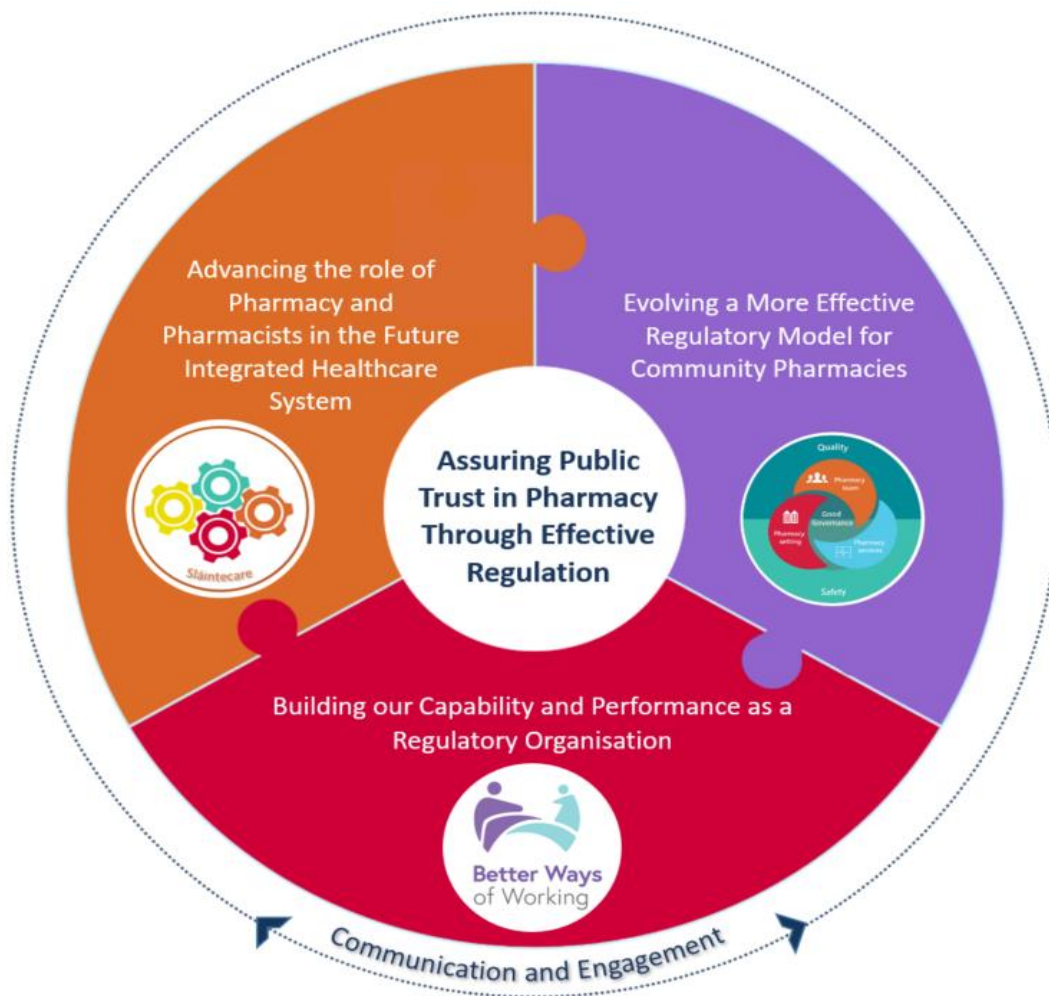


Report of the Interim Registrar



Report to Council Meeting of 3rd March 2022

Highlights from the Interim Registrar

Update on Rules to regulate the temporary absence of pharmacists

Judicial review proceedings brought against the Pharmaceutical Assistants Association (“PAA”) against the Council of the PSI, Minister for Health, Ireland and the Attorney General in 2019 regarding statutory rules to regulate the temporary absence of pharmacists at pharmacies which had been drafted by the PSI for approval by the Minister for Health, have now been struck out with no order as against the PSI. The PSI will now commence a process of further engagement with the Department of Health and other stakeholders in order to address this matter in the interest of protecting public health and safety and managing risk in the temporary absence of a registered pharmacist in community pharmacies.

