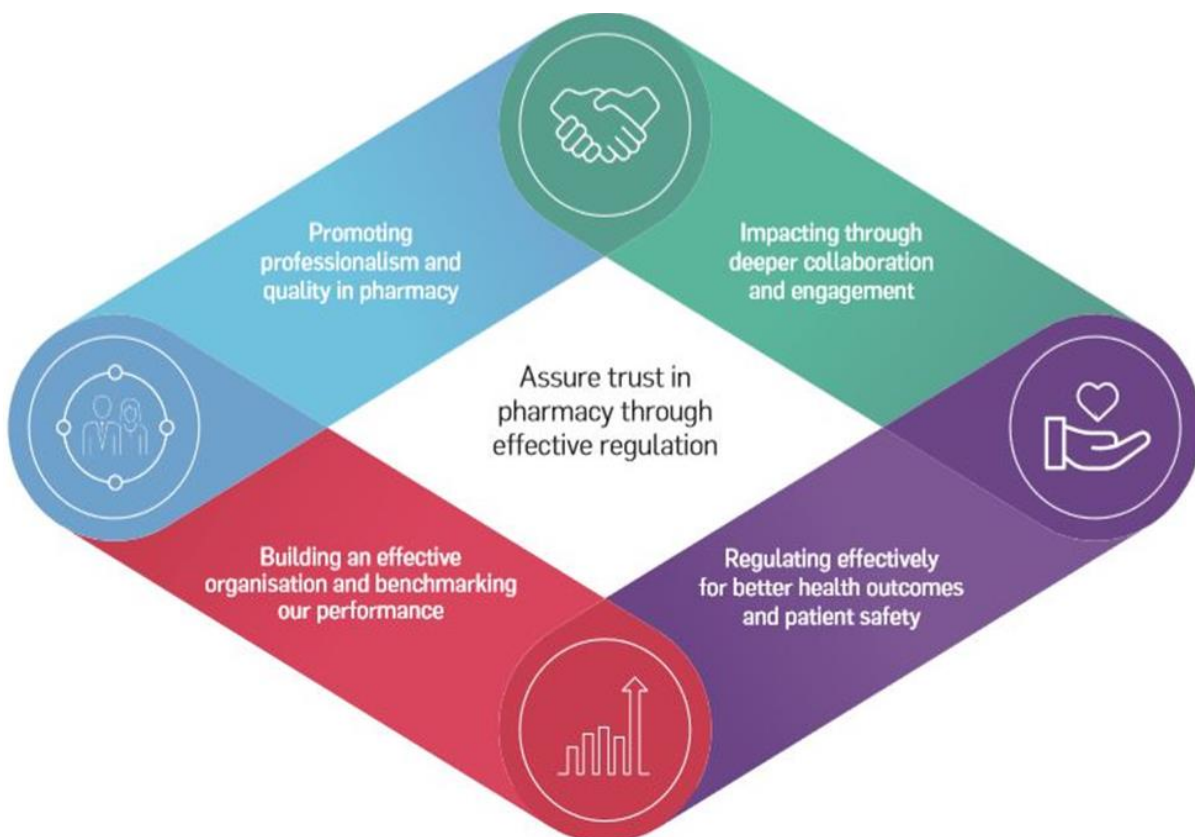


Report of the Registrar



Highlights from the Registrar

Recognition for Excellence: Our work directed towards making our submission for recognition under the EFQM Excellence Model continues apace. The process requires us to consider many searching questions as to how we seek to deliver on our mission and whether we are clear as to desired results and their underpinning methodologies. While I believe we are in a position to submit extensive evidence to support our application and to demonstrate our commitment to excellence, it remains a challenge to meet our June submission deadline given the competing needs of other change projects which are currently underway.

Regulatory effectiveness, impact and risk: We had a very successful seminar with guest speaker Jan Robinson, Registrar of the Ontario College of Veterinarians, on 5 March. All PSI staff attended an interactive session in the morning which explored how risk can be understood in the context of a regulatory body. This was followed by a further discussion session in the afternoon involving senior PSI staff together with invited guests from other professional regulators (CORU, Dental Council, Medical Council, Veterinary Council), the Mental Health Commission and the Department of Health. Feedback was very positive from attendees.

