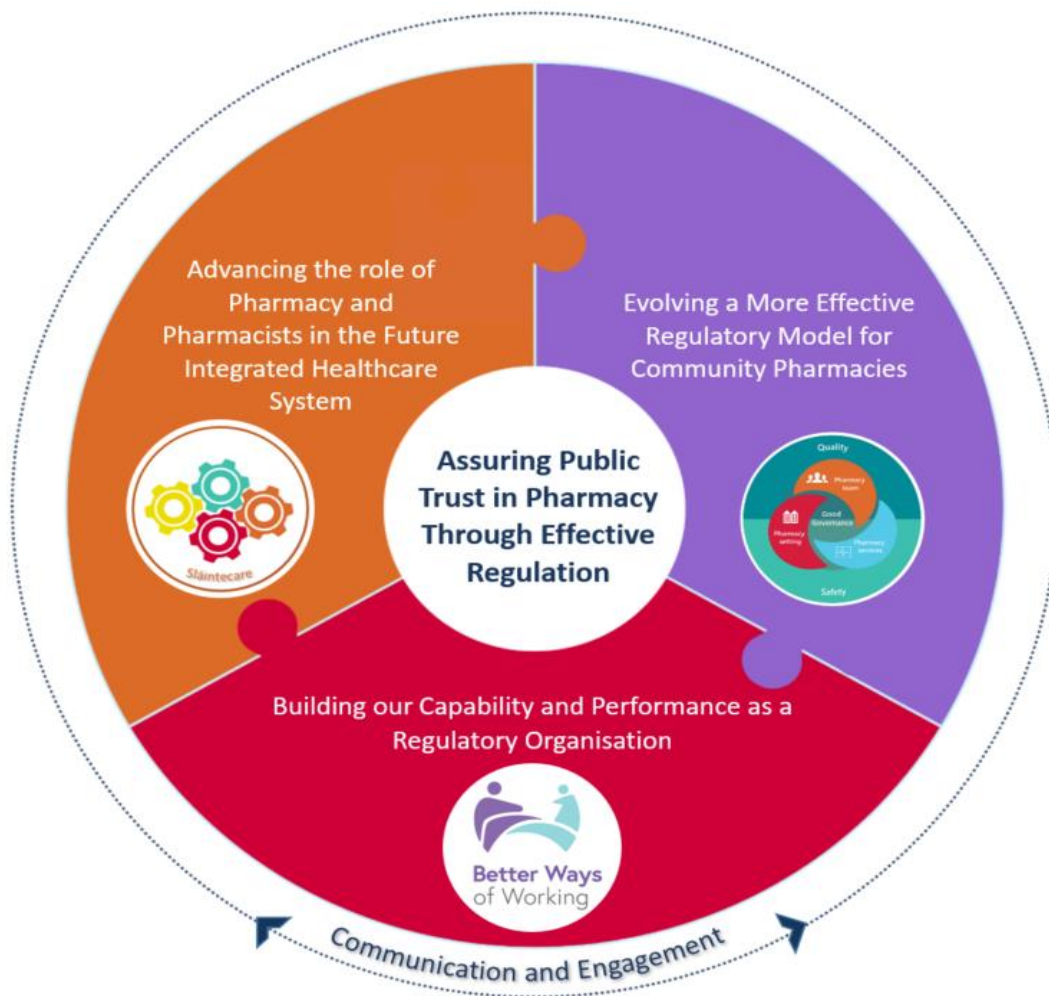




The Pharmacy Regulator
An Rialtóir Cógaisíochta

Report of the Interim Registrar



Report to Council Meeting of 23rd June 2022

Highlights and general engagement updates from the Interim Registrar

Update on managing our response to COVID-19

We continue to participate in the weekly meetings of the HSE's vaccination pharmacy working group which have been taking place since January 2021. As of 26 May, pharmacies had administered 903,827 COVID-19 vaccines. Their involvement in the current booster programme continues, with 921 pharmacies having received deliveries of booster vaccines in 2022, out of a total 1,100 who are registered to provide COVID-19 vaccinations. Discussions are ongoing on the part pharmacy will play in the longer term, as the HSE plans for the general population needs next Autumn/Winter and the alignment of the 'flu and COVID-19 vaccines.