Appeal against decision by Council of PSI on Sanction in Fitness to Practise inquiry not upheld

An appeal by a registrant following a sanction of temporary suspension from the register imposed by the Council of the PSI in late 2021 following a fitness to practise inquiry relating to a complaint against that pharmacist, was not allowed by the High Court and the decision of the Council was confirmed. Judge Emily Egan who heard the matter, gave judgment on 11 February 2022.

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. More than 770,000 COVID-19 vaccines have been administered by pharmacies to date, with 400,000 of these administered in December and January. This is reflective of the significant contribution of pharmacies to the national booster campaign. It is expected that pharmacies will continue to play an important role in the booster campaign, with those who had confirmed COVID-19 infections at the peak of the Omicron wave, and had to wait three months for their booster, becoming eligible.

Age-Range	Total Vaccines Administered in Community Pharmacy (as of 15 February)
12-15	54324
16-19	71479
20-29	195506
30-39	139228
40-49	103454
50-59	122498
60-69	95668
70-79	14811
80-89	2717
90+	491

Approval of COVID-19 vaccination training – Comirnaty for Children Aged 5-11 Years

Following the approval of the Comirnaty for Children Aged 5-11 Years vaccine in December, we convened our expert Assessment Team to complete a review of the training developed by the National Immunisation Office in support of the delivery of this new vaccine product. The Assessment Team had previously completed four rounds of training review in 2021. The team recommended this latest round of training for approval for pharmacists, and it was subsequently approved by the Registrar on 14 January under the delegated authority provided by Council. The team also made a number of quality improvement recommendations to the training which were shared with the NIO, the majority of which have been incorporated into subsequent updates.

Changes to legislation

The COVID vaccination programme continues to necessitate changes to the Medicinal Products Prescription and Control of Supply Regulations. PSI has been assisting the DoH in the review of these draft statutory instruments. A further two statutory instruments were drafted between the previous Registrar's Report and year end 2021, with a total of 16 statutory instruments being drafted in 2021.

PSI pharmacist colleagues in the HSE centralised vaccination centres

Following a request from the HSE, four of our PSI-employed pharmacist colleagues supported the COVID-19 vaccination programme in January, working up to a day per week in medicines management roles in a number of HSE vaccination centres.

Communication and Engagement Updates

Overview of recent external meetings and engagements attended by Interim Registrar and staff

January and February (monthly)	HSE Community Pharmacy Planning Forum: This forum has so far met twice in 2022. The group is chaired by Pat Healy, National Director, HSE and is meeting monthly to allow for 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.
January and February (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
17 January	RCSI Internal Quality Review Meeting regarding the IOP
2 February	Meeting with superintendent pharmacists from a number of pharmacy groups organised by the IPU in relation to current pharmacy workforce matters
2 February	Meeting organised by National Cancer Control Programme (NCCP) with HPRA and PSI re NCCP contingency arrangements in relation to extemporaneously compounded parenteral Systemic Anti-Cancer Therapy (SACT)
10 February	National Near Patient Testing (NPT) Consultative Group meeting
11 February	Meeting with Interim Registrar and Principal Officer, Department of Health, Medicines, Controlled Drugs & Pharmacy Legislation Unit
16 February	Medical Council stakeholder group meeting on strategies to address overprescribing of controlled drugs
23 February	Fitness to Practise Regulators Forum

Additional information about recent stakeholder engagement:

In January, the Head of Community Pharmacy Assurance attended a meeting to discuss the finalisation of the 'use-and-learn' of FMD, as part of the wider stakeholder group, the National Safety Features Oversight Group.

Staff from Strategic Policy and Communication attended the Medical Council stakeholder group on strategies to address overprescribing of controlled drugs. The stakeholder group includes representatives from the Medical Council, HSE, HPRA, Department of Health, the PSI and ICGP.

Staff from Strategic Policy and Communication also attended the National Near Patient Testing (NPT) Consultative Group in February. This 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. The group now includes representatives from RCPI, the Association of Clinical Biochemists in Ireland and the Academy of Clinical Science and Laboratory Medicine and the HPRA.

