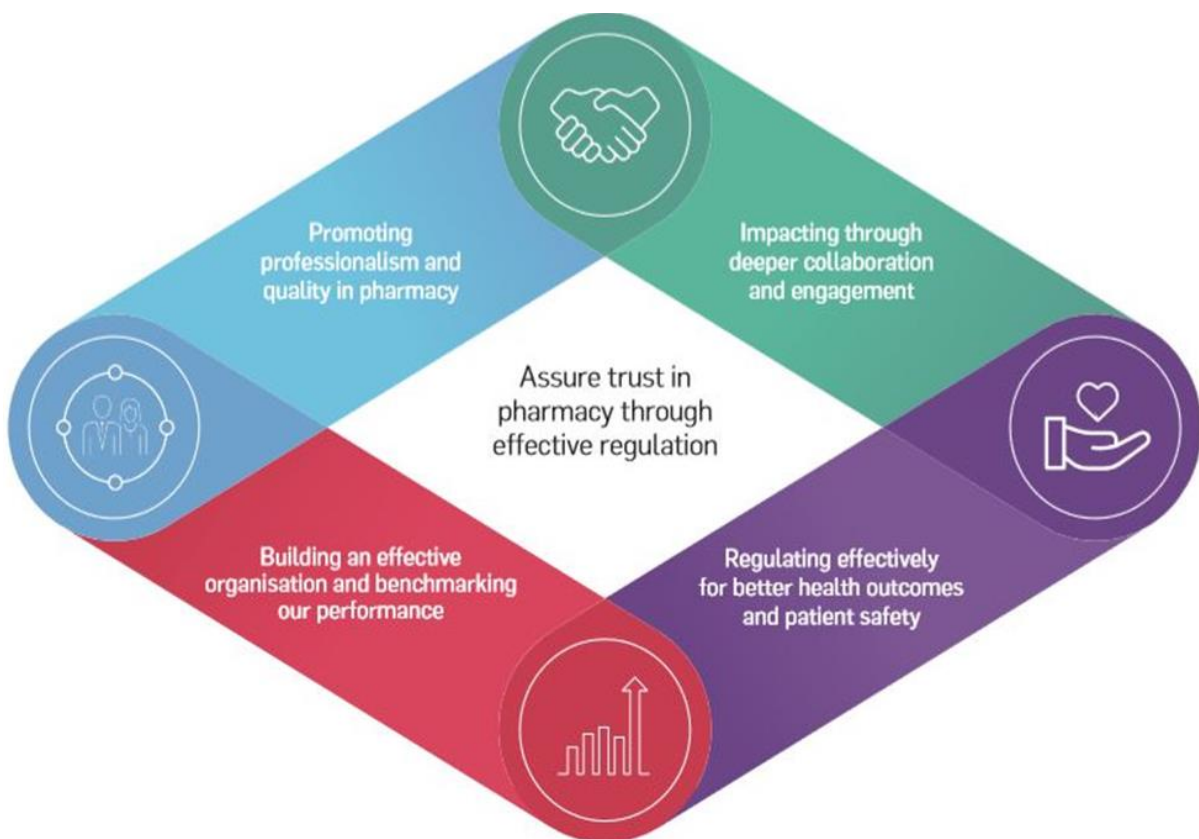


Report of the Registrar



Highlights from the Registrar

Records Management Week: As part of our ongoing work to ensure PSI is compliant with GDPR requirements as well as ensuring that good general housekeeping is maintained in PSI House, we designated the week commencing 28 May as “Records Management Week”. Over the course of the week, everyone took time to review, in keeping with our record retention policy, current records being held in hard copy and otherwise and to identify records which could be destroyed. We had a particular focus during this initial week on records held in hard copy. As a result of the efforts made by all of our PSI colleagues, we have filled over 130 confidential waste bags (weighing an estimated 2,000 kilos) with destruction certificates now held for all destroyed records. As well as ongoing work to maintain our holdings of records in keeping with our policies, we plan to hold another Records Week in late Autumn. Special appreciation is due to our colleague Ruth Baily for organising many of the details of this successful initiative.

