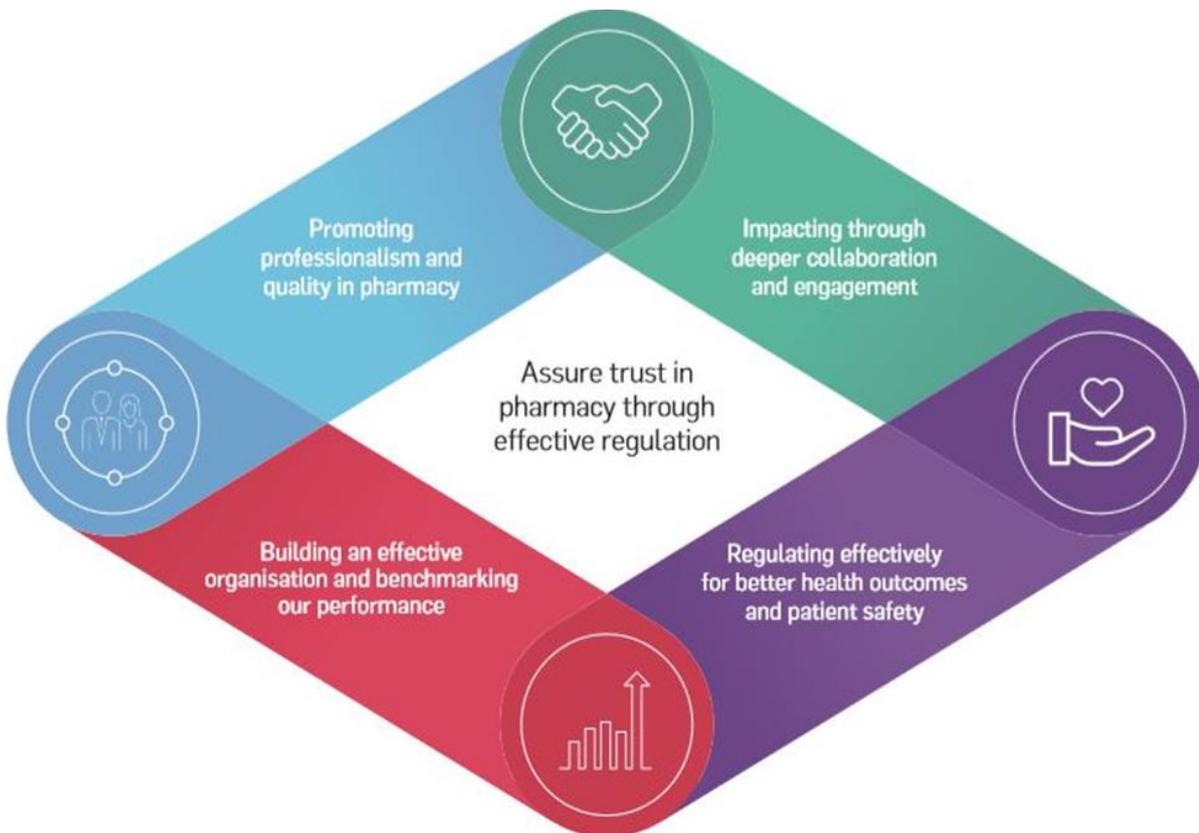


Report of the Registrar



Report to Council Meeting of 13 February 2020

Highlights from the Registrar

- **Next PSI Corporate Strategy:** As 2020 is the final year of the current Corporate Strategy 2018-2020, the development of the next PSI strategy is a priority project for this year. Initial planning and scheduling for phased development of the strategy has commenced. Council members have been invited to participate in a subgroup of the Council, which will aid the Council and Executive in completing our strategy development project over the course of 2020. The Council's Development and Planning Day in March will focus on strategy issues, and the management team will kick-off its strategy considerations at a facilitated session on 19 February.

Key external meetings and events attended since Council's last meeting

19 December: Together with our Head of Policy, I met the Department of Health to discuss our ongoing work to progress reform of the Pharmacy Act.

15 January: Together with PSI colleagues, I met with representatives of the HSE National Antimicrobial Resistance Team who are responsible for initiatives to increase awareness of resistance at community and primary care level.

28 January: Together with our Head of Operations, I met the CEO of Codec who are our contracted solution provider for our digital transformation.

29 January: I attended a conference on "Person-Centred Care" at the Royal College of Physicians of Ireland.

31 January: I attended a stakeholder consultation event at the Department of Health on the development of a healthcare performance assessment framework for the Irish healthcare system.