Public consultation submissions:

Since the start of the year, following consultation submissions have been made by PSI:

- in response to the public consultation on the National Clinical Guideline for Infection Prevention and Control (IPC). This draft National Clinical Guideline has been developed by the Infection and Prevention Control Guideline Development Group (GDG), by HSE - Antimicrobial Resistance & Infection Control (AMRIC) and key stakeholders including Health Protection Surveillance Centre (HPSC) and Infection and Prevention Control Practitioners.
- In response to the HIQA public consultation to inform recommendations on a consent model for the collection, use and sharing of health information.



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

Key updates

Review of the Core Competency Framework

In February, we held our fourth workshop with the project's Working Group. This group comprises 50 members who responded to an expression of interest process, with the majority being pharmacists from a variety of practice settings. The group were asked to consider the redrafted CCF and provide their feedback for consideration in advance. This was then discussed at the workshops and is being considered as part of a further round of editing.

Pharmacist Workforce project: Assess emerging risks to the continued availability of a professional pharmacy workforce within community and hospital pharmacy in Ireland

Robust data for Ireland are needed to be able to determine current landscape, assess future health system needs and associated challenges now and into the future, and decide what actions are to be recommended to address Ireland's needs for a pharmacist workforce in the delivery of healthcare services as Ireland's healthcare system evolves. We have commenced planning process for the various stages of this project and considering how best to establish the various research interventions that will be required to build a comprehensive picture of the future health service needs for a pharmacist workforce.



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

Advance Reform of the Pharmacy Act project

A draft PSI position paper on the need for reform of the Pharmacy Act is being developed as part of the Advance Reform of the Pharmacy Act project. It is expected that the position paper will be brought to the Regulatory and Professional Policy (RPP) Committee in March for consideration and recommendation to the Council meeting on 24 March.

Subject to Council's approval the aim is to submit the position paper to the Department of Health to inform PSI's discussions with the Department on this important matter.

Falsified Medicines Directive (FMD)

COVID-19 had a significant impact in late December 2021 and community pharmacies rose to the challenges of the booster vaccination programme. It was agreed by the National Safety Features Oversight group to pause FMD compliance activity until end of January 2022. 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.

The next two phases (3 and 4) will commence on 28 February and will allow pharmacies to view if decommissioning has been successful using a Red/Amber/Green alert system.

Phase 5 will follow on 14 March which will focus on pharmacies resolving alerts generated at a local level.

The final phase will be activated on 30 May and will signal the end of 'use-and-learn'.

The PSI continues to engage with retail pharmacy businesses (RPBs) to "engage, explain and encourage" compliance during the 'use-and-learn' period. We will be escalating our regulatory approach and communicating on a regular basis with pharmacies and those in governance roles with low compliance rates. We will be focusing on the few who have not engaged to date, strongly encouraging engagement prior to introducing enforcement measures. The Department is currently consulting with the PSI with regards to draft legislation to invoke regulatory enforcement measures.

The Department of Health had requested a PSI action plan update in January on our work to improve FMD compliance in pharmacies. It requested a further strategy of action in February which PSI has also submitted.

New National Veterinary Prescription System (NVPS)

Article 57 of Regulation 2019/6 legislates for the collection of comparable data on the sales and usage of antimicrobials in a harmonised and standardised manner throughout the EU and subsequent reporting of this data to the European Medicines agency (EMA). The new regulations have been in effect since 28 January 2022. The focus of these new regulations is to protect human health and address the challenge presented by antimicrobial resistance (AMR).

The NVPS is a secure electronic prescription system developed by the Department of Agriculture, Food and the Marine (DAFM) in order to meet certain requirements within the new EU Veterinary Medicines Regulation 2019/6. The NVPS is being introduced over the next number of months on a phased basis. This is to ensure that all stakeholders are familiar with the system, any practical application issues are identified and resolved and to ensure optimal functionality before full functionality is made available.

The PSI is engaging with the DAFM with regards to how legislative changes are impacting the dispensing process for community pharmacies. Exchanges of correspondence by the Interim Registrar with the DAFM occurred in January and is ongoing.

