/Omicron BA.1.

The training has been approved for the purposes of Regulation 4F(b) of the Medicinal Products (Prescription and Control of Supply) Regulations (S.I. No. 698 of 2020) for the purposes of facilitating pharmacist vaccinators in supplying and administering these vaccines, as part of the COVID-19 national vaccination implementation plan.

The approval process involved the convening of an Assessment Panel with competencies in the following areas: academic expertise in pharmacy; expertise in COVID-19 vaccination matters; current experience of vaccine administration by pharmacists; quality assurance/assessment and/or accreditation/certification expertise; and Health Service Executive and/or NIAC representative.

The Assessment Panel reviewed the training module and provided their feedback both in writing and at an assessment panel meeting. The Executive drafted a report, approved by the assessment panel, setting out the Assessment Team's approval of the training and recommendations by way of feedback. The training was subsequently approved by the PSI's Interim Registrar based on the recommendation of the assessment panel.

The Executive would like to sincerely thank the following members of the Assessment Panel who assisted with the review at short notice and against very tight deadlines: Sarah Chambers, Dr Denis O'Driscoll, Margaret Donnelly and Maria Donovan.

- **Review of annual vaccination guidance**

The PSI has reviewed and amended its annual influenza vaccination guidance to support pharmacists in preparation for the 2022/2023 influenza season. These have been reviewed in line with national guidance emanating from the National Immunisation Advisory Committee and the HSE. The PSI website has also been updated to reflect these revisions and updates.

- **Pharmavax**

The HSE Pharmavax Portal, which is a secure, online portal developed by the HSE, will be used this season to record Influenza vaccines and Pneumococcal vaccines. We wrote to all registrants on 29 September setting out what pharmacists must do in order to satisfy record-keeping legislative requirements for the supply and administration of Influenza and Pneumococcal vaccines.

Increase in volume of applications for qualification recognition and registration

We are seeing an increase in applications for qualification recognition and registration across all of our non-national routes. Our Third Country Qualification Recognition (TCQR) route has received 87 applications to date in 2022, whilst the average number for the preceding three years was 42 in each year. Applications received from EU and UK applicants also appear to be on a trajectory towards returning to pre-pandemic levels, particularly from applicants holding an EU qualification. To date in 2022, we have registered 57 applicants under the EU route and another 57 applicants with a UK qualification (34 and 56 respectively in 2021, 54 and 100 respectively in 2020, 46 and 160 respectively in 2019).

Communication and Engagement Updates

Overview of recent external meetings and engagements attended by Interim Registrar and PSI staff	
June – October (weekly/bi-weekly)	National COVID-19 Vaccination Programme – Pharmacy Workstream Working Group: this group meets to discuss ongoing roll-out of the COVID-19 vaccination programme in community pharmacy. It is chaired by the HSE and also includes representatives from across the HSE, from the IPU and the Department of Health as well as the PSI.
14 July 2022	IOP Quarterly Operational Meeting
14 July 2022	We attended a meeting with Lloyds Pharmacy Group regarding current workforce issues
20 July 2022	Bi-Annual IOP Strategy Meeting
28 July 2022	We attended a Strategic Workforce Plan meeting with other Health and Social Care Regulators during which all regulators discussed workforce issues within their relevant sectors and agreed to meet again with a view to providing a report which could be shared with relevant government departments.
29 July 2022	Meeting with Crowe consultants on behalf of the National Patient Safety Office (NPSO) as a stakeholder as part of the Department of Health commissioned research on patient safety incidents
29 July 2022	Meeting with the National Cancer Control Programme (NCCP)
31 August 2022	Meeting with HSE-PCRS to discuss upcoming vaccination season
01 September 2022	Meeting with DOH regarding pharmacist workforce matters
08 September 2022	Department of Agriculture, Food and the Marine met with the Department of Health and the PSI on the European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022
14 September 2022	We attended a demonstration of the Pharmavax system by the Health Service Executive. The purpose of the demo was to assist PSI in its consideration of the system's ability to record influenza vaccinations and its compatibility with the legislative requirements.
21 September 2022	Medical Council stakeholder group meeting on strategies to address overprescribing of controlled drugs (this stakeholder group includes

	representatives from the Medical Council, HSE, HPRA, Department of Health, the PSI and ICGP)
28 September 2022	DOH-PSI Governance meeting (3/3 meetings held in 2022)
30 September 2022	President of College of Anaesthesiologists presented to the PSI President and Executive on the proposed National Learning Analytics Unit

In June and July we issued a number of communications to registrants in relation to an important update that the National Immunisation Advisory Committee (NIAC) made to the Anaphylaxis chapter for the Immunisation Guidelines for Ireland. The update stated that adrenaline (epinephrine) auto-injectors are not recommended as first line treatment by health professionals for the immediate management of anaphylaxis or suspected anaphylaxis following vaccination unless they are the only source of adrenaline available, as they may not allow intramuscular delivery of an age-appropriate dose.

