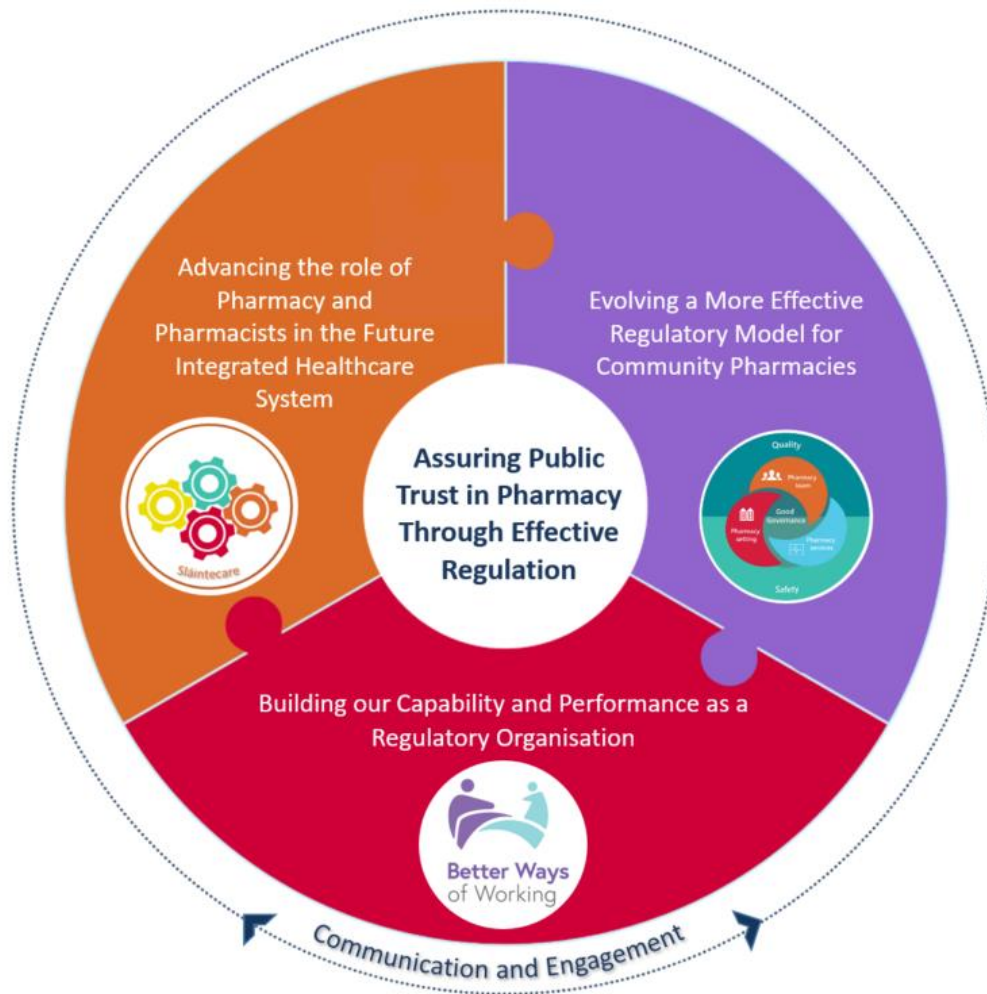




The Pharmacy Regulator
An Rialtóir Cógaisíochta

Report of the Registrar



Report to Council Meeting of 22 April 2021

Highlights from the Registrar

Governance meetings with Department of Health: The first governance meeting of the year was held with representatives from the Department of Health on Wednesday, 7 April. A copy of the agreed minutes from the governance meeting, held between PSI and the Department on 8 December 2020, have been added to the 'General Information' folder on Council iPads.

Elections to Council: The count for the election of pharmacist members to the PSI Council will take place on Friday, 23 April at the offices of the Dublin County Returning Officer, who is assisting the PSI with the election. Suitable arrangements have been made to ensure the count can take place safely while also according with the relevant Rules.

