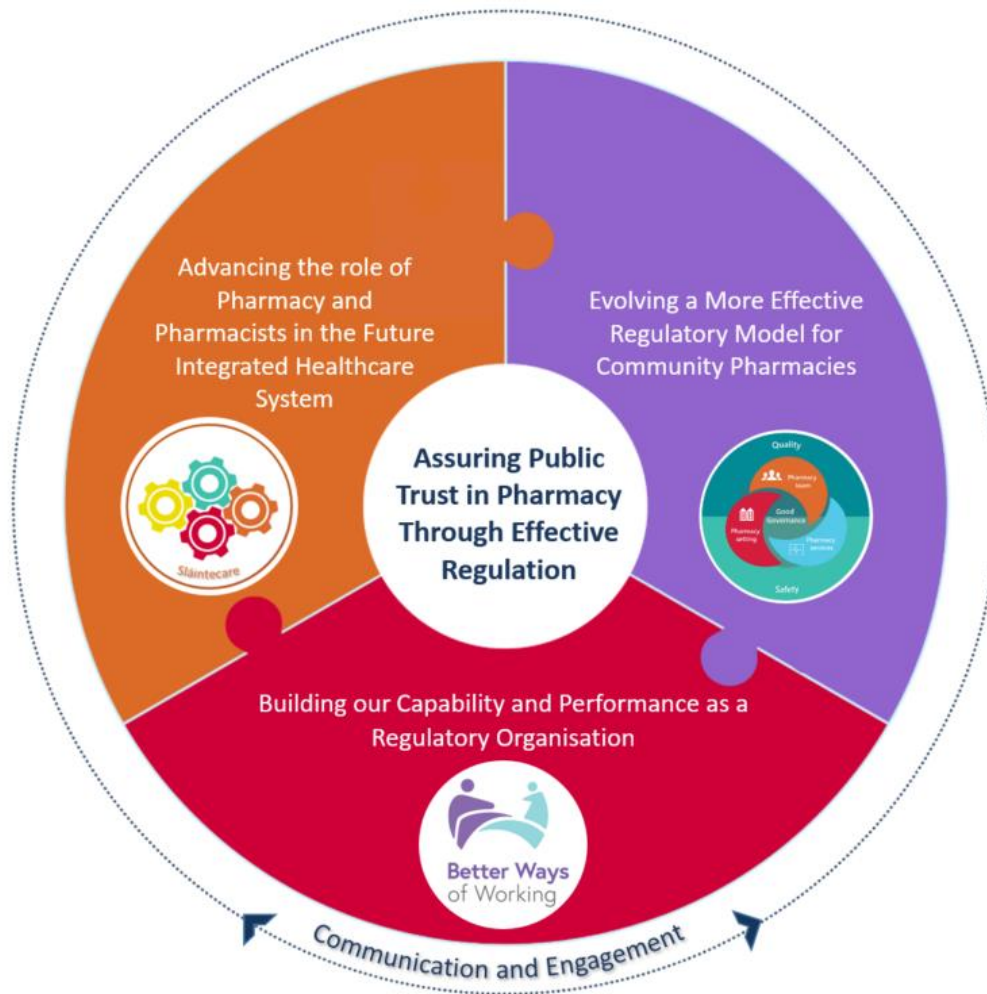




The Pharmacy Regulator
An Rialtóir Cógaisíochta

Report of the Registrar



Report to Council Meeting of 24th June 2021

Highlights from the Registrar

Organisation Development Project: As Council is aware, we have been working on this project, with support from BearingPoint since autumn of last year. Since last reporting on progress in April, intensive further work has taken place in partnership and collaboration with all staff of PSI. We have now reached an important milestone in the project whereby we are sharing the final version of our Target Operating Model with our colleagues in the week of 21 June. Our objective all along has been to develop an operating model which is flexible, adaptable and which facilitates lateral collaboration and cross-functional working. Also, and very importantly, a model which is based on the principle that “structure follows strategy” and which will facilitate the organisation in delivering upon the Council’s current Corporate Strategy. I am very satisfied that this is what we have achieved through the project and through the input and involvement of all of my colleagues. We are now moving into detailed implementation planning which will see us working, with the support of BearingPoint, to implement the model in full over the period to October 2022. A full briefing on the model, on the benefits which it will help realise, and on the detailed implementation plan, will be provided to Council at its meeting on 7 October.