We attended the Building One Health Action under Ireland's Second One Health National Action Plan on Antimicrobial Resistance (iNAP2) conference on 23 June. The event brought together stakeholders from across the One Health sectors – human health, animal, plant health and the environment to acknowledge the work done under Ireland's first National Action Plan on Antimicrobial Resistance, and to recognise the publication of iNAP2 (2021 – 2025).

In July, we met with consultants from Crowe who have been commissioned by the National Patient Safety Office in the Department of Health to undertake research for the Independent Patient Safety Council in relation to the culture and principles underpinning the management of patient safety incidents. The purpose of the meeting was to discuss the key issues from the PSI's perspective in relation to this.

In July, we also met with the National Cancer Control Programme (NCCP) to discuss areas of mutual interest including Non-Medical Prescribing (NMP) and aseptic compounding.

Public consultation submissions:

- **HIQA Consultation on draft recommendations on a model for health information standards to support the delivery of health and social care services in Ireland**

In July, we developed a submission to HIQA's consultation on draft recommendations on a model for health information standards to support the delivery of health and social care services in Ireland. The recommendations support the need to strengthen how health information standards are developed, implemented and adopted across the health and social care system in Ireland.



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

Key updates

Assess Emerging Risks to the Continued Availability of the Pharmacist Workforce project

The procurement process to appoint external experts to assist PSI in this project is almost concluded. Key deliverables for the external appointed experts will be to:

1. Provide an overview of current landscape, to include a literature review on workforce planning and challenges, and international best practice/strategies for management.
2. Support the design of a workforce survey to establish a baseline picture of the current workforce, carry out analysis of survey results, and report on the outputs of the analysis
3. Support facilitation of meetings of the Working Group being established comprising external stakeholders
4. Produce a cohesive report on future pharmacy workforce considerations for Ireland, containing outputs from deliverables 1-3 above

We have written to relevant stakeholders requesting nominees to sit on a working group as part of this project. A series of one-to-one early engagement meetings with those individuals nominated, along with other stakeholders, has commenced and these engagement meetings will continue over the coming weeks. The output of these meetings will be presented to the working group. An expression of interest is in development for publication to request participation in focus group sessions with members of the profession who work in different pharmacy settings.

Core Competency Framework

Work is continuing following the public consultation of the revised Core Competency Framework. A review of the themes emerging from the responses received is underway. Meetings with relevant stakeholders regarding the implementation of a revised CCF have commenced and are ongoing.

Ukraine Emergency Response Group

The PSI Ukraine Emergency Response Group with members from across PSI business areas, continued to meet weekly/fortnightly throughout the summer months to coordinate and address matters arising from the conflict in Ukraine.

This included:

- PSI continued engagement with the Department of Health, national healthcare and non-healthcare professional regulatory bodies, IPU and other key stakeholders in relation to providing a coordinated regulatory response.
- Managing the overall PSI response to queries from potential registrants, existing registrants and others, in order to provide effective support and advice on registration to Ukrainian qualified pharmacists who wish to register in Ireland.
- Providing a weekly update to the Department of Health, regarding any important matters relating to refugees from Ukraine, including statistics around qualification recognition.
- Continuing to engage with colleagues in the HSE-PCRS to keep apprised of any relevant issues arising for people arriving from Ukraine, in particular, in accessing medicines and health advice from pharmacists and pharmacy teams in Ireland.

As most matters relating to the ongoing war in Ukraine are at this stage related to qualification recognition, the group decided at its meeting of 22 August to postpone further group meetings and for matters to be managed at team level within the organisation. Should the need arise, the group will be re-convened.



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

Falsified Medicines Directive (FMD)

The National Safety Features Oversight Group met on 23 September 2022 to evaluate FMD progress within Ireland since 'use-and-learn' ended on 30 May 2022. Ireland's overall compliance rate has ranged between 60-65% since ending of use and learn. Overall, Ireland is continuing in an upwards trajectory regarding compliance.

The PSI continues to monitor FMD compliance with retail pharmacy businesses (RPBs) and continues to engage, explain and encourage compliance. The Department of Health continues to consult with the PSI about improving FMD compliance in pharmacies under S.I. No. 270 of 2022 of Medicinal Products (Safety Features on Packaging) Regulations 2022.