End of S. 77 temporary registration provisions

In response to the Covid pandemic in March 2020 an amendment to the Pharmacy Act 2007 was introduced which allowed for temporary registrations for previous registrants, under Section 77. While initially intended to be in place until 31 December 2020, a number of extensions were confirmed after that date. 30 June 2022 will see the expiry of this temporary amendment, and the registrations of those currently availing of this facility will cease.

Since March 2020 the PSI received a total of 63 applications for Section 77 registration (61 pharmacists and 2 pharmaceutical assistants). Some Section 77 registrants have chosen to cancel their registration since March 2020, and currently there are 37 registered (35 pharmacists and 2 pharmaceutical assistants).

The support of these s.77 registrants in contributing to the effective response of the pharmacy sector to dealing with the pandemic is acknowledged and appreciated.

Any registrants who are currently registered via Section 77, who wish to remain on the register after 30 June 2022 will be able to apply for restoration or re-registration to the register, depending on their registration status prior to the Section 77 registration.

PSI has been in regular communication with these registrants keeping them informed of the relevant dates, and the options available to them.

Communication and Engagement Updates

Overview of recent external meetings and engagements attended by Interim Registrar and PSI staff	
May & June (weekly)	National COVID-19 Vaccination Programme – Pharmacy Workstream Working Group: this group meets weekly to discuss ongoing roll-out of the COVID-19 vaccination programme in community pharmacy. It is chaired by Pat Healy, HSE and also includes representatives from others within the HSE and the IPU.
26 April	We attended a meeting of the CPD Executives Group who meet to discuss topics of interest relating to CPD across a range of professions
3 May	Meeting with DOH regarding FMD
4 May	Meeting with IPU regarding workforce stakeholder group
4 May	Medical Council stakeholder group meeting on strategies to address overprescribing of controlled drugs
17 May	We attended a Quality and Qualifications Ireland (QQI) event entitled 'Quality Assuring programmes and higher education qualifications in a changing world'
30 May	National Near-Patient Testing (NPT) Consultative Group meeting
31 May	As part of our membership of the European Directorate for the Quality of Medicines and Healthcare, which is a Directorate of the Council of Europe, we attended a Pharmacare Stakeholder Day
2 June	We met with the heads of the three Schools of Pharmacy and APPEL to discuss ongoing matters of mutual relevance and interest
7 June	As part of the EU DG REFORM TSI Project on Health and Social Care Workforce Planning in Ireland, we attended an International Workshop on Health and Social Care Workforce Planning in Ireland. The aims of the workshop were to: (a) inform recommendations for improvement and the preparation of an integrated Health and Social Care Workforce Planning Strategy for Ireland; and (b) increase visibility of the project at national and international levels
7 June	The UK Care Quality Commission invited the PSI to attend joint UK and Irish national meeting to discuss concerns relating to the issue of controlled drugs across health and social care sectors
8 June	We attended the fourth meeting of the HSE Community Pharmacy Planning Forum. The group is chaired by Pat Healy, National Director, and aims to facilitate ongoing engagement and consultation with the pharmacy sector to support consideration of the strategic direction for the future development of community pharmacy services in line with Sláintecare. The forum will also provide a process for ongoing strategic planning required for the future of community pharmacy in the longer term and also in the context of the ongoing COVID-19 Public Health Emergency.
10 June	Meeting with Department of Health, HSE and Medical Council regarding potential changes to the Medicinal Products and Misuse of Drugs regulations
16 June	Invited by TCD School of Pharmacy to present to delegates from Bosnia and Herzegovina, Serbia and Croatia on the role of the PSI in pharmacy education

	as part of the 'Innovating quality assessment tools for pharmacy studies in Bosnia and Herzegovina' (IQ Pharm) project which aims to enhance the quality of and modernise pharmacy studies in the public universities of Bosnia and Herzegovina
16 June	Department of Health-PSI Governance meeting (2 nd of 3 of 2022)

The PSI President together with PSI staff attended the Medical Council stakeholder group meeting on strategies to address overprescribing of controlled drugs on 4 May. The stakeholder group includes representatives from the Medical Council, HSE, HPRA, Department of Health, the PSI and ICGP.