Joint meeting with Secretary-General of Department of Health: During April, I, together with the heads of the other State bodies under the aegis of the Department of Health were invited to a joint introductory meeting with Robert Watt, recently appointed Secretary-General. The meeting took place on 28 April. Mr Watt outlined some of his priorities in relation to taking the helm at the Department. Among these was a commitment to work closely with the various agencies in the interests of delivering on the Department’s key public health objectives, including Slaintecare implementation as well as the ongoing work in relation to COVID-19. He further committed to meet individually with the head of each agency during 2021 to discuss agency-specific issues in more detail. This was welcomed by all in attendance and I am keeping a list of matters relevant to PSI which I would intend to raise at this meeting once it is scheduled.

Elections to Council: The count for the election of pharmacist members to the PSI Council took place on Friday, 23 April at the offices of the Dublin County Returning Officer, whom we had again contracted with to assist PSI with the election process and the count. Suitable arrangements were in place to ensure that the count could take place safely while also meeting the requirements of the relevant Rules. This included online streaming of video of the counting process for candidates and their agents. We were also pleased that Dr. Cecily Roche, MPSI and Mr. John Lynch, MPSI were available on the day to volunteer as scrutineers. The process ran very smoothly, and the results were posted on the PSI website that evening and the Minister notified shortly thereafter. I would like to thank my colleague, Dr. Cheryl Stokes, for her highly effective oversight of all of the arrangements.

Update on managing our response to COVID-19

COVID-19 vaccination training: In May 2021, the Registrar approved, under Regulation 4F (b) of the Medicinal Products (Prescription and Control of Supply) Regulations (SI 698 of 2020), the National Immunisation Office (NIO) training in respect of the Janssen Covid-19 vaccine, for pharmacist vaccinators in supplying and administering this vaccine as part of the COVID-19 national vaccination implementation plan.

Most recently, in June 2021, the Registrar approved the requirements and NIO training in respect of the Comirnaty/ Pfizer BioNtech and the Moderna vaccines, for pharmacist vaccinators in supplying and administering these vaccines, as part of the COVID-19 national vaccination implementation plan, under the governance of retail pharmacy businesses. Prior to this most recent decision, training had been approved for the supply and administration of these vaccines by pharmacists at mass vaccination centres only.

COVID-19 vaccination services via community pharmacies: We continue to participate in the weekly meetings of the HSE group which is overseeing the planning and roll-out of COVID-19 vaccination services in community pharmacies. Since mid-February, the HSE, PSI and IPU have worked together very effectively to put in place the key components (regulatory and operational) to support the safe roll-out of vaccination services via community pharmacies. As we are all aware, the programme has been subject to uncertainties due to vaccine supply issues and side-effect concerns. This has required revisions and re-prioritisation at various stages. It has been very positive to see how the partner bodies have worked together, in the public interest, to overcome these challenges.

As of 14 June, the programme has commenced in community pharmacies with the administration of the Janssen vaccine to people aged over 50. Just under 800 pharmacies are involved in this aspect of the programme. Later in June, a subset, of approximately 350 pharmacies, will begin supporting an extension to further age cohorts with the administration of the Pfizer vaccine. The particular focus here is on supporting local communities that are some distance from the vaccination centres. PSI will continue to work with the HSE to update the relevant operational guidance to take account of the additional requirements for this mRNA vaccine.

We are communicating with all Superintendent Pharmacists responsible for pharmacies involved in the programme to thank them for their participation and to remind them of the regulatory requirements in place to assure the safety of this service. We will continue to work with the HSE as this important public health programme rolls-out via pharmacies over June and into July/August.

Testing for SARS-CoV-2 in pharmacies: The PSI is aware that testing services/kits are being offered to the public via some pharmacies, either directly or in association with third parties. This includes rapid antigen and/or antibody testing, together with PCR testing. PSI have engaged directly with some of the pharmacies involved. The national advice and policy in relation to COVID-19 testing is under continuous review and is evolving. The PSI, therefore, has been engaging with the DoH, HPRA and the HSE to understand the current public health advice on the appropriate use of these particular tests before we communicate any advice to the profession.

