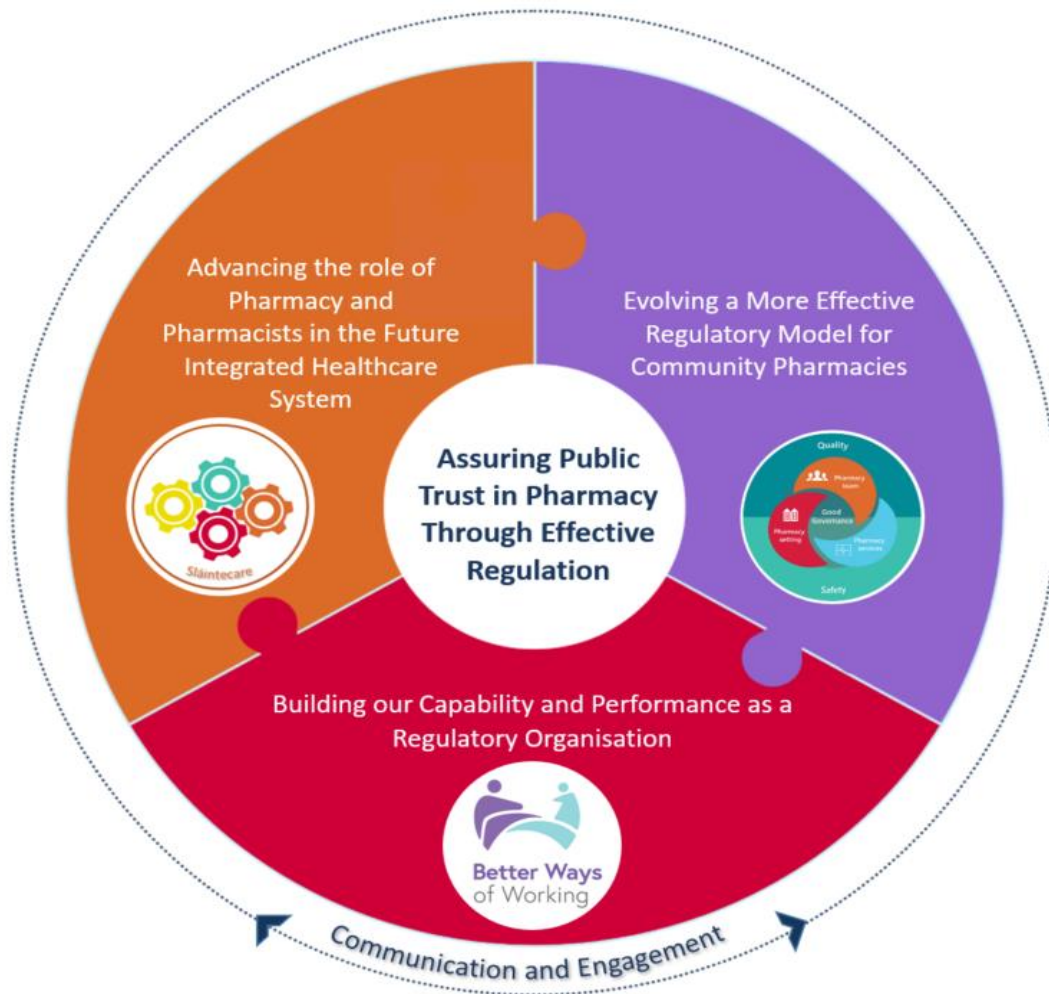


# Report of the Interim Registrar



Report to Council Meeting of 28 April 2022

## Highlights from the Interim Registrar

### **Ukraine Response Group established**

A PSI Ukraine Emergency Response Group was established on 14 March, with members from across PSI business areas, to coordinate and address matters arising from the conflict in Ukraine. The group meets weekly to cross-organisationally discuss and coordinate a range of issues which have arisen or are expected to arise in the context of people fleeing the conflict in Ukraine, including issues around qualification recognition for Ukraine qualified pharmacists and access to medicines to those arriving to Ireland from Ukraine.

