

Report of the Registrar



Report to Council Meeting of 12 December 2019

Highlights from the Registrar

- Launch of the Code of Conduct for Pharmacists:** The launch of the Code took place on the 25th September 2019 at a very successful event in the Irish Architectural Archive. As part of promoting the Code and engaging with our stakeholders on the new Code, we provided press releases to trade and national media. The launch received a range of coverage across national and trade publications, including the Irish Examiner, Independent.ie, the Avondhu, IPU Review and Irish Pharmacy News.

Engagement roadshows were also held in conjunction with the Launch with a total attendance of almost 200 pharmacists:

Dublin City (PSI House)	25th and 26th September	57 attendees
North Dublin	1 October	44 attendees
Galway	2 October	34 attendees
Limerick	9 October	40 attendees
Athlone	10 October	23 attendees

Due to unforeseen circumstances the event in Cork did not take place and it is planned this will now be held early in 2020. Feedback from attendees at each event was very positive and there was a clear desire among attendees for PSI to host more events of this type on a regional basis. We plan to run a range of engagement events during 2020 in cooperation with the pharmacy sector.

- Service Plan 2020:** Having commenced the process of business and budget planning for 2020 in August and discussed proposed priorities with Council on 24 October, the draft 2020 Service Plan and Budget are for decision by Council on 12 December. The Service Plan is designed to further advance the strategic priorities under our current Corporate Strategy, as we move into its final year. The input of PSI staff and of Council members has been important in deciding which, of potentially many priorities can, and should, be advanced in 2019.
- Next Corporate Strategy:** Amongst the key priorities to pursue in 2020 will be the Council's development of the PSI's next Corporate Strategy. The process, the required planning and timelines for this work will be considered by the Council and PSI Executive in early 2020.
- Judicial Review proceedings:** A further affidavit on behalf of the Council was submitted during October. The matter was due for mention before the High Court on 2 December but was put back to 13 January 2020 as a request for voluntary discovery is due to be served on PSI. We have yet to be served with the letter seeking voluntary discovery.

- **Building collaboration with other Regulators:** Since earlier this year, I have been working with an informal group of other regulators (representing the Mental Health Commission, Charities Regulator, Food Safety Authority, Sea Fisheries Protection Authority, Central Bank and Dental Council) to explore structures which would support and enable mutual learning and collaboration across the regulatory community in Ireland. As part of this, the group hosted a seminar with Professor Malcolm Sparrow from Harvard at Dublin Castle on 5 December. This attracted an audience of Chief Executives and senior managers from across a diverse range of regulatory bodies. The group will now follow-up with attendees and central government to see if there is willingness to commit to develop a structured “community of practice” along the lines of the *Government Regulatory Practice Initiative* in New Zealand (see <https://g-reg.govt.nz/>).

Key external meetings and events attended since the 19 September Council meeting:

25 & 26 September: I attended evening Code of Conduct information events at PSI House.

2 October: I attended the evening Code of Conduct information event in Galway.

3 October: Together with PSI colleagues, I met with representatives of the Irish Pharmaceutical Healthcare Association, at their request, to provide OSI with an update on their activities and strategy.

3 October: Together with PSI colleagues, I met with representatives of the Irish Pharmacy Students Association. We now meet the Association twice annually to ensure good communication is in place between PSI and the Association.

7 October: Together with our Head of Policy, I met the head of the Commission for Utility Regulation to discuss the recent review of CRU which was conducted by the OECD.

9 October: I attended the evening Code of Conduct information event in Limerick.

17 October: Together with our Head of Policy, I attended a further meeting at the Medical Council of the multi-stakeholder group which is discussing ways to reduce benzodiazepine use in Ireland. The group will meet again in January and PSI has volunteered to assist with drafting an action plan.

22 October: I attended a meeting of the informal group of regulators exploring structured collaboration (as referred to earlier).

5 November: Together with our Head of Professional Development & Learning, I met representatives of the IIOIP to discuss strategy issues.

8 November: Together with our Head of Corporate Governance I met consultants who are engaged in work to review governance procedures and practices at the Veterinary Council.

13 November: I, together with PSI colleagues, attended the National Patient Safety Conference.

19 November: I, together with PSI colleagues, met the management team of the HPRA for one of our regular liaison meetings.