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 in early 2020. This facility continues to help ensure that pharmacists have access to a tool to facilitate their ongoing CPD needs in this area, thereby helping to facilitate safe practice on behalf of patients. Th Hub is updated on a continuous basis as new information is available. The IOP recently hosted their 25th webinar on "[Strengthening Our Connections](#)".



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

Key updates

Core Competency Framework (CCF)

The Steering Group, established to oversee and assist in the review and development of a revised CCF, has met four times to date with its next meeting scheduled for Tuesday 22 June 2021. A draft project plan and key milestones are near finalisation.

An Expression of Interest process to establish Working Groups who would support in the delivery of the project, closed on 9 June 2021. PSI welcomed the response from 50 individuals interested in assisting with the Review of the Core Competency Framework for Pharmacists project, representing all sectors including community, role emerging practice, hospital, industry and regulation. The PSI hopes to host a series of workshops over the summer and autumn months to assist in the development of a revised competency framework, as per the recommendations in the report approved by the PSI Council on 8 October 2020.

Review of the CPD Model for Pharmacists

As part of its on-going work on a review of the CPD Model for pharmacists, the PSI conducted a survey of pharmacists between 1 April to 23 April 2021. Over 520 responses were received to the survey, and a report has been generated from the data received. PSI appreciates the input of all those who took the time to participate and share their insights into the current model. The PSI will be hosting semi-structured focus groups with stakeholder organisations in the coming months to further inform the scope of the review.

Meeting with NAHPT

The Registrar and Head of Education meet with representatives of the National Association of Hospital Pharmacy Technicians (NAHPT) on 25 May at the request of the Association. We had a useful discussion regarding the role of the Association and the role of PSI. The Association is interested in, among other things, the possibility of regulation being introduced for their members. We explained what statutory regulation entails and that the creation of new categories of regulated persons is, in the first instance, a policy matter for the Department of Health. We agreed to stay in touch and to meet again when the Association had further considered the whole area of possible regulation.



Evolving a More Effective Regulatory Model for Community Pharmacies

Key updates

Overview Report on COVID-19 Operational Standards for Pharmacies:

We have developed an Overview Report documenting how we developed these Standards and what we learned, on an initial basis, through assessing their impact in a small number of pharmacies. This Report is for Council's consideration at its meeting on 24 June. Currently, our plan is to continue to work with the community pharmacy sector through an extended "learn-and-use" process through to the end of 2021.



Falsified Medicines Directive:

The Head of Regulation attended a number of meetings 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). In recent National meetings, one of the key decisions taken was to end use and learn. However, this date has not yet been finalised.

As part of encouraging registrants with FMD compliance during the use and learn period, the PSI has

1. contacted 135 Retail Pharmacy Businesses (RPB) regarding FMD scanning activity issues.
2. issued an email to 81 RPBs whose FMD scanning activity wasn't detected on the IMVO repository system during selected dates, with an inclusive survey to better understand issues surrounding FMD non-compliance, to be completed by 27th May.

Internet Supply

Uncertainty over Brexit and EU legislation has increased the number of internet supply queries. There are a number of internet supply investigations under review. Registered websites must display the EU common logo on every web page that offers non-prescription medicines for sale.

This is a requirement across the EU which was introduced by the Falsified Medicines Directive. The Directive introduced an obligatory logo that will appear on the websites of legally operating online

pharmacies and approved retailers in the EU. We continue to monitor and audit registered internet supplier websites for compliance under the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, notifying any registered supplier of issues of compliance. We have recently added a Frequency Asked Question on our internet supply page to improve engagement with public and registrants.

Crime Prevention

We are liaising with the Garda National Crime Prevention Unit and their network of Crime Prevention Officers who carry out checks on controlled drugs safes and provide security advice to pharmacies throughout the country. We will be issuing advice on storage of Controlled Drugs Keys in our next newsletter.

Specialist Surveyors

We have awarded a contract for specialist surveyor (mystery customer) services over the next two years. The specialist surveyors will be utilised to assess quality and safety aspects of specific pharmacy services (to be determined) in the coming year. The surveyors are also utilised to provide information in respect of specific pharmacies which are the subject of concerns from members of the public.