Planning for the Future Irish Healthcare System: On 31 May, I attended a seminar at the ESRI where the research findings from the Hippocrates projection model of healthcare demand were presented as well as other research work in relation to planning for the future Irish healthcare system. Sessions at the conference were chaired by Jim Breslin, Secretary-General, Department of Health, Muiris O’Connor, Assistant Secretary, Department of Health and John Connaghan, Acting Director-General, HSE. A panel discussion also took place with speakers from TCD, the INMO, the HSE and the RCSI. Further information and copies of the slides are available at <http://www.esri.ie/event/conference-on-planning-for-the-future-irish-healthcare-system/>

World Health Professions Regulation Conference 2018: I attended this Conference in May. The aim of the Conference was to provide participants with insights, perspectives and discussion on current challenges in health professional regulation worldwide. Speakers from a variety of countries and health professions presented on areas of relevance to our strategic agenda in PSI including the lessons learned from competence-based approaches to regulation, developing new regulatory models and how to promote best practice in regulatory governance and performance. The presentations are available at <http://www.whpa.org/whpcr2018/presentations.htm>.

Green Ribbon Month: To mark the end of Green Ribbon month in May (a national initiative to encourage people to end mental health stigma), to promote awareness of mental health wellbeing (and to support staff during an intense week of records management) activities, we dedicated the last week in May to ‘Mental Health Awareness in the Workplace’. Each day staff received an email with articles, tips, hints and YouTube videos which focused on specific themes and topics associated with mental health wellbeing. A mental health fitness workshop on “*Challenging Change – Being OK with Life’s Ups and Downs*” was delivered by a Medical and Psychology Coach on 30 May. Thanks to our colleague Beatrice Lebrun for organising.



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

- Head of Education and Registration, and the Education Manager met with Mr Damian Day, Head of Education at the General Pharmaceutical Council (GPhC) at PSI House in May 2018. Constructive engagement and discussion followed, building on the previous meeting held between the GPhC and Pharmaceutical Society Northern Ireland (PSNI), where the challenges of the withdrawal of the United Kingdom from the European Union were discussed. Additionally, the GPhC indicated that they are seeking to implement an integrated 5 year MPharm across the UK, and are interested to learn about the PSI's experience in this area.
- Further to the information provided to Council regarding new recommendations from the European Medicines Agency (EMA) to avoid valproate exposure in pregnancy and the ongoing roll-out of required safety initiatives, pharmacists have been issued with a Direct Healthcare Professional Communication (DHPC) on this matter. A PSI communication was sent to all registrants in early June highlighting the support resources which all pharmacies should have received from the Marketing Authorisation Holder (MAH), and available via the [HPRA website](#). Pharmacists were again reminded of the serious risks to children who are exposed to valproate in the womb and the necessary steps that they need to take to ensure the safe supply of this medicine. The PPD Department continues to engage with all relevant stakeholders, including patient groups, in supporting this initiative.
- A new query submission form has been introduced for use by pharmacists with pharmacy practice-related queries. The form highlights the numerous resources available on the PSI website to assist pharmacists in resolving their queries, including pharmacy and medicines legislation, pharmacy practice guidance, inspectors' advice on improving compliance, pharmacy practice updates and frequently asked questions (FAQs). Highlighting the resources available is intended to encourage pharmacists to seek an outcome to their query themselves and to use their professional judgement before seeking to raise a query directly with PSI staff. It is hoped that this will reduce the number of unnecessary practice and advice queries received from pharmacists and to reserve scarce staff time for those queries requiring intervention by PSI pharmacist staff.
- The General Data Protection Regulations came into force on 25 May 2018. In light of this change in legislation, the PSI Guidance on Data Protection for Pharmacists is no longer

current and has been withdrawn from the website. An email was sent to all registrants highlighting that this guidance is no longer current, and it signposts to the extensive information and resources available on the Data Protection Commission's website, while also highlighting the need for pharmacists and pharmacies to meet and action their requirements regarding data protection law in the interest of their patients.

