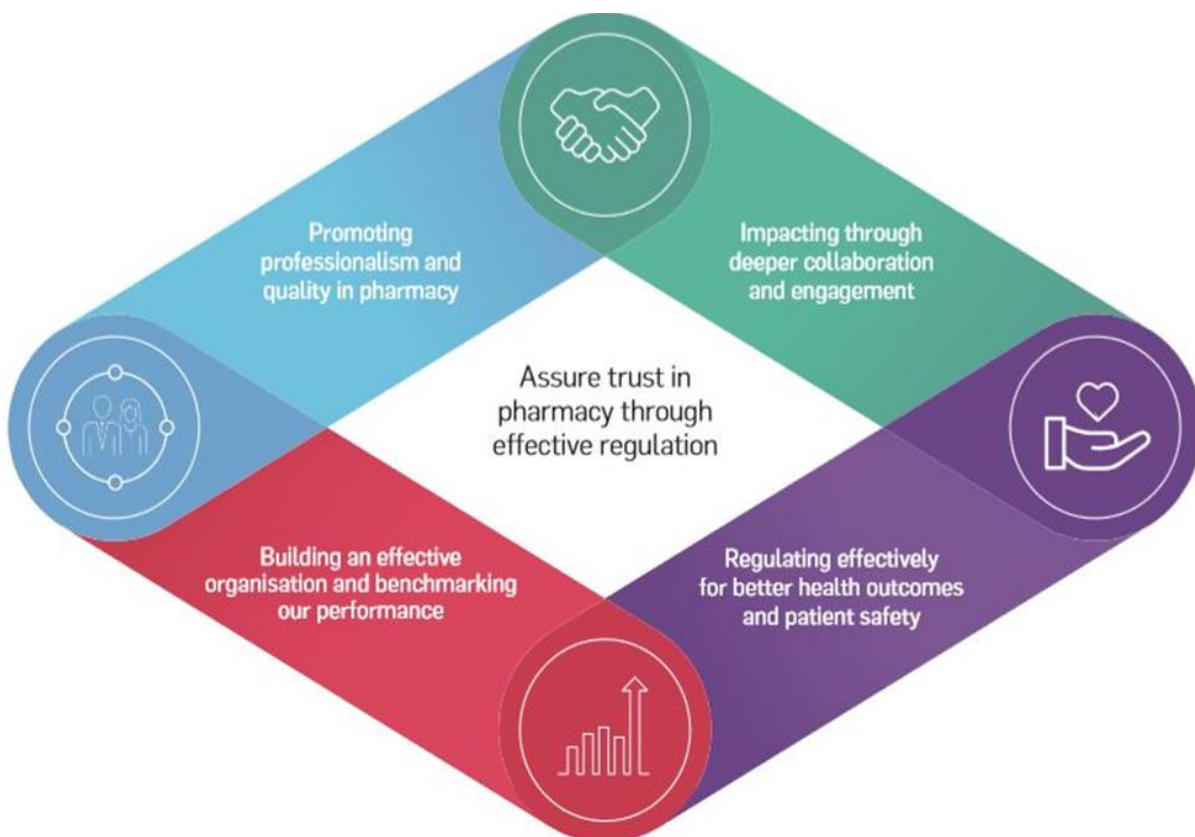


Report of the Registrar



Highlights from the Registrar

- **Review of Structures:** Having engaged BDO Eaton Square consultants to assist in this process, we are now well-advanced with this review. The wider management group of PSI (acting as a design team) has had detailed engagement with the consultants, both in group workshops and on a one-to-one basis. We are now close to the point where a small number of options as to future structures will be available for detailed consideration.
- **Brexit and Medicine supply:** PSI is supporting the work being coordinated by the Department of Health to ensure there is no unnecessary anxiety among the public as to medicines availability post-Brexit. A multitude of stakeholders are involved in this work which is being progressed in a highly-effective way with a clear focus, by all involved, on the health and welfare of the public.
- **Brexit and professional recognition:** The issue of recognition of UK qualifications continues to occupy our time. Regular meetings of the key stakeholders are being hosted by the Department of Health. While progressing our work on the review of the PSI Third Country Route to Recognition, we are also intensively examining the legislation to determine if a non-TCQR process can be applied to UK applications post-29 March and pending the introduction of a revised TCQR. We are also in fortnightly contact with the General Pharmaceutical Council in London.
- **Master's Degree in Pharmacy:** A protest was recently held by students enrolled on the MPharm programme. A report compiled by the students' representative association was handed in to PSI. We undertook to review the report and to correspond further with the student association.
- **Key external meetings and events** attended by the Registrar since the previous Council meeting:
 - 23 January – Multi-stakeholder meeting at the Department of Health concerning medicine supply post-Brexit.
 - 23 January – Seminar on “Innovation at Leadership Level” hosted by DPER and focussed on innovation within the Dutch National Police.
 - 25 January – Further meeting in a series at the Department of Health concerning professional recognition and Brexit.
 - 4 February – Co-hosted the Health Professional Crossing Borders Conference (with CORU) at Dublin Castle.
 - 6 February – Quarterly meeting with representatives of the IPU.
 - 7 February – Attended the 2019 Health Summit event at Croke Park.