Meeting with the Chairs of the Disciplinary Committees: It is important for the Executive, on behalf of Council, to maintain a dialogue with the Chairs of the Disciplinary Committees around how formal complaints are processed and how fitness to practise matters are heard before the Committees. In keeping with this objective, the Registrar, the Head of Regulation and the Legal Affairs Manager generally met with the Chairs of the Professional Conduct Committee and Health Committees during April. A meeting with the Chair of the Preliminary Proceedings Committee will follow in early May 2021. Items discussed with the Chairs of the Conduct and Health Committee related to remote hearings of inquiries and how these are working in practice, training and development needs for the Committees, the selection process for Committees and the hours during which it is reasonable for a Committee to sit to hear an inquiry. We plan to meet again later in the year.

Update on managing our external response to COVID-19

The PSI COVID response group continues to meet on a bi-weekly basis. There are a number of workstreams ongoing across the organisation in relation to our external response to COVID-19.

- **Roll out of the COVID-19 vaccine programme**

This is a priority area for PSI and work is ongoing on both the approval of the available training courses for the approved COVID-19 vaccines and working with the HSE on the roll-out of the COVID-19 vaccination programme via community pharmacies.

Approval of training programmes for the COVID-19 vaccines: The [Medicinal Products \(Prescription and Control of Supply\) \(Amendment\) \(No.7\) Regulations 2020 \(S.I. 698 of 2020\)](#) allow a registered pharmacist to supply and administer a COVID-19 vaccine where he/she has received training approved by the PSI. To date, the PSI has approved the HSE National Immunisation Office (NIO) COVID-19 vaccination training for the Comirnaty (Pfizer/BioNtech), Moderna and AstraZeneca vaccines.

An expert group has again been convened to review the NIO vaccination training programme for the Janssen COVID-19 Vaccine. The review team has met to discuss the training, with a view to compiling a report which will reflect a view as to whether the training can be approved under Regulation 4F of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (SI 698 of 2020) shortly (this approvals function has been previously delegated by Council to the Registrar).

Preparations for the roll out of COVID-19 vaccinations via community pharmacies: The HSE is preparing to expand the number of locations from which a COVID-19 Vaccination service can be delivered to include suitable community pharmacy locations.

PSI is participating in a vaccination programme subgroup which the HSE has established to discuss and prepare for the roll-out of the service in community pharmacies. The HSE, PSI and IPU have worked together, via this group, over the last number of weeks to develop comprehensive, and supportive, operational guidance on how COVID-19 vaccination services will operate in community pharmacies. This operational guidance, in draft form, has been made available by HSE to pharmacy contractors.

In preparation for the rollout, the HSE has also issued an expression of interest (Eoi) to all community pharmacies requesting that pharmacies conduct risk and capacity assessments to determine if their site is appropriate and safe (premises and staffing levels) for the administration of the COVID-19 vaccines and to determine the number of vaccinations that they could administer safely.

The PSI wrote to all superintendent pharmacists on 31st March to highlight the key governance role of superintendent pharmacists in these preparations and the importance of their clinical leadership in the safe and successful delivery of the COVID-19 vaccination service within their pharmacy/pharmacies.

PSI will continue to work with the HSE as preparations for the roll-out continue over the coming weeks.

- **COVID-19 Operational Standards for Pharmacies:**

The **COVID-19 Operational Standards for Pharmacies** have been developed which aim to provide guidance and support to those in leadership and governance positions in the retail pharmacy sector, in continuing to ensure safe services and a safe environment for patients, public, and staff. The Standards are being implemented initially through a ‘use and learn’ period.



PSI staff completed 16 standards visits between October-December in the initial ‘use and learn period’. Three of these were remote virtual visits and 13 were onsite visits. An expression of interest email was issued to superintendent pharmacists seeking volunteers to facilitate further visits in 2021.

Remote virtual visits are currently being adopted as part of our developing standards methodology and are arranged on an appointment basis. PSI staff undertook 25 virtual visits in the March-April period. Further virtual standard visits are being planned for the coming months. An expression of interest will be issued again, seeking additional pharmacies to participate in virtual standards visits as we continue to develop the virtual standards methodology. A summary overview report will be drafted in the coming weeks for discussion at the RPP Committee, with the intention of presenting the report to Council at its June meeting. This report will reflect learnings, both for pharmacies and for PSI, from the initial ‘use and learn’ period.