19 November: On the invitation of the IPU, I attended an evening event where, together with representatives of the Department of Health and HSE, we met with the Chief Pharmaceutical Officer of the Scottish Government.

27 November: Together with our Head of Corporate Governance, I attended the third governance meeting of the year with Department of Health officials. This meeting also coincided with the President's attendance to meet Department officials for the first review of the PSI's *Performance Delivery Agreement and Oversight Agreement*, which is a requirement under the Code of Practice for the Governance of State Bodies. The minutes of the previous governance meeting have been made available on Council members' devices.

5 December: Together with PSI colleagues, I attended a collaboration event for regulators at Dublin Castle (as referred to earlier).



Promoting professionalism and quality in pharmacy

We will act to support professionalism within pharmacy and the delivery of safe and reliable pharmacy services.

Key updates

- **Governance and Accountability Standards:** This project has advanced well in 2019. Given the degree to which Standards development is new to the sector and to PSI, more time is required to ensure that Standards are developed which are fit-for-purpose and which are the product of extensive consultation. This project is a priority under the proposed Service Plan for 2020.
- **National Patient Safety Conference:** The PSI took a stand at the National Patient Safety conference on 13th November 2019, where general information on the PSI was provided, as well as information on our Regulatory Risk Statement and the updated Code of Conduct.
- **Code of Conduct activities:** In order to promote the revised Code of Conduct, we communicated directly to all pharmacists and placed advertisements in the Irish Pharmacist, Irish Pharmacy News and the IPU Review. Feedback forms/satisfaction surveys were provided to attendees at our initial information events - feedback was uniformly positive with 100% of those replying agreed that the seminar was a useful way of learning more about the Code of Conduct.
In tandem with hosting these events, PSI staff have developed a suite of resources, (including two videos, FAQ tools and an ethical decision-making framework) to support the launch and ongoing use of the Code. This information is available in a dedicated section of the [PSI website](#) and forms part of the materials to be used in the continuing roll out of the Code. Further initiatives relating to the Code will be undertaken as part of Service Plan 2020.
- **CPD - Practice Review:** The fourth Practice Review event took place on 19th and 20th October. A report on the Practice Review event will be issued to the PSI from the IIOP in December. A total of 86 pharmacists were notified of their selection for the Practice Review event in April 2020.
- **Student placements:** To date, our two 4th year pharmacy students undertaking their experiential placements at PSI, have been involved in significant projects across different

departments in the PSI to gain experience in relation to our varying functions and work areas. Both have integrated very well with their PSI colleagues and will complete their 16-week placement with the PSI on 22 December. Their contribution and fresh attitudes are a welcome addition to the process of ongoing development and change in PSI.



Impacting through collaboration and engagement

We will deepen our engagement and communication with stakeholders to ensure our work is making an impact and that we are focused on the key outcome areas.

Key updates

- **National Clinical Guideline Development:** The PSI continued to contribute to the HSE Identification, Diagnosis and Treatment of Tobacco Addiction - Clinical Practice Guideline Development Group. This group forms part of the [HSE Tobacco Free Ireland Programme Implementation Plan 2018-2021](#).
- **Presentation to Pharmacy Students:** On 14 October 2019 and 31 October 2019, the PSI presented to TCD pharmacy students on the developments in pharmacy practice in recent years and the role of the pharmacist.
- **IPL Working Group:** The Education Unit participated in a second session with the Interprofessional Learning (IPL) Working Group on 18 October 2019. This Group, representative of a number of healthcare professional regulators, is working to advance the development of interprofessional learning in the education of future healthcare professionals in Ireland.
- **HSE Video:** The PSI was pleased to participate in the HSE's Winter Ready campaign this November. The HSE approached the PSI initially for assistance in communicating with pharmacists about the opportunity to participate in their Winter Ready campaign. We were then invited to take part in one of the short videos for HSE social media, the aim being to encourage the public to prepare adequately for the winter months and to understand the role their pharmacist might play in that preparation. We believe this was a useful opportunity to highlight the role of a regulated community pharmacist and to promote an important public health initiative. The video has been shared on the HSE's Facebook and Twitter platforms, and on the PSI Twitter account.



Regulating effectively for better health outcomes and patient safety

We will regulate in ways that are proportionate, effective and risk-based, with a focus on the key areas relevant to patient health and safety.