Regulatory Risk Statement Policy

The Regulatory Risk Analysis and Response Group, set up as part of the operationalisation of the Regulatory Risk statement in 2021, has met on six occasions to date, with two meetings held in 2022. The Group has analysed five identified regulatory risks to date and made recommendations for consideration by the Executive Leadership Team as to actions to be taken to assist in mitigating the risks identified.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Business Transformation Programme Update

The Business Transformation Programme is entering into a new phase of delivery with the implementation of phase 1.1 (an additional stage to phase 1), which incorporates some elements that were not completed within phase 1 and some elements from phase 2 (complaints, queries and concerns) that relate to registration ie the application of conditions to registration. Phase 1.1 is currently at definition and planning stage and will see an agreed scope of future system enhancements being made to the new online registration system.

As part of the ongoing embedding of the new 'REGIE' system, significant supports have been put in place to help both internal and external users to use the new system. The PSI continues to encourage feedback from all users. To date, feedback has been received on areas for improvement and areas that have worked well, all feedback and retrospective learning will be considered as part of the continuous improvement of the system.

Organisation Development Project (ODP) Update

We continue to implement the agreed ODP changes, with this implementation phase scheduled to run through to October 2022. The project is overseen by the Executive Leadership Team (ELT) as the Steering Group and with the support of a Coordination Group, comprising individuals from across the organisation who are involved in key elements of implementation at this time.

The implementation plan for this phase is broken down into three workstreams: 1) Governance and Communications, 2) Change the Way we Work and 3) Develop our People, and all remain in progress. Delays to our progress were acknowledged in December and while there is successful progress occurring in several areas, the project Steering Group is examining prioritisation of detailed next steps for implementation as a whole. As part of the mid-February Stage Gate review, the Steering Group has assessed useful feedback on implementation of the project to date from a short survey of the wider management team and the ELT. This project is an important one for the PSI and runs alongside other significant work being undertaken, including the business transformation project, and other strategic and operational commitments.

Under workstream two, our Programme Delivery function was set up and launched at the start of February. Our aim is to standardise the approach to project management across the PSI, increase

efficiency, and contribute to prioritisation and resource capacity planning over time. The roll-out of project supports and templates to project managers and management has taken place, making use of the DPER/Public Service project management toolkit that has been adapted for use within the PSI.

Strategic HR Update

- **Workforce planning and recruitment:**

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

- Business Support Services Assistant (Permanent)
- Head of Practitioner Assurance (Fixed-term - Secondment backfill)
- Regulatory Solicitor (Permanent)

We have one competition ongoing (Project Pharmacist) and have received sanction to recruit for the post of Registrar/Chief Officer which will be commenced shortly.

Business cases for six replacement posts are currently with the Department of Health for sanction.

- **Business continuity and blended working:** In line with the Government announcement at the end of January 2022, we are actively planning a phased return to the office and advised staff that attendance in the office no longer requires a business need. Staff have also been advised that they will be required to be onsite, starting with one day a week in March to meet with their team members. A staff survey has been issued, the results of which in conjunction with public health guidance at the time will inform the requirements for the remaining phases.

Disciplinary Committee development

The PSI is committed to supporting its Disciplinary Committees in the performance of its statutory functions under Part 6 of the Pharmacy Act 2007 and in the particular, provides continuous training to members around and legal and regulatory basis for the consideration of complaints against pharmacist and pharmacy owners.

On 12 January Fitness to Practise Induction Training was carried out for new Preliminary Proceedings Committee members, and on 17 February, Fitness to Practise Induction and Refresher training was carried out for new members of the Professional Conduct Committee.

ICT Security

The PSI continues to monitor and improve its security profile. All recommendations from the August 2021 Penetration test report were completed in December with the implementation of the low priority recommendations. Our first penetration and vulnerability testing of 2022 started in February with report to be provided in March. This will validate the improvements made and apply the industry standard tests for PSI's ICT security.

End of year reporting for 2021

Compilation of the annual report for 2021 is at an advanced stage and the external auditors are completing their audit on the PSI's financial statements for the year. Following consideration by the management and relevant committees, the annual report and audited financial statements for 2021 will be provided to the Council for its 24 March meeting, before they may be submitted to the Minister for Health by 31 March, in accordance with our statutory requirement.