We also attended the National Near-Patient Testing (NPT) Consultative Group meeting on 30 May which convenes under the auspices of the Faculty of Pathology of the Royal College of Physicians of Ireland (RCPI) and represents national laboratory medicine organisations and regulatory bodies with an interest in NPT. This group now includes representatives from RCPI, the HPRA, the Association of Clinical Biochemists in Ireland and the Academy of Clinical Science and Laboratory Medicine. The group plans to revise the Irish National Near-Patient Testing Guidelines during the summer months and plan to invite feedback from relevant stakeholders.

PSI staff attended a meeting with the Department of Health, HSE and Medical Council on 10 June to explore potential changes which may need to be made to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) and the Misuse of Drugs Regulations 2017 (as amended) to ensure continuity of patient care, in anticipation of the revocation of certain provisions which were made specifically to address circumstances arising from the COVID-19 emergency.

Public Consultation Submissions:

- **HIQA Consultation on ICT enablement of Older Persons Services**

A response to HIQA's request for a submission on its draft recommendations on ICT enablement of Older Persons Services was made. The recommendations are intended to ensure that an older person's health information can be shared safely and effectively between systems across their care journey and to address the needs of all the healthcare professionals involved, while placing the older person at the centre of care.



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

We are in the process of procuring external expertise who will assist PSI in this project. Market sounding has been carried out and we are aiming to publish the Request for Tender (RFT) in June. Key deliverables for phase one of the project that are being set out in the RFT cover the following:

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

The project team is planning to complete a series of one-to-one early engagement meetings with key stakeholders with an interest in the pharmacy sector over the coming weeks. The purpose of these meetings will be to gather information on emerging risks to the continued availability of a professional pharmacy workforce within community and hospital pharmacy. The intention is to present the information gathered during the early engagement meetings at future meetings of these stakeholders later this year to the working group to be established by the PSI as part of the project.

Revision of current Third Country Qualification Recognition Route

This project is continuing to make progress with a view to the revised route being approved by Council at its December 2022 meeting and the new system commencing in early 2023. An external expert has been commissioned to review the proposed stages and content of the revised process and which is to include commentary on any risks identified in the proposed implementation process of the revised TCQR route and proposed mitigation actions, if any. A draft report from the external expert is currently being reviewed by the project team.

It is anticipated that changes to the current TCQR route will be proposed to Council in October 2022 with implementation of the revised route to commence start of 2023, subject to the amended registration rules being approved and signed by the Minister.

Ukraine Emergency Response Group

A PSI Ukraine Emergency Response Group with members from across PSI business areas, continues to meet weekly to coordinate and address matters arising from the conflict in Ukraine.

This includes:

- PSI 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.
- On 29 April, a letter was issued from the PSI President and Interim Registrar to the Ambassador of Ukraine to Ireland, to outline PSI's role and how we may be involved in supporting Ukrainian pharmacists who are considering working in their professional capacity while in Ireland.
- Since the beginning of June, PSI has been providing a weekly update to the Department of Health, regarding any important matters relating to refugees from Ukraine, including statistics around qualification recognition.
- PSI continues 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.

Building One Health Action under iNAP2

We are attending the Building One Health Action under iNAP2 event on 23 June, hosted by the Department of Health and the Department of Agriculture, Food and the Marine and supported by the Environmental Protection Agency.

This One Health event aims to acknowledge the work done under iNAP1 in tackling antimicrobial resistance and to promote further learning and collaboration under iNAP2 across the One Health sectors.



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

Falsified Medicines Directive (FMD)

The National Safety Features Oversight Group, following consultation with all relevant stakeholders, has ended 'use-and-learn' on 30 May 2022 for FMD implementation in Ireland. As a reminder of this key date, the PSI sent an email to superintendent pharmacists at the end of May, copying all registered pharmacists, setting out their requirements and responsibilities, and link to supportive materials available from the IMVO. PSI has been invited to attend the European Medicines Verification Organisation meeting on 15 June.

The PSI has engaged with retail pharmacy businesses (RPBs) to engage, explain and encourage compliance during the 'use-and-learn' period. During the 2022 'use-and-learn period' the PSI has contacted 541 pharmacies at least once regarding low scanning and decommissioning rates. Overall, Ireland is continuing in an upwards trajectory regarding compliance. The Department of Health is consulting with the PSI about improving FMD compliance in pharmacies and draft legislation to invoke regulatory enforcement measures. S.I. No. 270 of 2022 of Medicinal products (safety features on packaging) Regulations 2022 has been signed into legislation by the Minister for Health on 1 June 2022.