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

- **MPharm Accreditation Visits:** The PSI will be conducting two on-site accreditation visits in February. The first on-site visit is scheduled to take place in University College Cork from 4th to 6th February 2020. The second on-site visit is scheduled to take place in Trinity College Dublin from 10th to 12th February 2020. The accreditation visit to RCSI is scheduled for March 2020.
- **Practice Review 2019:** The PSI received the outcomes report of the Practice Review that took place in October 2019. The IOP undertook the review in line with the IOP Practice Review Policy as approved and reviewed by PSI Council on 19 September 2019. A total of 58 pharmacists participated in Practice Review in October 2019. 98.3% demonstrated competence in all competencies.
- **Code of Conduct activities:** Following the five successful information events in Q4 of 2019 to raise awareness of the new Code and help support pharmacists in using it in their day to day practice, we held another two events on 4 and 5 February in Cork and Kilkenny respectively. At the first event guest speaker Dervla Kelly PhD MPSI, who is a lecturer in Medical Education at the University of Limerick and works part-time as a community pharmacist, spoke about Principle 4 - Work with Others. At the event in Kilkenny guest speaker Conor McCrystal PhD MPSI, who is a community pharmacist and currently a PSI expert witness for fitness to practice inquiries spoke about Principle 3 - Communicate Effectively.



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

- **Collaboration and Engagement in 2020:** As part of our Service Plan delivery in 2020, we recognise that our work will require and benefit from significant external stakeholder input across a variety of projects. We are developing our engagement plans and priorities for the year so that we undertake those exercises in a useful and effective way, and so that we might make ourselves available in different ways to our registrants and the public.
- **IPL Working Group:** The Education Unit participated in a third session with the Interprofessional Learning (IPL) Working Group on 11 December 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. The Group is due to meet again on 14 February 2020.
- **Membership Body CPD Executives Meetings:** The Education Manager attended a meeting of this Group on 21 January 2020. The Group membership comprises representatives from other regulatory and professional bodies. The Group meets to share learning and experience of CPD, including the use of eLearning platforms and CPD compliance policies. At this meeting compliance with CPD was discussed.
- **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.
- **Food Safety Authority of Ireland (FSAI):** The Food Safety Authority of Ireland (FSAI) have contacted PSI in relation to concerns relating to non-compliant nutrition and health claims on food supplements. FSAI have proposed the two organisations collaborate to develop communications on the area of health claims on food supplements for pharmacies. PSI and FSAI will meet later in February to explore further messaging that build towards increasing awareness of the requirements and improved compliance.



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 National Safety Features Oversight Group has been closely monitoring progress of the implementation of the EU Falsified Medicines Directive since go-live on 9th February 2019. This group comprises of 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). Since February 2019, the system has been in a ‘use and learn’ period to allow additional time for the system to stabilise. The Safety Features Oversight Group has agreed that this ‘use and learn’ period will end on a phased basis starting from 2nd March 2020. The end of ‘use and learn’ will be implemented for manufacturers and wholesalers in the first instance with pharmacies and hospitals proposed for September 2020. The HPRA will be communicating directly with those stakeholders for whom use and learn will end first. Over the next months the PSI will work with IMVO to communicate with pharmacies to ensure the requirements of the Falsified Directive are known and to increase scanning rates in Ireland.
- **Legislative Reform:** The Registrar and Head of Policy met with the Department of Health on 19th December to discuss progressing reform of the Pharmacy Act. The PSI proposed to commission a review of models of regulation of pharmacy and other relevant healthcare services to provide an evidence brief to underpin the case for reform of the Act. Discussion with the DoH on the scoping of the review is in progress.
- **Pharmacy Assessment System:** Copies of the booklets required for pharmacies to complete the Pharmacy Assessment System for 2020 were issued to all pharmacies in December 2019.
- **Disciplinary Committee Training:** A training session for all members of the Health Committee and Professional Conduct Committee was held on 5 December. The session covered topics of relevance to the Committees such as dealing with expert witnesses, the elements of a good decision including the need for reasons and making recommendations on sanction.
- **Sanctions Guidance:** work has continued on the review of the Sanctions Guidance which is used as part of the inquiry process. It is anticipated that the updated Guidance will be available in Q2 2020.
- **Medical Council Stakeholder group regarding developing strategies to address the overprescribing of Benzodiazepines:** The Head of Policy attended a meeting in January of the Medical Council Stakeholder group regarding overprescribing of Benzodiazepines. This is a wide stakeholder group including of the Medical Council, HSE, HPRA, DoH, PSI and ICGP that are focussed on developing strategies to address the overprescribing of benzodiazepines.