- The Head of the PPD Department and the Head of Policy attended a meeting with members of the Human Products Authorisation and Registration department of the HPRA regarding collaborating on issues of mutual concern.
- As part of the terms of accreditation, the annual reports from the Bachelor of Pharmacy degree programmes at each of the three Institutions of Higher Education have been received and accepted by the PSI.
- The Irish Institute of Pharmacy (IIOF) has furnished its report on the April 2018 Practice Review Events. 64 pharmacists attended the events, held over two days. 63 pharmacists demonstrated competence in all competencies with 1 pharmacist requiring further review in the Clinical Knowledge competency. 0 pharmacists require further review in the Standardised Pharmacy Interactions competency. 1 pharmacist did not participate in the event.
- The Accreditation Standards for CPD Programmes in Pharmacy has been revised following the responses to the public consultation process and are ready for approval by Council at this meeting. The standards seek to assure a streamlined quality assurance mechanism for the accreditation of CPD training programmes and courses for pharmacists.
- The Working Group on the strategic future of the IIOF has been set up, supported by the Head of Registration and Education, and an initial meeting was held on 19 June to discuss how best to approach this work.
- As part of our ongoing work to promote the recommendations of the Future Pharmacy Report to key stakeholders, the Registrar and Head of Policy met the National Director of the HSE Quality Improvement Division on 11 June. A meeting with the National Patient Safety Office is scheduled for 19 June and meetings with the Director of Research and Planning in the Department of Health and with the ESRI are being organised.
- We have written to the Department of Health seeking to meet to discuss what roles may be envisaged for pharmacists under the forthcoming legislation for the termination of pregnancy.



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

- A nominee from the PSI Executive attended the first meeting of the HIQA Advisory Group on ePrescribing. This Group includes nominees from a range of key stakeholders, and will advise on the draft ePrescribing recommendations to be made to the Minister for Health and will also advise on any further steps, including the implementation of recommendations.
- Building on from the InterProfessional Learning (IPL) Conference in Dublin in 2015, and meetings held with East Tennessee State University (ETSU) in 2017, the PSI, hosted an interprofessional learning workshop on 29 May 2018, with representatives from The Medical Council of Ireland, The Dental Council and The Health and Social Care Regulator (CORU). The attendees have agreed to form a working group to further the development of interprofessional learning across the professions. The terms of reference for the group will be agreed at the next meeting of the group in September. The group is hopeful of working together to adopt common “language, values and standards” in the context of IPL to improve interprofessionalism across the disciplines and improve patient outcomes.
- The PSI is hosting two visitors from the Pharmacy Board Malaysia, from Monday, 11th June to Tuesday, 19th June 2018. Mr. Othman is in charge of accreditation of pharmacy programmes and Ms. Shafie is in charge of provisionally registered pharmacists and qualifying examinations to practice pharmacy at the Pharmacy Board Malaysia. As part of this visit, PSI were grateful for the significant engagement and support received from colleagues who hosted the visitors at community and hospital pharmacies, schools of pharmacy, at APPEL and at the HPRA. The visitors provided presentations to the PSI on their roles and pharmacy practice in Malaysia.
- Two members of the Education Unit attended face-to-face preceptor training at Trinity College Dublin, on 15 June 2018 with a view to developing the training programme for the MPharm students who will take up their statutory practice placements at PSI in September 2018. The nominated ‘tutor’ pharmacists for the students will complete online training when this becomes available.

- The Registrar and members of the Management Team met representatives of the principal locum agencies on 21 May to discuss matters relating to safe and appropriate use of locum pharmacists in retail pharmacy businesses. A useful meeting was had and it was agreed to meet again in the Autumn.
- The Registrar and members of the Management Team met representatives of the Irish Pharmacy Union on 6 June for our regular liaison meeting. This was a positive meeting and the next meeting will happen in late Autumn.
- PSI Authorised Officers (Inspectors) conducted 8 pharmacy inspections in May 2018, concurrent with inspections carried out by inspectors from the HSE. Both agencies conducted separate inspections, which included prescribing and dispensing practices.