Supervising/Superintendent Pharmacist regulation

We continue to review all applications of Supervising and Superintendent Pharmacists Requirement under sections 27(c), 28(b) and 29(c) which state that at the premises where a retail pharmacy business is carried on, there must be “a registered pharmacist who has a 3 year minimum post-registration experience in whole time charge of the carrying on of the business there” and for a Superintendent Pharmacist under sections 27(b), 28(a) and 29(b) which state that in the carrying on of a retail pharmacy business “the part of the business that consists of the management and administration of the sale and supply of medicinal products is under the personal control of a registered pharmacist who has a 3 year minimum post registration experience”. We perform regular audits of compliance to ensure that pharmacies are complying with this legislation. We are receiving reports of pharmacy owners having difficulty in sourcing supervising pharmacists, this obviously leads to longer lead time in appointing supervising pharmacists. The situation is monitored continuously.



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', Phase 2, 'Current State Analysis' and Phase 3 'Future Organisation Structure'. The Target Operating Model (TOM) and Organisation Structure have been approved by the Steering Group. Phase 4 'Develop Change Management Plan' is currently extended for 10 days until 15 June 2021 to allow for sufficient considerations of the Implementation Plan, and in particular the comprised organisation wide Skills and Competencies Assessment Analysis and Development Plan (training plan). The Implementation Plan also includes an Implementation Roadmap and Action Plan; a Communications & Engagement Plan and a Benefits Realisation Log, and will be the basis for the work throughout Phase 5 of ODP. The external consultants from BearingPoint will have a more advisory role in Phase 5, and the Executive Leadership Team will take charge of the implementation process and will continue to give all staff full opportunity to engage with the process. The Coaching Programme for the PSI Executive Leadership Team is continuing through Phase 5, 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.

Business Transformation Project (BTP) Update:

The final round of User Acceptance Testing (UAT) for Phase 1 of the BTP commenced 6 May and is nearing completion. The launch of this phase, which will deliver our new online system for registration, is scheduled for the end of July. In advance of launch, we will be hosting a number of meetings with representative organisations, superintendents, and pharmacy owners to provide an overview of the system and its benefits. Training for PSI colleagues, delivered by our technology partner, Codec, will take place week commencing 19 July. Phase 2 of the project, which will be a new system for the management of Complaints, Queries and Concerns, will commence in September.

Strategic Financing Review (SFR) Update:

Following Council's agreement of the parameters that set the scope of the Strategic Financing Review (SFR), work has been progressing on defining the elements that will inform the various scenarios that will be used for modelling purposes. The key assumptions underpinning each scenario have been agreed with the Chair of the Performance and Resources (P&R) Committee and are being shared for comment with the P&R Committee. Each scenario is intended to create a suitable level of

differentiation to accommodate as wide a range of options for consideration. The three scenarios address the following: (i) maintenance of status quo; (ii) full corporate strategy implementation; and (iii) full corporate strategy implementation and assume worst case scenario for other assumptions. The plan is to base the prospective expenditure analysis and financial projections on these three agreed scenario assumptions and present these to the P&R Committee at its 1 September meeting.

Strategic HR Update

- **HR Strategy 2021-2023:** Engagement with management and staff to input into the new HR Strategy took place over 4 separate workshops in May and June, providing informed insights into organisational and individual needs. Key objectives were approved by the Performance and Resources Committee at its 19 May 2021 meeting and the HR Strategy 2021-2023 will be presented to Council for adoption at its 24 June meeting following its approval by the Executive Leadership Team on the 15th of June.

- **Workforce planning and recruitment:** Two *Regulatory Executives* were appointed in May and June 2021 following an open recruitment competition. Initially, they will respectively be supporting the Education and the Fitness to Practise and Legal Affairs teams. The recruitment for a permanent *Quality Assessor – Pharmacy Services* is ongoing. Several business cases for replacement posts are pending submission to, or with, the Department of Health for consideration for sanction.