- **HSE Community Pharmacy Contingency Planning Forum:**

The PSI continues to participate in the *Community Pharmacy Contingency Planning Forum*, established by the HSE to discuss contingency planning for community pharmacy services in the context of the challenges arising from COVID-19. The group meets fortnightly and answers to the Office of the Chief Clinical Officer (CCO), in the HSE, and is chaired by Dr Philip Crowley, HSE National Director for the Quality Improvement, and co-Lead of COVID-19 public health response. A main focus of the forum at the moment is the COVID-19 vaccinations.

- **COVID-19 Information Hub:**

At the request of the PSI, the IOP developed a single source of up-to-date and comprehensive information on COVID-19 during 2020. This is updated on a continuous basis as new information is available. The IOP recently hosted a webinar on the [Medicines Management in HSE Centralised Vaccination Clinics; The Role of Pharmacists in Vaccine Stewardship](#).



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

Key updates

Core Competency Framework (CCF): Meetings of the Steering Group have been held over the last number of weeks. The project is in the early stages and the Steering Group has been dedicating these initial meetings to clearly identifying the function, role and purpose of the framework, as part of the review, with due regard to the direction of the Council as expressed in the report produced in 2020 on the review of the current CCF. Recent work has also been undertaken in benchmarking how other regulators have undertaken reviews of their competency frameworks.

Review of the CPD Model for Pharmacists: A survey to gain input and feedback from registered pharmacists on the current CPD Model was issued on 1st April 2021. Pharmacists have been made aware of the survey by email, through the PSI Newsletter and through our website. The closing date for submissions is 23rd April 2021. The information gained from this feedback will be used as part of the scoping exercise for this project.

CPD Executives meeting: The Education Unit recently took part in the CPD Executives Meeting (April 9th). The Forum joins CPD providers to share learning on CPD provision. Members include organisations from medical, financial, legal and engineering fields. The focus of the meeting was to share experiences of how the pandemic has impacted the delivery and preferences for the delivery of CPD, how CPD offerings and requirements from organisations have changed, and the associated impact on operations, facilities and working arrangements.

Overprescribing of benzodiazepines: PSI's Head of Policy attended the Medical Council stakeholder group on strategies to reduce overprescribing of benzodiazepines on 18th March. This stakeholder group, which includes representatives from the Medical Council, HSE, HPRA, Department of Health, the PSI and ICGP, is focussed on developing strategies to address the overprescribing of benzodiazepines. The group have also focussed on the additional risk of overuse of opiates and reviewed trend data in the prescribing of opiates provided by the HSE PCRS.

Antimicrobial resistance: PSI has made a submission to the National Patient Safety office to inform the development of Ireland's second *National Action Plan on Antimicrobial Resistance 2021- 2025*, to be called iNAP2.



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

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

- Because of the challenges of Covid-19, the Group has decided that FMD will remain in a use and learn period until further notice.
- PSI newsletter issue 1 (April 2021) featured FMD reminding pharmacists that they are legally required by EU legislation to verify the safety features on the packaging of medicinal products and decommission the product.

Audit of Retail Pharmacy Businesses in Hospital Settings: The PSI continued its work examining the provisions of the Pharmacy Act 2007 as they apply to hospital pharmacy departments registered under the Act as retail pharmacy businesses (RPB). All registered hospital pharmacy RPBs were invited to participate in a survey which allowed further analysis of the nature of the pharmacy services provided and the extent of their provision. The objective was to bring clarity for all involved as to the precise regulatory remit of the PSI in the hospital pharmacies. A total 68 pharmacies engaged in this audit survey by mid-February. A summary of preliminary findings was presented to the Regulatory and Professional Policy Committee on 9th April.

Patient engagement: The Head of Policy participated in a stakeholder engagement process on the development of a draft policy on supporting and facilitating patient representatives as “Patient Voice Partners”. This was hosted by the National Patient Safety Office of the Department of Health.