Key updates

- **Falsified Medicines Directive:** The Head of Regulation and the Head of Policy 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). This group has been closely monitoring progress since go live on 9th February 2019. The system has been in a ‘use and learn’ period to allow additional time for the system to stabilise. The ‘use and learn’ period will end on a phased basis from Jan 31st 2020.

As part of our ongoing collaboration with the Irish Medicines Verification Organisation, Authorised Officers visited pharmacies to assess the implementation of the Falsified Medicines Directive. During the 63 visits, pharmacists were asked about the issues they are encountering while scanning the 2D barcodes on medicinal products. While all pharmacists were aware of the requirement to scan, multiple pharmacists reported having issues with their scanning software and demonstrating they were scanning on a continuous basis.

- **Regulatory risk:** PSI staff presented a poster on the development of the PSI’s Regulatory Risk Statement at the National Patient Safety Conference on 13 November. This was very well-received by attendees at the poster round.
- **Audit of Retail Pharmacy Businesses in Hospital Settings:** An audit of registered retail pharmacy businesses in hospital settings has been carried out in 2018 & 2019. The first part of the audit was to ensure that only those pharmacies that fall under the definition of a Retail Pharmacy Business (RPB) in the Pharmacy Act 2007 (the “Act”) are registered. [Under the current legislation, the registration of a hospital pharmacy as an RPB is only required where the hospital pharmacy sells or supplies, in the course of its overall activities, any medicinal products to outpatients, to staff or to patients on discharge.] The second part of the audit carried out over the summer sought to explore the nature and level of such services provided from those registered pharmacies.

Overall, 72 pharmacies in hospital settings state they are engaged in one or a combination of dispensing to outpatient, staff, patients on discharge. One pharmacy cancelled registration, and one had been re-categorised as a community-based pharmacy. A further four pharmacies had been identified as no longer deemed to be engaged in the range of activities which would fall within the definition of a retail pharmacy business as set out in the Pharmacy Act and have therefore been contacted regarding cancellation of their registration.

The nature and level of services provided by the pharmacies that fall under the definition of the Act varied considerably. Overall

- **58%** reported dispensing and/or sale of OTC medicines to **Staff**
- **78%** reported dispensing to patients on **Discharge**
- **92%** of RPBs in hospitals reported dispensing to **Outpatients**.

A presentation on the results of the audit was provided to the Regulatory and Professional Policy Committee at their recent meeting. The PSI Service Plan for 2020 will include the continuation of this work in relation to retail pharmacy businesses in hospital settings.

- **Council Training:** A training session for Council which focused on its statutory role in the imposition of sanction was held on 21 November 2019.
- **Disciplinary Committee Training:** A further training session was held on 5 December for the Health Committee and the Professional Conduct Committee, focusing on matters relating to the effective discharge of their role as part of the inquiry process. This was the Committees' second training session in 2019.



Building an effective organisation and benchmarking our performance

We will build an agile and high-performing organisation, capable of delivering on our mission and have our performance independently assessed.

Key updates

- **Advisory Committees:** The review of the operation of the Council's Advisory Committees was completed in October with a workshop session held as part of the Council's Development and Planning Day. The feedback is, overall, very positive, while noting that the new committees are still in their early stage of operation. The Special Purposes Committee met to consider particular aspects of that feedback at a meeting in November and an update on this will be provided at the December 2019 Council meeting.
- **Revised scheme of delegation:** As previously reported to Council, the Executive has been undertaking work to review the existing delegations of Council, further to recommendations from the Better Boards review of Council's committee sub-structure. While this work has progressed, due to competing priorities, it is not yet complete. The intention remains to simplify and clarify all delegations, to remove any unnecessary delegations and to generally assign to the Registrar responsibility for all administrative functions under the Act. This will enable PSI to operate effectively and efficiently while ensuring appropriate oversight from Council and that appropriate functions are reserved to Council. A revised scheme of delegation will be brought to Council for approval at its February meeting.
- **EFQM:** Further to being awarded the EFQM 4* recognition for excellence, four PSI staff members attended the annual EFQM conference, held this year in Helsinki during October. PSI participants attended workshops on the newly-revised EFQM model, the EFQM Innovation Lens and the EFQM Circular Economy Lens. Our 2020 Service Plan will see PSI continue to utilise and embed the EFQM framework in our planning, delivery and analysis of our work. PSI Council members can review the suite of documentation relating to the PSI's EFQM submission and feedback on their devices.
- **Business Transformation Programme:** Following the Council meeting in September, contracts have now been signed with Codec for delivery of our Digital Services Transformation Project through the Master Services Agreement and via the first Call-off Contract as approved by Council in September 2019.