Review of COVID-19 legislation

The PSI met with national stakeholders to discuss the revocation of the COVID-19 emergency provisions as set out in S.I. 98 and S.I. 99 of 2020. Following a Department of Health request, the PSI has submitted a joint statement that was prepared in conjunction with, and agreed with, the Medical Council in relation to the revocation of the COVID-19 emergency provisions as set out in S.I. 98 and S.I. 99 of 2020. This joint statement set out an underpinning rationale to support the introduction for consideration by the Department of an enabling mechanism in the legislation to allow a pharmacist to supply a controlled drug in certain emergency circumstances, either at the request of a prescriber or a patient, where in the opinion of the pharmacist it is unreasonable for the patient to obtain a new prescription for that controlled drug and that, it is safe, appropriate and necessary for the continued treatment of the patient for the emergency supply to be made.



Building our Capability and Performance as a Regulatory Organisation

Disciplinary Committees & Council: training update

Providing professional training to the Disciplinary Committees to support them in the effective discharge of their statutory functions in relation to the consideration of complaints is an ongoing objective for the PSI.

In June 2022, the PSI welcomed back to PSI House, the Professional Conduct and Health Committees for a full day's training in person, delivered by our Legal Affairs Manager and supported by La Touche training. The session involved refresher training and updates on fitness to practise and professional discipline proceedings, fair procedures, recent legislation and case-law. It was also an opportunity for the Committees to meet in person and discuss Committee matters for the first time in over 2 years. Both Committees also adopted on this date, new updated written procedures which govern the conduct of business before the Committees including the management of inquiries. The procedures were updated to reflect recent changes in legislation, the impact of intervening case-law in quasi-judicial hearings, and the updated landscape of remote hearings. The procedures had last been reviewed in 2015.

Follow-up training was delivered to the Chairs and Acting Chairs of the Professional Conduct Committees on 20 September 2022 in relation to the function of writing reports as required under s47 of the Pharmacy Act 2007, and which was also facilitated by La Touche Training.

Fitness to Practise training for newly appointed Council members was delivered on 15 July and 14 August by the Executive.

On 14 September 2022, the Preliminary Proceedings Committee also received training at PSI House in relation to PPC Decision Tree and the recent McEvoy V PPC & The Medical Council Judgement.

Strategic HR Update

- **Workforce Planning and Recruitment**

The following positions were filled since the last Interim Registrar's Report:

- Business Support Services Assistant (Clerical Officer – Permanent)
- Professional Standards Officer (Engineer II – Specified Purpose Contract)

- Quality Assessor (Engineer II – Permanent)
- Registrar and Chief Officer (5-year fixed-term contract) recruitment process has concluded. Council to formally consider the appointment at its meeting on the 6th of October.

The Department of Health has authorised another extension to the Interim Registrar's contract for three further months up to 30 December 2022 to ensure continuity pending the commencement of the new Registrar.

We have two competitions ongoing:

- Finance and Support Services Manager (Grade VIII – Specified Purpose Contract for a career-break cover)
- Regulatory Executive (Executive Officer – Permanent)

The Department of Health has reviewed the business case submitted to it in May 2022 in relation to the additional 11 posts as part of the target operating model (TOM) approved by Council. The Department has asked PSI to submit a proposal in relation to priority posts for further consideration.

Business continuity and blended working

Work is continuing on the development of a Blended Working Policy, which will shortly be considered by ELT following staff consultation. We are also at the final stages of agreeing a contract with a third-party provider to carry out the VDU assessments, which will form part of the application process under the new policy. A training provider to train managers in the effective management of a distributed workforce has also been identified which will accompany the roll-out of the Blended Working Policy.

Business Transformation Project (BTP) Update

PSI continues on our digital transformation journey with the next phase (Phase 1.1) of the BTP to be deployed mid Q1 2023, which is slightly later than expected. Whilst this delay is disappointing, the PSI has built on the foundations that Phase 1 delivery provided with the recent release of a 24/7 support mechanism through a chatbot (a computer program that simulates human conversation to solve customer queries) for our registrants/applicants. The chatbot will be available on the registration portal and will be able to assist registrants/applicants with queries they have in relation to eligibility for routes of registration, registration/eligibility questions etc. The chatbot builds upon all of the supports already developed such as FAQs and videos to support registrants/applicants. It is hoped that this will streamline further the registration process and increase efficiency by reducing the number of email and phone queries received. We will also be able to analyse the data to determine FAQs in order to improve the information available to registrants/applicants. The PSI will assess the effectiveness of this support model early in 2023 and listen to the feedback from our registrants/applicants and also PSI staff as we seek to further enhance the online registration portal.