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

- The Legislative Reform Working Group has been set up, supported by the Head of Policy, and an initial meeting was held on 13 June to discuss how best to approach this work. The Registrar and Head of Policy will meet the Department of Health on 12 July to discuss how this proposed strand of our strategy will integrate with the future plans of the Department.
- The project to review the operation of the Pharmacy Assessment System is ongoing. As part of the review, a survey was issued to all pharmacists, pharmaceutical assistants and pharmacies, and responses were collected over three weeks in April/May. Over 600 responses were received, and analysis is underway. PSI inspectors also visited 101 pharmacies in May to review the use of the Pharmacy Assessment System. The report of the review of the operation of the Pharmacy Assessment System, including the survey results and findings from the pharmacy visits, will be provided to Council at its meeting in September 2018.
- At the 101 pharmacy visits to review the use of the Pharmacy Assessment System, PSI inspectors also review the pharmacy's awareness of the updated patient safety information on Valproate-containing medicines.
- An internal project Steering Group, made up of members of the senior management team, is in place to oversee the Inspection & Enforcement Unit projects included in the 2018 Service Plan. Four meetings of this group have taken place.
- The Preliminary Proceedings Committee's Annual Report for 2017 has been completed and sets out the Committee's observations regarding pertinent issues raised as part of complaints made to the PSI in 2017. The Committee has highlighted issues which the profession should be mindful of and which might be of assistance in the future to avoid complaints being made to the Regulator.

- Greater use of the callover system is now being made whereby early applications for undertakings, in appropriate cases, are being presented to the Health and Professional Conduct Committees for their consideration at an early stage in the investigative process. We feel it is appropriate to facilitate such applications in appropriate cases with a view to trying to regulate proportionately as set out in our strategy. Also, we committed to looking at what we could do with our current system until the amendments to the Act are finalised.
- A new system is currently being piloted for the Health Committee and Professional Conduct Committee whereby their reports following an inquiry are now being drafted and stored centrally on *Sharefile*. The aim of the new system is to introduce a greater level of confidentiality and security surrounding the process of drafting and finalising Fitness to Practise reports. The new system being piloted will avoid the necessity of Chairs and Committee members having to use email to finalise their report and should assist PSI with complying with our obligations under GDPR.
- We have written to the Department of Health seeking to meet to review where we have reached in our consideration of the precise remit of PSI in relation to regulating certain activities of hospital pharmacies. The Head of Policy and Head of Regulation have engaged with GPhC colleagues to understand the approach to regulation of retail pharmacy businesses in hospitals in that jurisdiction.



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 review of sub-Council Committee structures is an agenda item for the June meeting, with the report from Better Boards available for consideration. The report sets out the process undertaken since April, and makes recommendations as to how the Council might proceed with this change process.
- A decision is awaited from the Department of Health on the suite of business cases for new posts that was submitted along with the Comprehensive Resourcing Review Report, incorporating the Strategic Workforce Plan, for 2018-2020. Ongoing contact is being maintained with the Department on this important matter.
- As part of PSI's ongoing health and safety developments, eight staff attended Fire Awareness/ Fire Warden Training programme delivered by Andrew Doyle Safety Consultants on June 5. Further health and safety training programmes are scheduled for the latter part of June and early July.
- We are working to continue to meet compliance with GDPR and updated data protection legislation across the organisation. This remains an ongoing work area. We met again with the Information Governance group from the various health and social care regulators in June, which provides useful knowledge exchange. We have also implemented the new document management policy and had a focused records management week at end of May.
- Staff consultation is commencing on the suite of new Information Security Policies that have been subject to external validation and which are designed to significantly enhance PSI's approach to information security governance and procedures.
- Following receipt of the final report on PSI's IT Security Assessment conducted by Ward Solutions, a number of critical/high recommendations are in the process of being implemented as a priority. The purpose of the security assessment was to determine the technical security posture of the PSI which involved penetration testing of the perimeter, an on-site penetration testing of the internal LAN, and an analysis of the existing technical security controls.