Project mobilisation has been overseen by our recently-appointed Business Transformation Project Manager working with the Codec project team and with PSI's

Business Analyst and Product Owners for Registration and for Finance, together with our in-house Subject Matter Experts.

- **Implementation of revised EU Directive on Payment Services (3D Secure 2):** In order to comply with a 2015 EU Directive, a new 3D Secure online payment procedure was introduced in November on the PSI registration website to ensure registrant card details are secure and safe. All online card transactions now have an extra step to authenticate payments to the PSI. The new 3D Secure 2 (3DS2) protocol is an authentication protocol that was designed to reduce fraud, increase customer security and reduce merchant liability to chargebacks. It is also the solution for the upcoming Strong Customer Authentication (SCA) regulations.
- **Sustainability at the PSI:** To raise awareness among our staff of our individual and organisational impact on the environment and ways we can alter our behaviour to minimise this impact, the PSI's Workplace Safety & Environmental Sustainability Committee, with the assistance of our pharmacy students on placement, organised a series of events as part of Global Climate Change Action Week at the PSI, from the 29 October – 1 November.
- **Workplace Wellbeing:** During 2019, the Workplace Wellbeing Group was very active and organised events throughout the year to enhance the physical and mental health of PSI staff. Such events included restorative yoga classes, the September 'Step' Challenge, a Mental Health workshop facilitated by Mental Health Ireland, in addition to fundraising events to raise money for this year's staff charities of choice in support of combating homelessness.
- **Workforce matters:** recruitment for the following sanctioned posts is as follows:
 - Acting Education Manager: maternity leave backfill cover role competition concluded successfully with interviews held on 29 November.
 - Finance Officer: competition closed on 28 November with interviews to be progressed.
 - Quality Assessor – Pharmacy Services: competition commenced on 4 December with a closing date of 19 December.

Three further competitions are in development for progressing prior to year-end.

- **Employee Engagement:** Further roll-out of our HR Strategy 2018-2020 (Building capability through people) continues with our second Staff Engagement Survey to be administered to staff in December. Our Engagement Survey Action Group (ESAG), comprising staff from across the organisation, has been progressing development of the Action Plan that emerged from the 2018 staff engagement survey. That Action Plan was accepted by the Executive Leadership Team and the ESAG is now monitoring its implementation. The ESAG also contributed to the content of the second survey and will have a role in reviewing the resulting report.

- Innovation at the PSI:** The public sector-wide framework for continuous development and innovation – [Our Public Service 2020](https://ops2020.gov.ie/app/uploads/2019/08/Our-Public-Service-2020-WEB.pdf) (see <https://ops2020.gov.ie/app/uploads/2019/08/Our-Public-Service-2020-WEB.pdf>) – contains 3 pillars, one of which is focussed on ‘Innovating for our Future’. The first Public Sector Innovation Week takes place 9-13 December 2019 and to mark this at PSI, a series of initiatives will be taking place over the course of that week to prompt and stimulate our engagement with innovation¹. All Secretaries General of Government Departments and Heads of Agencies have been requested to sign up to the Declaration on Public Service Innovation which PSI will also do during Public Sector Innovation Week. A number of staff are attending the half-day Innovation Conference on 10 December and staff also attended the DPER-organised half-day event on 30 October on “Our People, Our Future”: Building a Diverse and Innovative Public Service.
- Update on current procurement activity for contract values in excess of €25K:

Services / Goods to be procured	Current Status
Digital Transformation Services	PROCUREMENT COMPLETE
Specialist Surveyors	Restricted Procedure utilised – Pre-Qualification Questionnaire phase completed. ITT phase is currently in progress. The closing date for receipt of Tenders is 11 th December.
Facilities Management	Preferred supplier has been informed and meetings are planned for commencement date and contracts to be finalised.
Website Development & Build	Restricted Procedure utilised on eTenders with the Pre-Qualifying Questionnaire published on 25 November 2019, closing date on 7 th January 2020