Some work strands to date include:

- PSI engagement with the Department of Health, national healthcare and non-healthcare professional regulatory bodies and other key stakeholders in relation to providing a coordinated regulatory response.
- Managing the 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.
- Meeting with the HSE Primary Care Reimbursement Service (PCRS) on 5 April to share information on refugees from Ukraine accessing medical care and treatment upon arrival in Ireland. The HSE-PCRS, including community care pharmacists, is the key point of contact for community pharmacies in assisting those arriving from Ukraine who require medicines and health advice.
- In response to a number of queries, the PSI Interim Registrar wrote to registrants on 16 March to highlight the government response to the conflict, in particular, the coordination of the national aid response on medicines or medical devices by the Department of Health and the most effective methods of support which PSI registrants who wish to provide humanitarian aid to Ukraine could provide.
- Information was published on the PSI website on 13 April to support people coming to Ireland from Ukraine, and to signpost pharmacies providing health services to those arriving from Ukraine to useful resources and information. This website resource will be updated as the situation continues to evolve.
- Preparing a communication to the Ukrainian Embassy in Ireland with the aim of establishing a communication link for regulatory matters which may arise.

### **Annual Report and Financial Statements 2021 submitted to Minister**

Following the approval by the Council of the Annual Report and the audited Financial Statements on the 24 March, these were submitted to the Minister for Health. We await notice from the Department that these are ready to be laid before the Houses of the Oireachtas. Both the Irish and English versions of the report will be published in due course and any statement or reflections on PSI activity and data from 2021 will be communicated at that time.

## Update on managing our response to COVID-19

### COVID-19 vaccination programme

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 21 April, 851,727 COVID-19 vaccines had been administered by pharmacies. Operational Guidance, reviewed by the PSI and IPU, is being issued by the HSE to community pharmacies to support their involvement in the booster campaign for 12-15 year olds. Community Pharmacy will also be involved in the roll-out of the next booster campaign, targeting those aged 65 years and over, and people who are immunocompromised.

Age-Range	Total
12-15	56,511
16-19	73,952
20-29	206,404
30-39	149,364
40-49	112,061
50-59	129,376
60-69	102,763
70-79	17,911
80-89	2879
90+	463

COVID-19 Vaccines administered by Community Pharmacy up to 21 April 2022

### Assessment of NIO training for Nuvaxovid® (Novovax COVID-19 Vaccine)

Nuvaxovid® is a new vaccine product approved by the European Medicines Agency (EMA) for those who cannot have an mRNA vaccine, or who have declined one. Training to support the delivery of this vaccine has been developed by the National Immunisation Office (NIO). As we have done for all other vaccine products to date, we convened an expert Assessment Team to carry out a review of the training. Following recommendation by the Assessment Team, the Interim Registrar has subsequently approved the training as being suitable for pharmacists. Use of this vaccine is limited to specialist clinics and centralised vaccination centres.

### Paxlovid® - Treatment for COVID-19

Use of this anti-viral medication will mainly be in primary care. As this is a new medication, with significant potential for interaction with other medicines, a webinar to support pharmacists was

hosted by the IOP on 12 April. The webinar was delivered by Muriel Pate and Marie Philbin from the HSE, and is available as a recording through the IOP website.

We updated all registrants via email on 14 April in relation to the approval of the NIO training for Nuvaxovid®, and signposted them to the Paxlovid® webinar.

### **Deferral of April 2022 Practice Review Event**

PSI Council was advised at its October 2021 meeting that Practice Review could proceed at full capacity in 2022, subject to conditions relating to the pandemic progressing as anticipated. This was in light of the improving situation in relation to the public health emergency, and the announcement by Government at the time with regards to the lifting of restrictions. It was always the intention that ongoing consideration would be given to the situation at the time of the event in relation to the COVID-19 pandemic, and the impact of requiring this number of patient-facing healthcare professionals to attend a central location (i.e., RCSI) to complete Practice Review. After a review of the COVID-19 situation at the time, where we were seeing extremely high rates of infection of the highly transmissible COVID-19 BA.2 variant, and having consulted directly with the PSI President, the Chair of the Regulatory and Professional Policy Committee, and the IOP, we took the decision to defer this Practice Review event. Those selected to attend were notified via email on 1 April, and it is intended that they will instead participate in the Practice Review event in October of this year.