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

- **Health-cards for Service Plan Projects 2020:** Project health-cards are being used again this year to aid the Executive in planning, and to provide relevant progress reports to Council and Committees, on the organisation's eight priority projects. At their first meetings of the year, the Professional and Regulatory Policy Committee and the Performance and Resources Committee have considered the project health-cards that will fall to be considered under their workplans for 2020.
- **Ethics in Public Office Acts:** In compliance with the statutory requirement under the Ethics in Public Office Acts, the PSI submitted statements of interests to the Standards in Public Office Commission in time for the 31 January deadline, following responses from Council members, as well as recording staff returns.
- **Business Transformation Programme:** The programme is progressing well between the PSI's business transformation team and the appointed providers, together with monthly governance oversight by the Programme Board and the weekly management Steering Group. An iterative approach is being taken to development and testing and the project delivery is being implemented on schedule and on budget. The first phase of this programme will be live in October 2020.
- **P&R Committee Pilot of iPad alternative:** The Performance and Resources Committee will be piloting a replacement system for the iPads. This will increase cyber security and user functionality. The pilot phase is due to conclude by the end of Q2 2020.
- **Microsoft Teams:** As part of our ongoing commitment to seek greater efficiency in the way we work and to improve our ability to collaborate within and outside of the organisation, we have begun upskilling staff in the use of Microsoft Teams. This will also help develop our staff skillset in readiness for delivering our digital transformation.
- **Staffing/HR /Recruitment Updates**
 - Our 2019 employee survey was launched on 18th December and closed on 15th January. The response rate was 83%. Report findings will be communicated by the external provider – SHRC – in February and follow-up workshops will be organised later in Q1 with all staff.
 - Three recruitment competitions were recently closed: Finance Officer (permanent), Acting Education Manager (maternity cover), Senior Pharmacist (maternity cover).

- Six recruitment competition are currently ongoing:
 - ICT Support Administrator
 - Finance and Support Services Executive
 - Quality Assessor – Pharmacy Services
 - HR Lead
 - Head of Policy
 - Front Desk and Support Services Administrator

- **Update on current procurement activity for contract values in excess of €25K:**

Services / Goods to be procured	Current Status
IT Support and Hosting	Invitations to Tender (ITT) have been issued to shortlist following the Pre-Qualification Questionnaire (PQQ) phase with a deadline of 26.02.2020. Expect to conclude tender evaluation and recommend of award to the 1 April 2020 meeting of the P&R Committee.
Specialist Surveyors	ITT phase close to conclusion with final evaluation to take place on 5 th February 2020.
Facilities Management	Preferred bidder appointed and services and SLA discussions commenced and contract in development. Expect new Framework Agreement to be in place by mid-February 2020.
Website Redevelopment & Build	Pre-qualification Questionnaire (PQQ) is currently being evaluated and it is intended to issue the Invitation to Tender documentation to successful applicants by mid-February 2020.
Provision of Organisation Development Services, including Organisational Design, Implementation and Change Management Support Services	Drafting of Supplementary Request for Tender for Framework Agreement for drawdown from an Office of Government Procurement (OGP) Framework in train.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 31 January 2020)

Fitness to Practise Concerns

Total concerns received in 2020	15
New concerns received since last report date (29 November 2019)	20
Concerns reviewed since last report date (29 November 2019)	49
Open concerns FTP	11

Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received in 2020	2
New complaints received since last report date (29 November 2019)	4
Open complaints	17*
Complaints considered by PPC since last report date (29 November 2019)	4**

* This figure may include complaints received prior to 2020 which are still being processed

** 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 year to date 2020	3*
Inquiries opened to date but adjourned / not completed	0
Heard since last report (29 November 2019)	4
Cases being investigated/prepared for hearing	27**

* 2/3 Inquiries met KPI for the Inquiry to be held within 2 years from when the complaint was received.

** (22 – PCC & 5 - Health Committee)

Mediation

Total referrals to mediation 2020	1
Held in 2020	0
Held since last report date (29 November 2019)	0

Sanction Hearings/ Undertakings/Dismissals before Council*

Heard year to date 2020	0
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 2020	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

Callovers heard year to date 2020	0
Since last report (29 November 2019)	1
Section 44 Applications (Withdrawals) Since Last Report (29 November 2019)	1

Prosecutions

Heard year to date 2020	0
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Suspension Applications

Heard year to date 2020	0
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Professional Registration (figures as at 31 January 2020)

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.
- 0 EPCs for establishment of service have been received to date in 2020 (new European route of entry to recognition and registration) – 1 EPC carried over from 2019 has been granted, and there are none in process.
- 2 Certificates of Current Professional Status have been issued to date.
- 1 Pharmacist Restoration application has been processed to date.
- 25 Voluntary Cancellation applications and 4 Involuntary Cancellations have been processed since 1st January 2020.
- 1 EU/TCQR Registration meeting held to date this year.
- 0 Third Country Qualification Recognition applications received to date this year, with an additional 78 applications in process.
- 0 TCQR registration application processed to date this year.
- 17 EU recognition/registration applications processed to date this year.
- 2 National route applications processed to date this year

Professional Registration (figures as at 31 January 2020)

Regulation of Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses	1952
Number of Retail Pharmacy Businesses Registered in 2020	17
Number of Retail Pharmacy Businesses Cancelled in 2020	21
Number of Changes in Supervising and Superintendent Pharmacists in 2020	67

Internet Supply	
Number of Pharmacies on Part A	50
Number of Non-Pharmacies on Part B	82

Inspection Activity 2020	
Total number of Inspections	13
Number of Registration-related Inspections	3
Number of pharmacy inspections	
- Systems	0
- Risk-based Inspections	10
- Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)	0
- Internet Supply	0

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
15	2	6
Investigation Fieldwork Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		2