Review of organisation structures: This process is now well advanced, following the methodology proposed by our external consultants – facilitation of a “design team” consisting of 11 senior members of PSI management. A draft proposed model has emerged from the process which I discussed on a 1:1 basis with each member of the design team in the week of 1 April. We are now close to adopting the model which I believe will generate effectiveness gains for PSI and, because it is based on the principle that “structure follows strategy”, will increase our ability as an organisation to deliver on our strategic change agenda – both the current strategy and the next.

Judicial Review proceedings: On 26 March, legal representatives for the Pharmaceutical Assistants’ Association made an application to, and received leave from, the High Court to apply for judicial review of the decision of Council on 14 February 2019 to make Rules governing temporary absence. PSI and the Minister for Health are cited in the application. A detailed set of papers in relation to the review were served on PSI on 2 April. These are currently being reviewed in conjunction with our legal advisers. The first date for the matter to come back before the High Court is 28 May. This matter is in its very early stages and it is likely that the case will only be for mention on that date.

Meetings and events attended since 14 February Council meeting:

10 – 15 March: I attended a course on the Strategic Management of Regulatory and Enforcement Agencies at the Kennedy School of Government.

26 March: I chaired the second meeting of the Standards Advisory Group which is advising on the development of governance and accountability standards for retail pharmacy businesses.

4 April: I met a delegation of five pharmacy students representing students at the three Schools of Pharmacy.



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-** The second meeting of the Standards Advisory Group was held on 26 March 2019, and the breadth of stakeholders involved in this work were well represented at the meeting. The Group were provided with a number of presentations detailing the progression of this project. Specifically the group were updated on the progression of the standards development project and the results of the scoping element of this process. This scoping work included a Literature Review, Patient engagement at the HSE National Patient Forum, a Pharmacist Focus Group and a Scoping Consultation survey with pharmacists and other stakeholders. The results of these four work streams were presented to the group at the meeting and the supporting reports had already been provided to the group for their consideration. Following the presentation of this work to the group, a substantial discussion on the issues raised in the scoping process was held. This discussion led into advice from the group on the areas that the draft standards should address. The PPD Department will work on the drafting of these standards in light of these discussions and the scoping results, and draft standards will be presented to the advisory group at their next meeting on 4 June 2019.
- Accreditation compliance visits have been conducted at the remaining Higher Institutes of Education: Trinity College Dublin (February 2019) and the Royal College of Surgeons in Ireland (March 2019) providing the integrated MPharm programmes in pharmacy. Both courses are accredited until June 2020.
- The PSI has accepted two students on Year 4 placements as part of the integrated MPharm programme for 2019. The students will gain experience across a variety of projects at PSI, commencing in September 2019.
- The first Practice Review event for 2019 was held on the 6 and 7 of April 2019. Seventy-two pharmacists, in patient facing roles, were called for the event in October 2018. Practice Review comprises of two components: Clinical Knowledge Review and Standardised Pharmacy Interactions. Pharmacists receive a Performance Feedback Report approximately eight weeks after undertaking Practice Review. This report outlines whether demonstration of competence was observed during Practice Review, in each of the four competencies dealing with patient care as indicated in the CPD Rules 2015.



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 pharmacist survey issued on 26 March 2019 with a view to gaining feedback on the current vaccination and emergency medicine training requirements for pharmacists. The feedback will be included in a report to Council at their June meeting.
- National and international stakeholders have been consulted as part of the initial phase of the review project for the Accreditation Standards for the five-year fully integrated Master's degree programmes in pharmacy in Ireland. These standards are required to be reviewed every five years. September 2019 will commence the delivery of the final year of the first 5 year cycle for the integrated Masters programmes in pharmacy.
- Following on from the student protest in January this year, PSI met with representatives of the pharmacy student body on 4 April. The meeting provided a platform for both parties to explore the roles and responsibilities of the pharmacy regulator. Students expressed concerns over the financial strain which will be imposed on students as the final year of the pharmacy MPharm programme is not funded by the HEA. The student representatives suggested meeting more regularly with the PSI, which the PSI is open to doing, subject to terms of reference being agreed. This will be advanced between both parties with the intention of meeting on a twice-yearly basis.
- Following the March meeting of Council, the Annual Report and financial statements were submitted to the Minister and acknowledged. As at 9 April, we await notice of them being laid before the Oireachtas, after which the Annual Report will be published.
- Communications plan for publication and roll-out of the Code of Conduct is in train. We await notice from the Minister of his consent.
- The HSE, Epilepsy Ireland, OACS Ireland and Trinity College Dublin held a National Conference on the Consequences of Sodium Valproate (Epilim): 50 Years On, on 22 March 2019. Two colleagues from the PSI attended, and the response of the PSI and the work done in communicating with pharmacists in relation to Sodium Valproate was acknowledged by OACS Ireland.