Building our Capability and Performance as a Regulatory Organisation

Key updates

Organisation Development Project (ODP) update: The Organisation Development Project has completed Phase 1, 'Mobilisation' and Phase 2, 'Current State Analysis'. Phase 3 'Future Organisation Structure' was extended to allow for sufficient considerations of the future Target Operating Model, which is currently undergoing final adjustments. Phase 4 'Develop Change Management Plan' is being prepared and will run until 4 June 2021. During Phase 4, PSI managers and our Change Champion Network will continue to be supported by BearingPoint in guiding PSI staff through the change process. In this Phase, the Change Management Plan and Implementation Roadmap will be developed. Also, an organisation skills assessment and gap analysis will be carried out, and a benefits definition and realisation management plan will be elaborated. The Coaching Programme for the PSI Executive Leadership Team is under way, with a focus on core leadership competencies aligned to the public service competency framework and specific actions to support the delivery of the PSI Corporate Strategy and the ODP Implementation Plan. Updates to staff continue to be provided through remote working channels, Team Brief session and on 'Clinics' with Units. The Leadership Team is very keen that all staff continue to have full opportunity to engage with the process and with our consultants through various channels, including 1:1 discussions.

Business Transformation Project (BTP) update: Phase 1 of the Business Transformation Project, which will deliver our new online system for registration, is progressing well, with an expected go-live date of 26 July. In advance of this, during May and June, a comprehensive round of testing of the final areas of the system that have been developed by our vendor, Codec, will be taking place involving PSI colleagues. Following this, in July, training will be provided to PSI colleagues to support a smooth launch and transition to the new ways of working. Throughout this time, ongoing communication and engagement will be provided to PSI colleagues, keeping them informed and involving them in the changes associated with the new system. We will also be engaging externally with key stakeholders to provide an overview of the new system and its benefits in advance of its launch. Support to staff whose roles are affected by the first implementation is being provided in conjunction with our change management consultants from BearingPoint.

Website project: Work on the requirements for the new website (as part of the procurement process) is at the final stages with the aim of going out to tender under a restricted procedure in the coming weeks.

Social Media activity: We continue to promote the work of PSI via digital communications through Twitter and LinkedIn, both through developing original content and b sharing content from other bodies, where it has public health or safety implications, or where it aligns with our key objectives and messaging.

Freedom of Information: One request was processed since the last meeting of Council.

Strategic HR update:

- Work on the design and development of PSI’s new HR Strategy 2021-2023 has commenced. Our ODP partner, BearingPoint, is providing expertise and inputs and is facilitating the engagement with management and staff into this new HR strategy. A visioning exercise was held with ELT and two workshops are now scheduled with management and staff to help further define the scope of the next HR strategy.
- Our new Regulatory Risk Coordinator was appointed in April 2021 following an open recruitment competition. There is currently one open competition for Regulatory Executive roles and several business cases are with the Department of Health for consideration for sanction.

Training for Disciplinary Committees: All three Disciplinary Committees have now attended training sessions on the amendments to Part 6 of the Pharmacy Act 2007 by the Regulated Professions (Health and Social Care) Act 2020. Those sessions took place over Microsoft Teams and involved a presentation from the PSI’s external legal advisers outlining the amendments to the Act and the impact it would have on the work of the Committees, along with a Q&A for Committee members.

Amended Complaints Guides and Fitness to Practice Procedures – Complainants, Pharmacists and Disciplinary Committees: When the relevant provisions of the Regulated Professions (Health & Social Care)(Amendment) Act 2020 were commenced on the 13th February 2021, this had the effect of either amending or creating new statutory provisions in relation to Part 6 of the Pharmacy Act 2007 which governs the disciplinary proceedings process. These amendments or new provisions in turn required a full review and updating of the suite of information/guidance documents published by the PSI in relation to the Complaints process. This included the Guide for Complainants, Guide for Pharmacists and Pharmacy Owners and Guide to Inquiry Process, all of which have now been updated and re-published on the PSI’s website. In addition, the Procedures for the PSI’s three Disciplinary Committees regarding the exercise of their functions have also now been updated and will shortly be formally reviewed and adopted by the Committees. Finally, any guidance documents for the Council of the PSI when considering fitness to practise matters have also been reviewed and are in the final stages of being adopted by Council.

Expression of Interest – Registered Pharmacists who are Pharmacy Owners: On 30 March 2021, the PSI published an Expression of Interest for its three Disciplinary Committees, seeking applications from registered pharmacists who are either sole traders, or directors of, or shareholders in a corporate body which carries on a registered retail pharmacy business. This is to ensure that the Committees of the PSI

remain quorate in accordance with recently amended provisions of the Pharmacy Act 2007. More information is available on the [PSI website](#). The deadline for applications is 5pm on Friday, 23 April 2021.