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 first of the three on-site accreditation visits scheduled for 2019 was conducted at University College Cork during January. The programmes delivered by the three HEIs are accredited until 2020, with accreditation visits scheduled to occur after the 4-month placements (September-December) in Year 4. The next accreditation visit will be to Trinity College Dublin on 12 and 13 February 2019.
- **Governance and Accountability Standards:** Work continues on the development of Governance and Accountability Standards for Retail Pharmacy Businesses, with a literature review currently been undertaken, with a view to sharing this with members of the Standards Advisory Group at its next meeting on 26 March. Two focus groups; one with patients, the other with superintendent pharmacists, are scheduled for 20 February, where the scope of the standards will be discussed. A short public scoping consultation is also planned for the end of February so that the views of all stakeholders are captured early in the development of these new standards for retail pharmacy businesses.
- **Code of Conduct:** Following Council approval in December, the Code was sent to the Competition and Consumer Protection Commission (CCPC). CCPC has responded indicating that having assessed the draft Code in the context of Section 12 (1)(a) of the Pharmacy Act 2007, it has concluded that the implementing the draft Code does not result in competition being prevented, restricted or distorted. Simultaneously, the PPD Department has worked on the design of the final Code with an external designer and engagement has taken place with the National Adult Literacy Agency (NALA). The Code will shortly be sent to the Minister for Health for approval and, subject to Ministerial approval, will be laid before the Houses of the Oireachtas. The activities of launch and roll out are currently being considered by the PSI Executive.
- **CLEAR Webinar:** The Council on Licensure Enforcement and Regulation (CLEAR) has invited the PSI to host a live webinar on 19 February to discuss how the PSI developed the new Code of Conduct for Pharmacists. This promises to be an interactive session, with attendance expected by several of our international regulatory colleagues.



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

- **IPL:** The Education Unit held a third session with the Interprofessional Learning (IPL) Working Group of regulators on 11 December 2018 in CORU's offices, Smithfield.
- **Network for Health Workforce Educators:** Two members of the Education Team attended the International Network for Health Workforce Educators (INHWE) Conference on 9 and 10 January 2019. This year's conference theme was Interprofessional Education.
- **HPCB Conference:** Together with CORU- the Health and Social Care Professionals Council, the PSI co-hosted the Healthcare Professionals Crossing Borders (HPCB) conference in Dublin Castle on 4 February. HPCB is a network of regulators and competent authorities that engage on regulatory and patient safety issues. This year's conference with the theme 'Mobile professionals, safe patients' attracted in the region of 120 delegates from across Europe, including those working in Departments of Health and Education, and UK and NI pharmacy regulators. The PSI was involved in local organisation, promotion, and chairing of sessions on the day. For more information see www.hpcb.eu, where conference presentations will be made available.
- **Falsified Medicines Directive:** The PSI continues to engage with a multi-stakeholder group, through the Department of Health, on the implementation of the Falsified Medicines Directive related to the verification of medicines commencing on 9 February 2019. The PSI has also assisted the Irish Medicines Verification Organisation (IMVO) with disseminating communication to pharmacists and pharmacies in preparation for commencement of, and compliance with, the Directive, as well as issuing direct messages from the PSI to registrants in this regard.



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

- **Pharmacy Assessment System:** The Pharmacy Assessment System content has been updated, in line with the review carried out in 2018. This update, Version 2 of the Pharmacy Assessment System, will be sent to all pharmacies in the coming weeks for their continued use of it for audit purposes.
- **Brexit engagement...** A Brexit webpage is being updated on the PSI website to provide information relevant to those engaging with us. Primarily, it refers to the national position on medicines and professional recognition matters, with links to other authorities. The aim is to maintain this as the Brexit scenario develops.
- **Paperless Inquiries:** We have commenced work towards moving to paperless Inquiries. We met with our external legal advisors and are now carrying out an internal review of the equipment which will be required to move to a paperless environment. Once this exercise has been completed internally, we will then engage the Chairs of the Health and Conduct Committees with a view to running a mock paperless inquiry, with all committee members, towards the latter half of the year.
- **Paediatric dispensing of Zantac:** Further to previous recommendations from the Professional Conduct Committee regarding dispensing errors by pharmacists when supplying Zantac Syrup to Paediatric Patients, the PSI is writing to the Marketing Authorisation Holder (MAH) and the HPRA to propose actions to facilitate safer care. The PSI is suggesting changes to the packaging and the formulation of Zantac Syrup, which may reduce the risk of dispensing errors when this product is supplied by pharmacists to paediatric patients. As the safety issues which have come to our attention relate to dose miscalculations, the PSI is also writing to the Schools of Pharmacy, in an advisory capacity, to alert them to this particular safety issue.
- **Falsified Medicines Directive-Update on National approach to implementation:** The EU Falsified Medicines Directive European and Delegated Regulation on Safety Features on came into operation across Europe on 9th February. The Delegated Regulation sets out detailed rules for the safety features appearing on the packaging of medicinal products for human use. These new requirements aim to enhance patient safety by protecting the medicines supply chain from infiltration by falsified (or counterfeit) medicines. More detail on the steps