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 Frameworks (Direct Drawdown) being progressed.
Website Re-Design Development, Hosting and Support Services	Restricted Procedure in progress. The Invitation to Tender document and related draft terms and conditions for issuing to shortlisted suppliers is close to being ready for publication.
Public Affairs and Communication Advisors	Competition specific Secondary Request For Tender (SRTF) has been drafted and provided to the Office for Government Procurement (OGP) who will support the running of this OGP Mini-Competition for PSI. The draft SRTF is currently under review by the OGP Category Specialist Team.

Redevelopment of the PSI website

We recognise that our website is an important source of information, which should support our mission and meet stakeholder needs. We have finalised a tender process, which will be made available on the eTenders website imminently to the bidders shortlisted from the first stage of the process. This will allow us to implement a contemporary and flexible PSI website that supports and facilitates all PSI digital offerings, aiming to enhance and increase visitor engagement with improved opportunities for awareness-raising about our role for all our customers.

Communications Strategy

In order to underpin the Corporate Strategy 2021-2023, we have prepared a Communications Strategy for 2021-2023. The Communications Strategy was developed in response to feedback received as part of the public consultation on the Corporate Strategy and in response to research conducted under the previous Communications Strategy. We have also been holding workshops internally to develop a communications and engagement plan to sit under the Strategy.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 14 June 2021)

For the purposes of this appendix, please note that references to 'last report date' refers to the Registrars Report dated 9 April 2021.

Fitness to Practise (FTP) Concerns

Total new concerns received year to date	76
New concerns received since last report date	22
Concerns reviewed since last report date	20
Open concerns with FTP	12

Fitness to Practise Complaints for Screening Committee (PPC)

Total new complaints received year to date	37
New complaints received since last report date	14
Total open active complaints	36*
Complaints considered by PPC remotely since last report date	22**

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

** 86% 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

Heard remotely* year to date	5*
Heard remotely since last report	1**
Cases being investigated/prepared for hearing	41

* (3 Professional Conduct Committee & 2 - Health Committee).

** This hearing stands adjourned and is not yet completed. This is a Health Committee matter.

Mediation

Total referrals to mediation year to date	2
Held year to date	0*

*2 expected to be heard in early Q3

Sanction Hearings/ Undertakings/Dismissals/Applications before Council*

Heard year to date	3
Sanction hearings/undertakings being prepared for Council	3

* 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	1

* This figure is reported on a per respondent basis.

Call-Overs and Other Applications Before Committees of Inquiry

Callovers heard year to date	1
Held since last report date	0

The next callover is scheduled for 15 July 2021.

Interim Suspension Applications

Applications heard by Council year to date	1
Held since last report date	0

Professional Registration (figures as at 17 June 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 application for the temporary & occasional provision of service has been received to date in 2021 and is in progress.
- 3 EPCs for establishment of service have been received to date in 2021 (new European route of entry to recognition and registration). 2 have been completed and 1 is in progress.
- 21 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.
- 63 Voluntary Cancellation applications and 13 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.
- 21 Third Country Qualification Recognition (TCQR) applications received to date this year, with 116 applications in total in process.
- 21 TCQR registration applications processed to date this year.
- 20 EU recognition/registration applications processed to date this year.
- 5 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 pandemic - 9 March 2020 to 17 June 2021.

No. of new registration applications received which are recorded on applications record db.	Registered	In-process
330	337 (less than 25 in process prior to 09 March 2020)	7

No. of New Restoration Applications Received in Accordance with S.61	Restored	In-process
27	24	3

No of S.77 Registrations Applications Received	Registered	In Process
	46 to date	0

Regulation of Retail Pharmacy Businesses (figures as at 10th June 2021)

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses	1,970
Number of Retail Pharmacy Businesses Registered in 2021	58
Number of Retail Pharmacy Businesses Cancelled in 2021	48
Number of Changes in Supervising and Superintendent Pharmacists in 2021	213

Internet Supply	
Number of Pharmacies on Part A	158
Number of Non-Pharmacies on Part B	102

Visits to assess against COVID-19 Standards (YTD)	
Total Pharmacy Visits	25
Onsite visits	0
Virtual visits	25

Inspection Activity 2021	
Total number of Inspections	4
Number of Registration-related Inspections	1
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) 	3

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
17	4	0
Investigation Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		6