## Communication and Engagement Updates

Overview of recent external meetings and engagements attended by Interim Registrar and staff	
March and April (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
14 March	Meeting with Interim Registrar and Principal Officer, Department of Health, Medicines, Controlled Drugs & Pharmacy Legislation Unit in relation to response to Ukraine emergency and update on PSI deliverables for the DOH
21 March	We met with Ciara Kirke and Muriel Pate from the HSE to discuss pharmacy workforce issues. We also received an update on the iSIMPATY project. <a href="#">iSIMPATY</a> is an EU funded project running until March 2023 across the three jurisdictions of Northern Ireland, Scotland and the border areas of the Republic of Ireland. The project ensures the best and most sustainable outcomes with medication use in patients taking multiple medicines, with the focus on effective medicine reviews.
23 March	PSI-Department of Health Governance meeting (first of three annual meetings)
28 March	We met with members of the HSE ePharmacy team who are tasked with development and implementation of the ePrescribing solution for Ireland. The purpose of the meeting was to share lessons learned from our experience of implementing our new registration portal as part of the Business Transformation Project, along with insights gathered from our work in relation to the Falsified Medicines Directive.
5 April	We met with Kate Mulvenna from the HSE PCRS in relation to people arriving from the Ukraine, and how those with health and medicines needs were being supported on their arrival, including discussion on the role pharmacists and their teams are playing in this regard.
5 April	Meeting with Department of Health (Medicines, Controlled Drugs & Pharmacy Legislation Unit) on FMD and online pharmacies
11 April	Health and Social Care Regulators Forum – meeting attended by Interim Registrar
11 April	Meeting with Indecon in relation to the European Commission and Department of Health Project on 'Health and Social Care Workforce Planning in Ireland'.
13 April	HSE Community Pharmacy Planning Forum: The third meeting of this group in 2022 took place in April. 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.



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

### Key updates

#### Public consultation submissions:

Since the March update to Council, the Strategic Policy team has coordinated the following consultation submissions:

- **Public Health Reform Expert Advisory Group (PHREAG)**

In March, the PSI submitted a response to a Public Health Reform Expert Advisory Group (PHREAG) consultation, with input from across PSI business areas. PHREAG is an independent expert group which has been established by the Minister for Health and the Minister of State for Public Health, Wellbeing and the National Drugs Strategy. Its mandate is to identify lessons learned from the public health response to the COVID-19 pandemic in Ireland with a view towards strengthening health protection generally and future pandemic preparedness specifically.

The PHREAG also aims to identify lessons from international best practice regarding reform and strengthening of other core public health functions, under the four key pillars of health protection, health improvement, health service improvement and health intelligence.

- **Revocation of COVID-19 Emergency Provisions**

The PSI also considered and provided feedback to the Department of Health in April on S.I. 98 and 99 of 2020, and the implications of revoking certain provisions which were made specifically to address circumstances arising from the COVID-19 emergency.

#### Emerging Risks to the Future Pharmacy Workforce project

The internal project team has now been established and is meeting fortnightly to progress the project. Market sounding is being carried out in advance of procuring external expertise who will be tasked with supporting delivery on some of the project milestones. We have also met with Indecon Consultants, who have been appointed under the European Commission, DG REFORM's Technical Support Instrument to undertake a major project on Health and Social Care Workforce Planning in Ireland. The project, which builds on the National Strategic Framework for Health and Social Care Workforce Planning, is being led by officials within the Strategic Workforce Planning Unit of the Department of Health, who will work in collaboration with the HSE and other key stakeholders, including the PSI, to deliver on this important initiative. We will continue to engage with Indecon as their work progresses, and look to identify opportunities for synergy between the two projects.

### **Update to Core Competency Framework (CCF)**

In March, we met with the project's Steering Group where we updated them on the outcome of the workshop held with the Project's Working Group and discussed next steps. Since then, work has continued on redrafting the CCF taking account of the feedback received to date. A meeting with the Schools of Pharmacy will take place in April to appraise them on progress to date. In addition, a competency framework expert has been sourced who will provide feedback on the revised CCF as a quality assurance step.



## 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, agreed a plan for ending ‘use-and-learn’ on a phased basis, concluding on 30 May 2022.

Phase 5 commenced on 14 March, which is the pilot phase for alert handling. Pharmacists are responsible for resolving alerts generated at a local level and for verifying that anti-tamper devices on medicinal products remain intact as part of FMD. Phase 6 will commence on 9 May when the ‘use-and-learn’ phase ends for wholesalers.