Position paper on the Regulation of Retail Pharmacy Businesses in Hospital Settings

Work continues on the development of this position paper. To inform the paper, a short survey was issued to a number of pharmacy regulatory bodies in the following jurisdictions: The Netherlands, Sweden, Canada (Alberta and Ontario), New Zealand, Australia, Northern Ireland and Great Britain. Responses have been received from two organisations with follow-ups in train. A separate survey is in development in relation to pharmacy services in Ireland not regulated under current pharmacy legislation. It is expected that the final paper will be presented to Council at its October 2022 meeting.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Organisation Development Project (ODP) Update

The project continues in its implementation phase and is overseen by the Executive Leadership Team (ELT) as the Steering Group, with the support of a Coordination Group comprising individuals from across the organisation which, in general, meets weekly. This project is an important one for the PSI and runs alongside other significant work, including the business transformation project. It is recognised as a project that we will steadily progress this year, although not at the pace we had hoped, and planned for initially.

We remain focused on the prioritised elements of the project as agreed by the Steering Group earlier in Quarter 2. This includes holding a meeting of all managers with responsibilities in the development and operation of the lateral/matrix reporting structure that is envisaged under the Target Operating Model (TOM). All feedback received to the latest (third) ODP staff sentiment survey has been provided back to staff, and a question and response session held in May.

Strategic HR Update

- **Workforce Planning and Recruitment**

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

- Quality Assessor (Permanent)
- Regulatory Executive (Permanent)

We have one competition ongoing (Business Support Services Assistant (candidate from panel)).

We submitted to the Department the overview of our new organisation structure and target operating model comprising the business case for the 11 new posts foreseen in the TOM and approved by Council. We hope to discuss the business case with the Department in the coming weeks.

The Department has also authorised the extension to the Interim Registrar's contract for 3 further months, which would bring the contract up until the end of September in order to ensure continuity while recruitment of a new Registrar is ongoing.

Hays Executive has been appointed to assist the PSI with executive search services for the substantive Registrar position and work is ongoing to commence the recruitment.

- **Business continuity and blended working**

Work is continuing on the development of a Blended Working Policy, with a survey issued to all staff and a draft policy considered by the Employee Experience Consultative Forum (EECF). The EECF is an employee group established to foster a high level of employee participation in implementing the 2021-2023 HR Strategy and advancing the HR agenda. Training providers are also being sourced to provide training to managers in the effective management of a distributed workforce.

Business Transformation Project (BTP) Update

PSI continues to work with our technology partner to enhance the effectiveness of the BTP; we have provided refresher training for staff to ensure we extract maximum value as we proceed on our digital transformation journey. An example of the benefits seen after Phase 1 of the BTP have been the enhanced reporting that a single customer view provides. This enhanced reporting has been used to analyse data to inform the workforce planning project, which is assessing emerging risks to the continued availability of a professional pharmacy workforce within community and hospital pharmacy in Ireland.

We remain on track to deliver the next phase of BTP in early Q4 this year. Feedback from registrants, applicants and from PSI staff has influenced the scope of work to be addressed in the next phase. One aspect of the next phase is to join up the public register with outcomes from the complaints process; another is to extend the register to include what is termed the 'Internet Supply List'; another is to address various items captured as part of Phase 1 feedback.

We continue to work with various governance fora to ensure tight budgetary controls are met.

Compliance with EU Web Accessibility Directive

Public bodies in Ireland must ensure their websites and mobile apps are accessible to all people, including people with disabilities. Regulations in Ireland (SI 358/2020) give effect since September 2020 to the European Union Web Accessibility Directive, which is the most recent requirement for website accessibility for public bodies.