- Two colleagues from the PSI attended a meeting co-ordinated by the Department of Health as part of BREXIT preparations - *Ensuring Continuity of Supply of Medicinal Products*. This was a joint meeting between DoH, HPRA, HSE and other relevant stakeholders.
- A member of the Executive attended a course on *Healthcare Professionalism, Leadership, Quality and Ethics*, held in RCSI. This course provided invaluable insights into a number of areas relevant to the launch and roll out of the revised Code of Conduct.
- The PSI is sitting on a Tobacco Addiction Diagnosis and Treatment Clinical Guideline Development Group co-ordinated by the HSE. This guideline is being developed to promote consistency of care in this area and will be submitted to the National Clinical Effectiveness Committee (NCEC) for approval as a national clinical guideline once completed. The guidelines are currently at drafting stage, a broad number of relevant stakeholders form the membership of this group.



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

- An application process was opened on Friday, 5 April to create a Disciplinary Committee panel in order to fill vacancies on the three committees over the next 2.5 years. To garner broad, diverse membership it has been circulated via registrants; stakeholders particularly public/patient advocacy networks; has been listed on the State Boards website with email also issued to State Board subscribers; a short media release issued. An assessment panel made up of two external people and two members of the Performance and Resources Committee will shortlist the applications received against the criteria provided. The Performance and Resources Committee has oversight of the process, and Council will be provided the recommended list of panel appointees at the June meeting.
- Following the review of the Pharmacy Assessment System, the content was updated, and Version 2 issued to all pharmacies in March. All registrants received an email notification that Version 2 is also available on the PSI website to complete online.
- The Professional Standards Authority held an Academic and Research Conference on '*What is it to be a good regulator?*' on 7 and 8 March in London. Two of our colleagues attended the conference, which was limited in numbers, to ensure maximum participation from all attendees. It was an extremely informative conference and afforded significant networking opportunities with other attendees and regulators from the UK, Canada and Australia across numerous specialities.
- An internal project group has been set up to oversee the potential move towards paperless inquiries. The project is currently still in the scoping stage to ascertain what technology will be required to ensure as seamless a move as possible. We expect the scoping stage to continue throughout quarter 2 of 2019.
- Following on from the review of the registrability of hospital-based RPBs undertaken late last year, we are now surveying all hospital-based RPBs to determine the level and nature of the professional services provided via the RPB.



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 election process is in train for purpose of filling four pharmacist member vacancies from mid-June. 11 candidates were declared following the nominations process and the election concludes on 17 April, with the count to be held in PSI House on Thursday, 18 April. Those selected will be notified to the Minister by the Returning Officer (the Registrar).
- Recruitment for six sanctioned posts is in progress as follows:
 - Interviews scheduled for following posts:
 - Communications and Engagement Executive
 - ICT Support Administrator
 - Education Standards Officer
 - Following posts have been advertised on Public Jobs:
 - Business Transformation Project Manager
 - Business Analyst
 - In-house Counsel.
- The staff-led Workplace Wellbeing Group marked National Workplace Wellbeing on Friday, 12 April with a series of activities for staff throughout that week.
- Following the staff survey, an all-staff engagement workshop was held on 9 April. Staff worked in teams to discuss the survey results and suggest recommendations to address some of the issues raised. An action plan will be developed with a staff implementation group to progress this area, with the aim of improving all of our staff engagements and initiatives. A second staff survey will be held during 2019.
- In relation to the Business Transformation Programme, the procurement process is in-flight (under the Competitive Dialogue Procedure) – see procurement update below. A second round of dialogue meetings is scheduled for the week commencing 7th May. A more detailed update will be provided by the Programme Board at the Council meeting.
- The PSI ICT Security User Manual which incorporates all ICT security policies was approved by ELT on 1st April. Policy roll-out will require a number of security improvements to ICT systems, applications and user awareness. Improvements will be rolled out over the next

two months. A new ICT Security User Manual is in development for Council and Committees to mirror staff requirements and obligations.