The PSI continues to engage with retail pharmacy businesses (RPBs) to “engage, explain and encourage” compliance during the ‘use-and-learn’ period. We are focusing on the few who have not engaged to date, strongly encouraging engagement prior to introducing enforcement measures. From our latest report from 3 April, the number of pharmacies with less than 100 decommissions is 238. These pharmacies have been notified of low decommissioning rates. The PSI has also contacted 209 pharmacies at least once in the last 4 weeks regarding low scanning and decommissioning rates. Overall, Ireland is now on an upwards trajectory regarding compliance. The Department of Health is consulting with the PSI with regards to improving FMD compliance in pharmacies and draft legislation to invoke regulatory enforcement measures.

#### Data Sharing Agreement

PSI signed a data transfer agreement with the HSE Health Identifiers Service in relation to pharmacy location data. HSE requires a weekly update of pharmacy location data to support the roll- out of the Covid Vaccination Programme.

#### 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.

#### New National Veterinary Prescription System (NVPS)

The PSI continues to engage with the Department of Agriculture, Food and the Marine with regards to the pilot phases of this new system and specifically with regard to seeking an update on the Department’s pilot study and its findings..





## Building our Capability and Performance as a Regulatory Organisation

### Key updates

#### Strategic HR Update

- **Workforce planning and recruitment:**

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

- Quality Assessor (Permanent)
- Regulatory Solicitor (Permanent)
- Project Pharmacist (Fixed-term contract)

We have three competitions ongoing (Quality Assessor, Regulatory Executive and Professional Standards Officer).

Business cases for two replacement posts have been sanctioned by the Department of Health, (HR Lead, and Finance and Business Support Officer). One career break cover (Finance and Support Services Manager) and two fixed-term roles to be converted to new permanent roles are currently with the Department of Health for sanction and subsequent open recruitment.

As PAS were unable to facilitate the recruitment for the post of Registrar, we are currently in the process of procuring an agency to support the recruitment process for the post of Registrar/Chief Officer.

- **Business continuity and blended working:** The phased return to PSI House is entering its second phase on 25 April with two days weekly presence in the office. Staff have been working onsite at least one day a week since March. The Blended Working Policy Framework for Civil Service Organisations was released by the Minister for Public Expenditure and Reform, Minister McGrath, on 31 March. Work is commencing on PSI's own blended working policy which is expected to be completed by the end of Q2.

#### Business Transformation Programme (BTP) Update

PSI continues on our digital transformation journey with the next phase (Phase 1.1) of the BTP expected to be deployed in early Q4 this year. We have sought to take onboard lessons learnt from Phase 1 and apply these to the next phase. We have made improvements to the quality of the online system before commencing with the next phase. Improvements made already have focused on the

payment experience for external users when completing applications on-line and the full integration of the online registration portal and the finance systems. Phase 1.1 encapsulates some further improvements arising from feedback from registrants, applicants and from PSI staff, the digitalisation of the registration process for internet supply and also the application of conditions to the public register.

### **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 being, including the business transformation project. A considerable amount of change and a large volume of work in general has been taking place across the organisation, which is recognised and appreciated. It is proving challenging from a time and people perspective to implement some elements of the envisaged ODP changes in the timeline originally set out, and as agreed with the Steering Group an incremental approach with prioritisation of some key items is in focus for Q2 of 2022.

Ongoing support is being received from the external ODP consultants to assist PSI with the phased implementation of agreed actions to change some of our ways of working, in particular. We have continued to survey staff about their feedback to these changes. The third of these surveys is just completed, and the entirety of the feedback will be made available to staff, with the Steering Group to consider how to respond to suggestions and feedback arising.

### **ICT Update**

Following the successful procurement process in Q4 2021, a new IP telephony system has been deployed. The new system allows all users the full features of a modern telephony system while in the office, at home or on the road. The system will reduce cost, has more features and integrates with our current systems.

We have also been testing and trialling new technology in our Council Room to better facilitate remote access to meetings when the majority of participants are attending in person. This should enable all participants to be actively involved in the meetings.