The National Disability Authority (NDA) is the monitoring body for these provisions and the PSI has been notified by the NDA in May that our website is included amongst a range of public body websites for a Simplified Review against the web accessibility requirements during 2022. This review provides us with useful information, resources and training that can be used to meet compliance with the Directive. The PSI website is currently partially compliant; we have not yet implemented the requirements of the EU Web Accessibility Directive. We are this year progressing with the overhaul of the PSI website and this will allow us to improve our compliance. Our tender for web development

services stipulated, amongst the requirements, the web accessibility standards that are required to be met. We are also making what improvements we can within the constraints of our existing website and its limited functionality. There is an important awareness and training element necessary too for the organisation, which our Communication and Engagement team are working on, and we are overall committed to improving equality of access to the information and services we provide as a public health regulator.

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

Service/goods to be Procured	Current Status
Remote Hearings	Pre-Qualification Questionnaire (PQQ) completed for restricted procedure with a closing date of 25 April. Next stage is in train

Appendix 1 – Statistical Summary

Fitness to Practise (figures as at 7 June 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 28th April 2022

Complaints for Screening Committee (PPC)

Total new complaints received year to date	19
New complaints received since last report date	6
Total open active complaints*	51
Complaints considered by PPC remotely since last report date **	14

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

** This took place over 3 meetings. 23% of these complaints 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

Total heard (all remotely) year to date *	5
Heard (all remotely) since last report **	2
Complaints being investigated/prepared for hearing	44

* of which 40% 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 and 1 took place before the HC

Mediation

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

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

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

*per registrant

High Court Sanction Confirmation Hearings

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

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) 2 (b) 3
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 22 September 2022

Interim Suspension Applications

Applications heard by Council year to date	0
--	---

Prosecution

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

Professional Registration (figures as of 13 June 2022)

Pharmacists

- 2 alerts have 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.
- 1 European Professional Card (EPC) application for the temporary & occasional provision of service have been received to date in 2022.
- 5 EPCs for establishment of service have been received to date in 2022 (new European route of entry to recognition and registration). 5 are approved
- 29 Certificates of Current Professional Status have been issued since 1st January 2022.
- 54 Voluntary Cancellation applications and 19 Involuntary Cancellations have been processed since 1st January 2022.
- Since March 2020 all EU/TCQR Registration meetings have been cancelled in light of the Covid-19 Pandemic.
- 36 Third Country Qualification Recognition (Non-EU/EEA qualified other than UK-qualified) applications received to date this year, with 154 applications in total in process.
- 5 Third Country registration applications processed to date this year.

Pharmacists

No. of New Registrations and Restoration Applications since 1 January 2022

Section 77 Applications are counted since 9 March 2020 in the context of the Covid-19 Pandemic (NB: this registration route and status will cease to be in effect on 30 June 2022)

No. of new registration applications received and registered (National and Non-national)	National – 13 Non-national (EU) – 23 Non-national (UK) - 15
No. of New Restoration Applications Received in Accordance with S.61 that are completed	7
No of S.77 Registrations Applications Received since 9 th March 2020	61 Pharmacists 2 Pharmaceutical Assistants
No of S.77 Registrations currently registered	35 Pharmacists 2 Pharmaceutical Assistants

Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses - numbers as at 13/6/2022	
Number of Registered Retail Pharmacy Businesses as at 13/6/2022	1981
Number of Retail Pharmacy Businesses Registered to date in 2022	New Openings (5) New Openings – Change of Ownership (26) New Openings – Permanent Relocation (2) Total = 33
Number of Retail Pharmacy Businesses Cancelled since 1 January 2022	Voluntary Cancellations - Closure (9) Voluntary Cancellations - Permanent Relocations (2) Voluntary Cancellations - Changes of Ownership (26) Total = 37
Number of Changes in Supervising and Superintendent Pharmacists in 2022	257

Internet Supply	
Number of Pharmacies on Part A	195
Number of Non-Pharmacies on Part B	162

Regulation of Retail Pharmacy Businesses (figures as of 03 June 2022)

Inspection Activity 2022	
Total number of Inspections (commenced February 2022 following COVID-19 government advice)	As of 03.06.2022 43
Number of registration-related Inspections	1
Number of pharmacy inspections	
- Risk-based Inspections	41
- Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)	1

Concerns

Total new concerns received year to date	51
New concerns received since last report date	21
Concerns reviewed since last report date	22
Open concerns	1

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
13	0	1
Investigation Activity (Section 67) – Interviews / Statements / Pharmacy Visits		7