- Update on ongoing and upcoming high value tenders (generally >€25k services contracts) as per PSI's Procurement Policy and 2018 Service Plan and budget:

Service/goods to be procured	June Status Update
New PSI website development and build	ITT developed - competition paused pending appointment of procurement advisory services provider (see below)
Internal auditors	Request for Tenders published on OGP website to Framework members in May - closed on 08.06.2018
Procurement support services	Request for Tenders published on OGP website to Framework members in May - closing on 22.06.2018

- The Education team at PSI have met with the Executive Director and Operations Manager of the IOP to determine and operationalise the new contract between the PSI and RCSI for the provision of the Irish Institute of Pharmacy. Under the new contract governance and financial reporting arrangements have been streamlined.

Appendix 1 –Statistical Summary

Fitness to Practise Concerns: information as at 13 June 2018				
New concerns received since last report date	Total concerns received to date in 2018	No of concerns open	No of concerns considered since last report date	Outcome of concerns considered:
17	66	10	26	10/26: Closed 06/26: Referred to other units for consideration/further action 10/26: Under review/further action required

Complaints: Screening Committee (PPC) Information as at 13 June 2018				
New complaints received since last report date	Total complaints received to date in 2018	Total no of complaints open	No of complaints considered by PPC since last report date	Outcome of complaints considered by the PPC
3	21	19*	6	<ul style="list-style-type: none"> 2/6: No further action 1/6: Further action - Referred to Conduct committee **KPI: 3/3 complaints: KPI met <ul style="list-style-type: none"> 3/6: still under consideration (2 adjourned pending criminal proceedings with further information sought in 1 case)

* The number of complaints open can vary from the number of complaints received in 2018 as there are complaints from 2017 which are being processed also.

**KPI: six months from when the complaint was received to when the PPC made a final decision

Complaints for Inquiry/Mediation as at 13 June 2018						
New complaints referred for Inquiry since last review date	Total open complaints being investigated/prepared for Inquiry	No of Complaints being investigated/prepared for the Conduct Committee	No of Complaints being investigated/prepared for Health Committee	No of Complaints at Mediation	No of Complaints heard by FTP Committee since last report date	*KPI
1	11	10	1	0	2	2/2: KPI met

*KPI = 2 years from when the complaint was received to when to the date the inquiry commenced.

Post Inquiry Complaints awaiting sanction/High Court confirmation hearing			
Complaints being processed after Inquiry	No of complaints for noting/sanction before Council	No of Complaints at High Court Sanction	Complaints dealt with by High Court since last report date
5	2	3	1

Investigations (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
24	1		7

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses as of 11/06/2018	1931
Number of Retail Pharmacy Businesses Registered since 1/1/2018	58
Number of Retail Pharmacy Businesses Cancelled since 1/1/2018	58
Number of Changes in Supervising and Superintendent Pharmacists since 1/1/2018	222

Inspection (1/1/2018 to 11/06/2018)	
Number of Registration – related Inspections (Section 19)	43
Number of pharmacy inspections (Section 67)	76
Number of pharmacy assessment system review visits, including a review of the pharmacy’s awareness of the updated patient safety information for Valproate-containing medicines	101

Internet Supply (as of 11/06/2018)	
Number of Pharmacies on Part A	44
Number of Non-Pharmacies on Part B	81

Registration of Persons	
Number of Registered Pharmacists as of 12/06/2018	6043
Number of Registered Pharmaceutical Assistants as of 12/06/18	336
Number of Registered Druggists as of 12/06/18	1

Internal Market System	
Number of Alerts issued as of 12/06/18	4
Number of EPC issued – host	7
Number of EPC issued – home	0