taken to ensure that we are regulating this new area both effectively and proportionately follows.

- The PSI has been working closely with the Department of Health, the Health Products Regulatory Authority (HPRA), the IMVO, the HSE and Private Hospitals Association (PHA) as part of a stakeholder group to monitor progress on the implementation of the new safety feature requirements across all sectors.
- This new medicines' verification system is a significant undertaking involving almost 2,000 pharmacies and hospitals, along with pharmaceutical manufacturers and wholesalers, stakeholder representatives and regulators, which sees over 95 million prescription medicines dispensed to patients every year.
- Notwithstanding the significant work undertaken to date and given the complexities associated with setting up a medicines verification system impacting manufacturers, wholesalers, parallel distributors, hospitals and pharmacies across Europe, it is anticipated that the initial period of operation may identify issues as the new system comes into effect Europe-wide.
- Following discussions at a national and European level with all stakeholders, it has been decided by the Department of Health and all stakeholders to adopt a pragmatic approach nationally to the implementation of the Delegated Regulation (and the associated statutory instrument) from the 'go live' date of **February 9th, 2019**.
- This approach aims to ensure that medicines continue to be provided to patients without delay and ensure that all stakeholders, manufacturers, wholesalers, pharmacists and other healthcare professionals work to build confidence in operating the new safety system.
- During the initial period of operation, the system will be considered to be in 'use and learn' phase including alert management. Wholesalers, pharmacies and hospitals should scan medicines bearing the safety features and continue to supply medicines in line with their normal procedures.
- National legislation including the provisions of Article 23 of the Delegated Regulation will be introduced, however, the offences provided for in the Regulations will not be commenced for a period of time to let the new system bed in.
- During this period, the alerts generated will be analysed by the Department of Health, IMVO, HPRA, PSI, HSE and the private hospitals association to determine why they are occurring and develop appropriate protocols for their resolution. Manufacturers (and marketing authorisation holders) will also be involved in the investigation of alerts generated against their products. The system will be reviewed again in three months' time.
- The PSI has informed all pharmacists and pharmacy owners of the national approach and we have published an FAQ document on the PSI website. The IMVO continue to provide support to pharmacies, wholesalers and manufacturers as the new system comes into operation.



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

- The first meetings of the Performance and Resources, and Regulatory and Professional Policy Committees took place in January. Updates and reports from the committees are scheduled for the 14 February Council agenda.
- Planning is in progress to fill vacancies arising on the Council in June this year. This includes liaising with the Department of Health, as well as preparing for nominations and elections for pharmacist members during Spring, in accordance with timelines specified under the Council Rules.
- In compliance with the Ethics in Public Office Acts, the PSI submitted all relevant returns to the Standards in Public Office Commission for the 31 January deadline, following responses from Council members, as well as recording relevant staff returns.
- Following review, a new information tool for reporting on the Service Plan has been developed to assist management and project leads in tracking, as well as reporting on, progress against strategic activities during 2019. The proposed reporting method, for use by the Performance and Resources Committee and by the Council, was considered by the Performance and Resources Committee at its 31 January meeting.
- As part of the implementation of the PSI's 2017-2020 Strategic Workforce Plan in line with Council's September 2017 decision to progress with the creation of 15 new posts, the Department of Health (DOH) approved the creation of 7 new posts with sanction received by the PSI in this regard on 21 December 2018. The remaining 8 posts and their associated business cases will be considered following the completion of the organisation structure review for follow-up with the DOH. Planning for the recruitment and selection of these and other replacement posts has commenced.
- A proposal to Council will be made to amend the September 2017 Council decision to offer appointments on the basis of two-year fixed-term contracts for the positions of Head of Policy and Patient Safety and the Registration Manager.
- The implementation plan to give effect to the HR Strategy, approved by the Executive Leadership Team (ELT) in December 2018, is in development. A new performance model is in development and an induction and onboarding programme is currently in progress with an aim to have it ready for launch in March 2019.