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

Service/goods to be Procured	Current Status
Legal Services	<ul style="list-style-type: none"><li>• Tender process concluded. Outcome letters issued 21<sup>st</sup> March.</li><li>• Contracts being put in place with successful providers.</li></ul>
Remote Hearings	<ul style="list-style-type: none"><li>• PQQ completed for restricted procedure.</li><li>• Contract notice published on 24<sup>th</sup> March.</li><li>• Date for query response: 25<sup>th</sup> April.</li><li>• Closing date: 24<sup>th</sup> May.</li></ul>

## Appendix 1 –Statistical Summary

### Fitness to Practise (figures as at 13 April 2022)

For the purposes of this appendix, please note that references to 'last report date' refers to the Registrar's Report submitted for the Council meeting on 3<sup>rd</sup> March 2022.

#### Fitness to Practise Complaints for Screening Committee (PPC)

Total new complaints received year to date	13
New complaints received since last report date	5
Total open active complaints*	51
Complaints considered by PPC remotely since last report date **	4

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

\*\*0% 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

Total heard (all remotely) year to date *	3
Heard (all remotely) since last report **	2
Complaints being investigated/prepared for hearing	39

\* of which 33% 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	1
Held year to date	0

#### Sanction Hearings/ Undertakings/Dismissals/Applications before Council\*

Heard since last report	3
Heard year to date	5
Sanction hearings/undertakings being prepared for Council *	6

\*per registrant

#### High Court Sanction Confirmation Hearings

Heard year to date	0
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	(a) 1
(b) Health Committee	(b) 2
Held since last report date	(a) 1
(a) Professional Conduct Committee	(b) 1
(b) Health Committee	

The next PCC and HC Callovers are scheduled for 09 June 2022

## Interim Suspension Applications

Applications heard by Council year to date	0
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## Prosecution

Cases being prepared for District Court Prosecution	1
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## Professional Registration (figures as of 19 April 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.
- 2 EPCs for establishment of service have been received to date in 2022 (new European route of entry to recognition and registration). 2 are completed.
- 20 Certificates of Current Professional Status have been issued since 1<sup>st</sup> January 2022.
- 6 Pharmacist Restoration applications in accordance with S.61 have been processed since 1<sup>st</sup> January 2022.
- 46 Voluntary Cancellation applications and 18 Involuntary Cancellations have been processed since 1<sup>st</sup> January 2022.
- Since March 2020 all EU/TCQR Registration meetings have been cancelled in light of the Covid-19 Pandemic.
- 26 Third Country Qualification Recognition (Non-EU/EEA qualified other than UK qualified) applications received to date this year, with 149 applications in total in process.
- 28 Non-National Route registration applications (Third Country including UK and EU) processed to date this year.
- 6 National Route 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<sup>th</sup> March 2020 in the context of the Covid-19 Pandemic

No. of new registration applications received and registered (National and Non-national)	34
No. of New Restoration Applications Received in Accordance with S.61 that are completed	6
No of S.77 Registrations Applications Received since 9 <sup>th</sup> March 2020	58
No of S.77 Registrations currently active	34

## Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses @ 20 <sup>th</sup> April 2022	1980
Number of Retail Pharmacy Businesses Registered since 18 <sup>th</sup> February 2022	New Openings (2)  New Openings – Change of Ownership (10)  New Openings – Permanent Relocation (1)  <b>Total = 13</b>
Number of Retail Pharmacy Businesses Cancelled since 18 <sup>th</sup> February 2022	Voluntary Cancellations - Closure (3)  Voluntary Cancellations - Permanent Relocations (1)  Voluntary Cancellations - Changes of Ownership (10)  <b>Total = 14</b>
Number of Changes in Supervising and Superintendent Pharmacists in 2022	199

Internet Supply	
Number of Pharmacies on Part A	197
Number of Non-Pharmacies on Part B	161

## Regulation of Retail Pharmacy Businesses (figures as of 20<sup>th</sup> April 2020)

Visits to assess against COVID-19 Standards (YTD)	
Total Pharmacy Visits	0
Onsite visits	
Virtual visits	

Inspection Activity 2022	
Total number of Inspections (commenced February 2022 following COVID-19 government advice)	21
Number of registration-related Inspections	0
Number of pharmacy inspections	
- Risk-based Inspections	20
- Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)	1

### Concerns

Total new concerns received year to date	30
New concerns received since last report date	10
Concerns reviewed since last report date	22
Open concerns	6

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
14	0	0
Investigation Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		4