The PSI continues to work on improving the experience for members of the public interacting with the regulator, as such, this will be an area of focus for our digital transformation journey through 2023.

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

Service/goods to be Procured	Current Status
Website Re-Design Development, Hosting and Support services	The vendor has withdrawn from entering into a contract with PSI on 21 July 2022. As the procurement has now been deemed to be unsuccessful direct market engagement is currently in progress.
Professional pharmacy workforce	Open Procedure published on 21 July 2022 with a closing date of 22 August 2022. Evaluation completed. The outcome letters are being finalised.
Internal Audit Services	OGP Framework drawdown published on 23 August 2022 with a closing date of 21 September 2022. The evaluation was completed on 27 September 2022. The outcome letters are being finalised
CPD Model Review [Pharmacists]	Open Procedure published on 5 August 2022 with a closing date of 6 September 2022. The evaluation is in progress.

Appendix 1 – Statistical Summary

Fitness to Practise (figures as 22 September 2022)

For the purposes of this appendix, please note that references to '*last report date*' refers to the Interim Registrar's Report submitted for the Council meeting on 23rd June 2022

Complaints for Screening Committee (PPC)

Total new complaints received year to date	42
New complaints received since last report date	23
Total open active complaints*	59
Complaints considered by PPC since last report date **	15

* This figure may include complaints received prior to 2022 which are still being processed

**These complaints were heard over 3 meetings. 26% of these complaints met the KPI of the PPC decision within six months from the date of receipt of complaint to the date of the final PPC decision.

Fitness to Practise

Inquiries

Total heard (all remotely) year to date *	6
Heard (all remotely) since last report **	1
Complaints being investigated/prepared for hearing	41

* of which 50% meet the KPI of the inquiry being heard within 18 months from the date of referral by the PPC to a committee of inquiry

**1 took place before the PCC

Mediation

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

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

Heard since last report*	2
Heard year to date*	11
Sanction hearings/undertakings being prepared for Council *	3

*per registrant

High Court Sanction Confirmation Hearings

Heard year to date	1
Cases being prepared for High Court confirmation	0

Appeals

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

Call-Overs and Other Applications Before Committees of Inquiry

Callovers heard year to date: (a) Professional Conduct Committee (b) Health Committee	(a) 3 (b) 4
Held since last report date (a) Professional Conduct Committee (b) Health Committee	(a) 1 (b) 1

The next PCC and HC Callovers are scheduled for 15 Dec 2022

Interim Suspension Applications

Applications heard by Council year to date	1
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Prosecution

Cases being prepared for District Court Prosecution	1
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Professional Registration (figures as of 28 September 2022)

Route/ Application Type	Applications Received 2022 to date	Applications in Process (including applications received in previous years)	Registrations Completed 2022
Third Country Qualification Recognition (TCQR) – excluding UK	87	190	7
Route/ Application Type	Registrations/ Actions Completed 2022		
National Route	13		
Non-National Route (EU only)	57		
Non-National Route (Third Country) – UK only	57		
European Professional Card – Establishment of Service (Qualification Recognition)	8		
European Professional Card – Temporary & Occasional Provision of Service	1		
Voluntary Cancellations from Register	73		
Involuntary Cancellations from Register	19		
Restorations to Register following Voluntary Cancellation	33		
Restorations to Register following Involuntary Cancellation	5		
Certificates of Current Professional Status issued	43		
IMI Alerts (Internal Market Information) issued by PSI	3		

Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses - numbers as at 28/9/2022	
Number of Registered Retail Pharmacy Businesses	1980
Retail Pharmacy Business Openings by Type	New Openings: 12 New Openings (Change of Ownership): 43 New Openings (Permanent Relocation): 5 Total = 60
Retail Pharmacy Business Cancellations by Type	Voluntary Cancellations (Closure): 14 Voluntary Cancellations (Permanent Relocations): 5 Voluntary Cancellations (Changes of Ownership): 43 Total = 62
Number of Changes in Supervising and Superintendent Pharmacists in 2022	336

Internet Supply	
Number of Pharmacies on Part A	188
Number of Non-Pharmacies on Part B	155

Regulation of Retail Pharmacy Businesses (figures as of 22/09/2022)

Inspection Activity 2022	
Total number of Inspections (commenced February 2022 following COVID-19 government advice)	As of 22.09.2022 71
Number of registration-related Inspections	3
Number of pharmacy inspections Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)	1

Concerns

Total new concerns received year to date	80
New concerns received since last report date	28
Concerns reviewed since last report date	30
Open concerns	3

Investigation Activity 2022 (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
14	1	0
Investigation Activity 2022 (Section 67) – Interviews / Statements / Pharmacy Visits		14