- Under the PSI as an employer of choice strand in the HR Strategy, the first PSI Staff Engagement Survey was administered end 2018 and the report was presented to all staff end January. There was strong participation with 88% of staff undertaking the survey. The survey has given valuable insight and we are currently in the process of developing a comprehensive action plan that will address each of these in line with the PSI Corporate Strategy and the 2018-2020 HR Strategy.
- An IT Security Assessment was conducted in 2018. A re-test was carried out in December 2018 to ensure the critical risks were resolved and this was confirmed from the re-test.
- Migration of a key IT system (case management system) was successfully completed recently with the key benefits being: enhanced disaster recovery, increased security measures, and little or no systems downtime due to network outages.
- In relation to the Business Transformation Programme, in parallel with the digital transformation services procurement process that is in train (see procurement update below), internal requirements gathering and business process re-design is ongoing across the organisation. As the PSI is so heavily reliant on paper processes, the scope for value-add is substantial when looking at how processes might work from an online and integrated perspective. In addition, the outputs from several key projects detailed in the 2019 Service Plan (Themed Reviews, Regulatory Risk etc.) will feed into the Business Transformation Project.
- The Project Steering Group continues to meet on a weekly basis to discuss issues, risks, make decisions and to keep the project moving forward. The first meeting of the Programme Board took place on Friday 1st February 2019, chaired by Fintan Foy. Fintan will provide an update from the Programme Board at the Council meeting.
- Procurement activity:

Procurement activity update (total contract value of €25k or more)	Public Procurement procedure utilised
Digital Transformation services	Competitive Dialogue Procedure. First phase – a Pre-Qualification Questionnaire (PQQ) – was published on 3 January and closed on 4 February 2019. Next phase is in train involving the evaluation of the PQQs and invitations to eligible potential vendors for the face-to-face meetings.
Specialist Surveyor services	This procurement is due to be published on eTenders on 10 February 2019. A two-phased process will be utilised – known as the Restricted Procedure. A pre-qualification questionnaire (PQQ) is utilised for short-listing followed by an invitation to tender.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 8 February 2019)

Fitness to Practise Concerns

Total concerns received in 2019	19
New concerns received since last report date (29 November 2018)	32*
Open concerns	12
Concerns reviewed since last report date (29 November 2018)	40

* This figure may include concerns received prior to 2019 which are still under review

Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received in 2019	6
New complaints received since last report date (29 November 2018)	8
Open complaints	27
Complaints considered by PPC since last report date (29 November 2018)	8**

* This figure may include complaints received prior to 2019 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	0
Heard since last report (29 November 2018)	0
Cases being investigated/prepared for hearing	16*

* (14 – PCC & 2 - Health Committee)

Mediation

Heard year to date	0
Heard since last report date (29 November 2018)	0
Cases being prepared for mediation	1

Sanction Hearings/ Undertakings/Dismissals before Council*

Heard year to date	0
Cases being prepared for Council Meeting on 14 February	1

* This figure is reported on a per respondent basis

High Court Sanction Confirmation Hearings*

Heard year to date	0
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* This figure is reported on a per respondent basis

Prosecutions

Heard year to date	1
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Suspension Applications

N/A

Appeal

N/A

Professional Registration (figures as at 01 February 2019)

- The bulk of continued registration period for registration certificates expiring at the end of December 2018 is complete. Hard copy continued registration applications processed to date are 219 and online applications processed to date are 4034.
- 0 alerts have been issued by the PSI 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.
- 3 EPCs for establishment of service have been received in 2019, one has been approved and two are in process (new European route of entry to recognition and registration). Of three applications on-going from 2018, one has been approved and one refused in 2019 and one application is in process.
- 3 Certificates of Current Professional Status have been issued to date in 2019.
- 4 restoration to the register applications have been processed to date in 2019.
- 56 voluntary cancellation applications and 2 involuntary cancellations have been processed to date.
- 1 EU/TCQR registration meeting has been held to date this year.
- 4 TCQR recognition applications received to date this year.
- 18 EU recognition/registration new applications received to date this year.
- 13 recognition/registration applications processed to date this year

Regulation of Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses (as at 8 February 2019)	
Number of Registered Retail Pharmacy Businesses as at 8/2/2019	1945
Number of Retail Pharmacy Businesses Registered in 2019	17
Number of Retail Pharmacy Businesses Cancelled in 2019	17
Number of Changes in Supervising and Superintendent Pharmacists in 2019	60

Internet Supply (as at 8 February 2019)	
Number of Pharmacies on Part A	50
Number of Non-Pharmacies on Part B	74

Inspection Activity 2019 (as at 8 February 2019)	
Number of Registration-related Inspections (Section 19)	7
Number of pharmacy inspections (Section 67) <ul style="list-style-type: none"> - 8 Risk-based Inspections - 8 Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d) 	16

Freedom of Information (FOI)

One FOI request has been received by the PSI in the year to date.