- An IT Security Assessment re-test was carried out in December 2018 to ensure the critical risks were resolved which was confirmed from the re-test. The few outstanding risks will be resolved by end of April.

Procurement activity update (total contract value of €25k or more)	Public Procurement procedure utilised and status
Digital transformation	The Preliminary Qualification Questionnaire (PQQ) stage of this Competitive Dialogue process is complete, and a shortlist for the Dialogue phase agreed. The evaluation team is in the process of meeting with the Dialogue participants. Contract award is anticipated for August 2019.
Merchant Services	We are drawing down from an OGP Framework contract. The suppliers have been notified, and we are currently going through the set-up process. Delivery is anticipated in May 2019.
Specialist Surveyors	This is being done through a Restricted Procedure (PQQ on eTenders followed by Invitation to Tender). The PQQ responses were evaluated on 11 th April, and the second part of the process has been put in train. A final outcome is expected in May 2019.
Facilities Management	Restricted Procedure will also be used for this procurement. Initial planning and specification meetings took place in early April. The tender process must be complete by mid July 2019.
Purchase of PC's, Laptops and Tablet Devices	We will draw down from an OGP Framework, and are currently awaiting the OGP to issue the tender submissions it has received from suppliers. The process is expected to be completed by June 2019.
New PSI website	An open framework tender will be used for the website redesign, hosting and support, with an initial two year contract. The request for tender document is currently being reviewed and finalised with an anticipated publication date of 30 th April.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 5 April 2019)

Fitness to Practise Concerns

Total concerns received in 2019	37
New concerns received since last report date (8 February 2019)	18
Concerns reviewed since last report date (8 February 2019)	25
Open concerns	8

Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received in 2019	20
New complaints received since last report date (8 February 2019)	14
Open complaints	30*
Complaints considered by PPC since last report date (8 February 2019)	10**

* 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	2
Heard since last report (8 February 2019)	2*
Cases being investigated/prepared for hearing	16**

* A further Inquiry opened since the last report date and was adjourned for a second day

** (13 – PCC & 3 - Health Committee)

Mediation

Heard year to date	1
Heard since last report date (8 February 2019)	1
Cases being prepared for mediation	1

Sanction Hearings/ Undertakings/Dismissals before Council

Heard year to date: sanction hearings	1
Cases being prepared for sanction hearing for Council	1*

* This case involves two pharmacists

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

Prosecutions

Heard year to date	1*
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* Proceedings withdrawn by Registrar at the District Court on foot of action taken by pharmacist Defendant

Suspension Applications

N/A

Appeal

N/A

Professional Registration (figures as at 5th April 2019)

- 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.
- 7 EPCs for establishment of service have been received (new European route of entry to recognition and registration) – 6 EPCs have been granted, and 1 is in process.
- 18 Certificates of Current Professional Status have been issued to date.
- 8 Restoration applications have been processed to date.
- 58 Voluntary Cancellation applications and 18 Involuntary Cancellations have been processed since 1st January 2019.
- 3 EU/TCQR Registration meetings held to date this year.
- 9 TCQR recognition applications received to date this year.
- 63 recognition/registration applications received to date this year.
- 1 National route applications received to date this year

Regulation of Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses (as at 5 April 2019)	
Number of Registered Retail Pharmacy Businesses as at	1943
Number of Retail Pharmacy Businesses Registered in 2019	49
Number of Retail Pharmacy Businesses Cancelled in 2019	51
Number of Changes in Supervising and Superintendent Pharmacists in 2019	148

Internet Supply (as at 5th April 2019)	
Number of Pharmacies on Part A	47
Number of Non-Pharmacies on Part B	76

Inspection Activity 2019 (as at 5th April 2019)	
Total number of Inspections	68
Number of Registration-related Inspections (Section 19)	35
Number of pharmacy inspections (Section 67)	33
- Systems	3
- Risk-based Inspections	20
- Re-inspections – including re-inspections following the Registrar's decision under Section 71(1)(d)	10

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
23	0	0
Investigation Fieldwork Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		2

Freedom of Information (FOI)

We have received two FOI requests year to date.