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

Services / Goods to be Procured	Current Status
Merchant Acquiring Services and Payment Gateway Services	OGP Single Supplier Framework (Direct Drawdown) being progressed.
Website Re-Design Development, Hosting and Support Services	Restricted Procedure in progress. Work continues on finalising the technical specification as part of the Invitation to Tender document for issuing to shortlisted suppliers (expected in May 2021).

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 9 April 2021)

Please note that the complaint & inquiry processes were suspended from 19 March to 22 May 2020 due to the COVID-19 public health emergency.

For the purposes of this appendix, please note that references to 'last report date' refers to 19 February 2021.

Fitness to Practise (FTP) Concerns

Total concerns received year to date	54
New concerns received since last report date	21
Concerns reviewed since last report date	24
Open concerns with FTP	3

Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received year to date	21
New complaints received since last report date	8
Open complaints	36*
Complaints considered by PPC remotely** since last report date	6***

* This figure may include complaints received prior to 2021 which are still being processed

** Held over Microsoft Teams

*** 100% of which met KPI of PPC decision being made within six months i.e. from when the complaint was received to when the PPC made a final decision

Inquiries

Heard remotely* year to date	4*
Heard remotely since last report	2**
Cases being investigated/prepared for hearing	35***

* Held using a software platform called TrialView

**This figure involves 2 respondents

**(31 – Professional Conduct Committee & 4 - Health Committee)

Mediation

Total referrals to mediation year to date	0
Held year to date	0

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

Heard year to date	2
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Sanction hearings/undertakings being prepared for Council	4
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* This is reported on a per respondent basis.

High Court Sanction Confirmation Hearings*

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

* This figure is reported on a per respondent basis.

Call-Overs and Other Applications Before Committees of Inquiry

Section 44 Applications* (Withdrawal of Professional Conduct Committee Complaint)	0
Callovers heard year to date	1
Held since last report date	1

* Held using a software platform called TrialView

Professional Registration (figures as at 13/04/2021)

Pharmacists

- 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.
- 1 EPC for the temporary & occasional provision of service has been received to date in 2021 and is in process. 0 EPCs for establishment of service have been received to date in 2021 (new European route of entry to recognition and registration)
- 12 Certificates of Current Professional Status have been issued since 1st January 2021.
- 4 Pharmacist Restoration applications in accordance with S.61 have been processed since 1st January 2021.
- 50 Voluntary Cancellation applications and 0 Involuntary Cancellations have been processed since 1st January 2021.
- Since March 2020 all EU/TCQR Registration meetings have been cancelled in light of Covid-19 outbreak.
- 17 Third Country Qualification Recognition (TCQR) applications received to date this year, with 119 applications in total in process.
- 12 TCQR registration applications processed to date this year.
- 10 EU recognition/registration applications processed to date this year.
- 2 National route applications processed to date this year.

No. of New Registration, and Restoration Applications, Including Section-77 Restorations, in the context of the COVID-19 Period - 9 March 2020 to 13 April 2021.

No. of new registration applications received which are recorded on applications record db.	Registered	In-process
310	315 (less than 25 in process prior to 09 March 2020)	11

No. of New Restoration Applications Received in Accordance with S.61	Restored	In-process
25	24	1

No of S.77 Registrations Applications Received	Registered	In Process
57	49*	0

*7 have since fully restored under S.61 and 1 has voluntarily cancelled from the register

Regulation of Retail Pharmacy Businesses (figures as at 13 April 2021)

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses	1,968
Number of Retail Pharmacy Businesses Registered in 2021	34
Number of Retail Pharmacy Businesses Cancelled in 2021	34
Number of Changes in Supervising and Superintendent Pharmacists in 2021	130

Internet Supply	
Number of Pharmacies on Part A	149
Number of Non-Pharmacies on Part B	78

Visits to assess against COVID-19 Standards	
Total Pharmacy Visits	25

Onsite visits	-
Virtual visits	25

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

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
13	2	1
Investigation Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		2