¹ The definition of innovation contained in the new EFQM model which we will adopt as our approach in first instance is:

Innovation is the practical translation of ideas into new or existing products, services, solutions, processes, systems, organisational structures or social interactions.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 29 November 2019)

Fitness to Practise Concerns

Total concerns received in 2019	139
New concerns received since last report date (6 September)	37
Concerns reviewed since last report date (6 September 2019)	28
Open concerns FTP	33

Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received in 2019	59
New complaints received since last report date (6 September 2019)	6
Open complaints	24*
Complaints considered by PPC since last report date (6 September 2019)	20

* This figure may include complaints received prior to 2019 which are still being processed

** 90% 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 year to date	11*
Inquiries opened to date but adjourned / not completed	1
Heard since last report (6 September 2019)	4
Cases being investigated/prepared for hearing	29**

* 73% of which met KPI for the Inquiry to be held within 2 years from when the complaint was received.

** (24 – PCC & 5 - Health Committee)

Mediation

Total referrals to mediation 2019	4
Held year to date	2*
Consent not received from the parties	3**
Held since last report date (6 September 2019)	1
Cases being prepared for mediation	0

*This figure includes one complaint referred to mediation in 2018.

** None of these were complaints of the Registrar.

Sanction Hearings/ Undertakings/Dismissals before Council*

Heard year to date	12**
Sanction hearings/undertakings being prepared for Council	2

* This is reported on a per respondent basis.

** One of these cases involved an Inquiry which was held in 2018.

High Court Sanction Confirmation Hearings*

Heard year to date	2
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

Callovers* heard year to date	3
Since last report (6 September 2019)	0
Section 44 Applications (Withdrawals)	2

* A further Callover is scheduled take place on 6 December 2019.

Prosecutions

Heard year to date	0*
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* Proceedings were commenced in 2018 for a case however the case was withdrawn by Registrar at the District Court on foot of action taken by pharmacist Defendant in February 2019.

Suspension Applications

Heard year to date	0
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Professional Registration (figures as at 29 November 2019)

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.
- 18 EPCs for establishment of service have been received (new European route of entry to recognition and registration) – 14 EPCs have been granted, 1 has been withdrawn, 1 has been refused and 2 are in process.
- 57 Certificates of Current Professional Status have been issued to date.
- 24 Restoration applications from pharmacists have been processed to date.
- 99 Voluntary Cancellation applications and 19 Involuntary Cancellations have been processed since 1st January 2019.
- 11 EU/TCQR Registration meetings have been held to date this year.

- 30 Third Country Qualification Recognition applications received to date this year, with an additional 67 applications in process.
- 5 TCQR registration applications processed to date this year.
- 190 EU recognition/registration applications processed to date this year.
- 163 National route applications processed to date this year

Professional Registration (figures as at 29th November 2019)

Regulation of Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses	1952
Number of Retail Pharmacy Businesses Registered in 2019	221
Number of Retail Pharmacy Businesses Cancelled in 2019	214
Number of Changes in Supervising and Superintendent Pharmacists in 2019	597

Internet Supply	
Number of Pharmacies on Part A	52
Number of Non-Pharmacies on Part B	77

Inspection Activity 2019	
Total number of Inspections	263
Number of Registration-related Inspections	106
Number of pharmacy inspections	157
- Systems	3
- Risk-based Inspections	71
- Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)	19
- Falsified Medicines Directive	63
- Internet Supply	1

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
19	0	0
Investigation Fieldwork Activity (Section 67) – Interviews / Statements / Pharmacy Visits		6

PSI Social Media

We continue to gain followers on our Twitter account and strive to evolve our content and outreach through both Twitter and LinkedIn, with a variety of audiences, to supplement other communication channels. We are making small but progressive gains in followers across both platforms. On Twitter, we have 75% more followers than at the end of 2018, and 690 followers on LinkedIn where we have good engagement rates on content; at the end of 2018 we had 223 LinkedIn followers.

We use these platforms to share and promote PSI's work and regulatory messages. Recent posts include promotion of PSI video content, the PSI's Patient Charter, the Code of Conduct and its themes, our Regulatory Risk Statement, and recruitment opportunities. We also support relevant content from other organisations on our social media platform, such as national/international/EU initiatives, on topics such as flu vaccination campaigns, antibiotic awareness, medicines safety and side-effect reporting.