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

Service/goods to be Procured	Current Status
Remote Hearings	<ul style="list-style-type: none">• Draft PQQ prepared incorporating recommendations from external procurement advisers• Next steps: finalise and issue PQQ by end of February subject to an assessment of future online inquiry needs.
Legal Services	<ul style="list-style-type: none">• Tender process complete.• P&R Committee approval of Interim Registrar's recommendation of successful tenderer via written process.• Tender outcome to be communicated to all tenderers by OGP.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 17 Feb 2022)

For the purposes of this appendix, please note that references to '*last report date*' refers to the Registrar's Report dated 07 Dec 2021.

Fitness to Practise (FTP) Concerns

Total new concerns received year to date	19
New concerns received since last report date	24
Concerns reviewed since last report date	21
Open concerns	10

Fitness to Practise Complaints for Screening Committee (PPC)

Total new complaints received year to date	8
New complaints received since last report date	9
Total open active complaints*	55
Complaints considered by PPC remotely since last report date **	8

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

**88% 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	1
Heard (all remotely) since last report *	3
Complaints being investigated/prepared for hearing	37

*2 took place before the PCC and 1 before the HC

Mediation

Total referrals to mediation since last report	2
Total referrals pending mediation	2
Held year to date	0

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

Heard since last report	4
Heard year to date	2
Sanction hearings/undertakings being prepared for Council *	4

*Relating to 7 registrants

High Court Sanction Confirmation Hearings*

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

Appeals

Heard year to date	0
Judgement received in case appealed following fitness to practise inquiry	1

Call-Overs and Other Applications Before Committees of Inquiry

Callovers heard year to date:	
(a) Professional Conduct Committee	(a) 0
(b) Health Committee	(b) 1
Held since last report date	(a) 1
(a) Professional Conduct Committee	(b) 1
(b) Health Committee	

The next PCC/HC callover is scheduled for 09 March 2021

Interim Suspension Applications

Applications heard by Council year to date	0
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Prosecution

Cases being prepared for District Court Prosecution	2
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Professional Registration (figures as of 17 February 2022)

- 0 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.
- 0 EPC applications 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). 1 completed and 1 is in progress.
- 8 Certificates of Current Professional Status have been issued since 1st January 2022.
- 3 Pharmacist Restoration applications in accordance with S.61 have been processed since 1st January 2022.
- 38 Voluntary Cancellation applications and 1 Involuntary Cancellations have been processed since 1st January 2022.

- Since March 2020 all EU/TCQR Registration meetings have been cancelled in light of Covid-19 outbreak.
- 10 Third Country Qualification Recognition (Non-EU/EEA qualified other than UK qualified) applications received to date this year, with 144 applications in total in process.
- 11 Non-National Route registration applications - 9 Third Country (both UK qualified and outside of UK)/2 EU processed to date this year.
- 2 National route applications processed to date this year.

Pharmacists

Pharmacists

No. of New Registration, and Restoration Applications, Including Section-77 Restorations, in the context of the COVID-19 pandemic - 9 March 2020 to 17 February 2022.

No. of new registration applications received which have either been Registered or are in process	Registered	In-process -EU/TCQR (UK qualified)
	551	22
No. of New Restoration Applications Received in Accordance with S.61	Restored	In-process
	41	0
No of S.77 Registrations Applications Received	Registered	In-process
57	34	0

Regulation of Retail Pharmacy Businesses (figures as of 18 February 2022)

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses @ 18 February 2022	1977
Number of Retail Pharmacy Businesses Registered in 2021 @ 18 February 2022	0 New Openings; 0 Permanent Relocations; 6 Changes of Ownership Total = 6
Number of Retail Pharmacy Businesses Cancelled in 2021 @ 18 February 2022	Voluntary Cancellations –

	4 Closure; 0 Permanent Relocations; 6 Changes of Ownership Total = 10
Number of Changes in Supervising and Superintendent Pharmacists in 2022	58

Internet Supply	
Number of Pharmacies on Part A	205
Number of Non-Pharmacies on Part B	162

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

Inspection Activity 2022	
Total number of Inspections (commenced February 2022 following COVID-19 government advice)	6
Number of Registration-related Inspections	0
Number of pharmacy inspections <ul style="list-style-type: none"> - Risk-based Inspections - Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d) 	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	4
Investigation Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		4