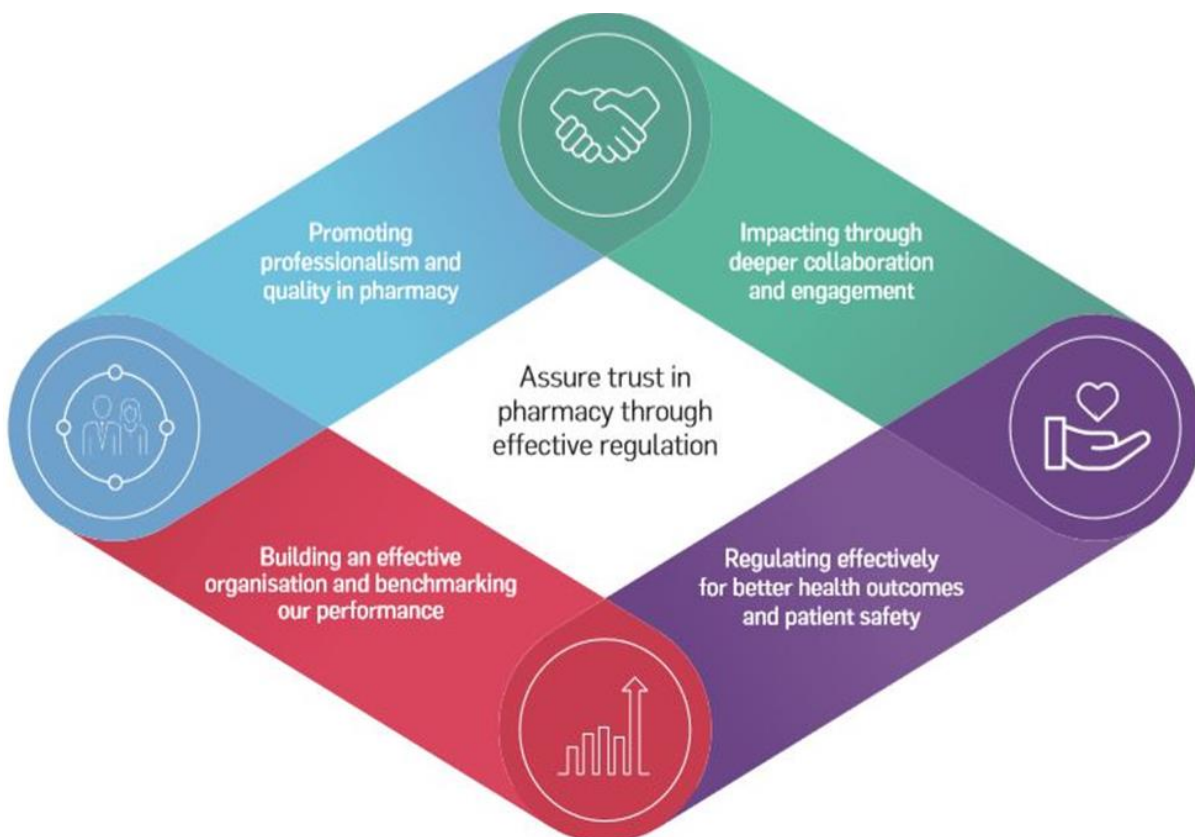


Report of the Registrar



20 June 2019

Highlights from the Registrar

Recognition for Excellence: We are making our submission for recognition under the EFQM Excellence Model in the week of 17 June. Despite many other competing priorities my colleagues have put extensive work into the submission and we are confident that this will be reflected in the results of the external assessment, scheduled to take place on 24 and 25 July. The submission preparation process has been a rich learning exercise and is an important plank in how we build a platform for increased organisational performance, effectiveness and quality over the next 3-5 years.

External relations: On 5 June, we hosted a meeting with the Chief Executives/Registrars of the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland. This was a very useful meeting which covered a range of matters of mutual interest, including Brexit. We have agreed to meet on a regular basis into the future.

ELT Review of Service Plan: The ELT had an off-site meeting on 1 May to review progress on this year's Service Plan objectives and related issues. Part of the day was also given over to a facilitated workshop for our wider management group on culture, change and compassionate leadership.

Election count: The count of votes in the election for pharmacist members of Council was held on 18 April. This was carried out in a smooth and timely way thanks to the efforts of my PSI colleagues, our independent scrutineers and the expertise of the Dublin City Council franchise staff.

Judicial Review proceedings: On 28 May, PSI's legal representatives attended at the High Court in relation to the judicial review proceedings initiated by the Pharmaceutical Assistants' Association. Leave was granted to PSI for a 4-week extension for submission of the PSI statement of opposition. The next date on which the matter will be for mention in Court will be in July.

Meetings and events attended since 17 April Council meeting:

11 May: I attended the Saturday session of the Irish Pharmacy Union Conference. Presentations from the morning's plenary session have been circulated to Council members for information.

16 May: I attended an initial meeting of a group of CEOs of regulatory bodies who are interested in working together on the design and implementation of risk-based regulation. A further meeting will take place later in the Summer.

16 May: I attended our regular meeting with the Chairs of both the Professional Conduct Committee and the Health Committee.

28 May: The PSI Executive met with representatives of the Irish Pharmacy Union for our regular liaison meeting.

29 May: I attended the regular meeting of the Governance Committee of the National Healthcare Quality Reporting System where I represent the Health and Social Care Regulators Forum.

6 June: I attended our regular Governance Meeting with the Department of Health. The 2018 Statement of Compliance with the Code of Practice for the Governance of State Bodies had been submitted to the Department prior to the meeting.

11 June: I attended a meeting with the Department of Health regarding the Council's objective to engage with the Department in a process leading to substantive reform of the Pharmacy Act, 2007. The meeting discussed the key points and the rationale for change and the areas potentially requiring reform. The DoH proposes further engagement with the PSI to develop the issues discussed and is supportive of legislative reform that promotes better standards, better accountability and better outcomes as regards public health and safety.



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

- The PSI received the outcomes report for ePortfolio Review 2018/2019 in May 2019, from the Executive Director of the Irish Institute of Pharmacy (IloP). The IloP undertook the review in line with the IloP ePortfolio Review Policy as approved by PSI Council on 21 June 2018, and according to the IloP 2018/19 ePortfolio Review Standards. A total of 1,338 pharmacists were invited to submit an extract of their ePortfolio for review in January 2019. 97.2% achieved an outcome of 'Standard Met'.
- The first meeting in 2019 of the Interprofessional Learning Working Group (of the health and social care regulators) was held at the offices of NMBI on 30 May 2019. The Group is continuing to work towards defining Interprofessional learning across the regulatory profession, and to promote collaborative care, in the best interests of patients and healthcare professionals.
- The revised Code of Conduct was approved by the Minister for Health on 14 May. Work continues in the PPD department on finalising the design of the revised Code and organising a programme of roadshows and webinars for pharmacists during Q3/4 this year and Q1/Q2 next year.
- Work continues on the first draft of Governance and Accountability Standards for Retail Pharmacy Business, ahead of the third meeting of the Standards Advisory Group on 25 June.



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 series of meetings have been held with stakeholders as part of the on-going work on the review project for the Accreditation Standards for the five-year fully integrated Master's degree programmes in pharmacy. 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.
- PSI, together with colleagues in the Irish Institute of Pharmacy (IIOP), attended the first meeting of CPD Executives, hosted by the Bar Council of Ireland. The Group membership comprises representatives from the Royal Institute of Architects in Ireland, Society of Chartered Surveyors Ireland, Society of Actuaries in Ireland, Society of Chartered Surveyors Ireland, Engineers Ireland and The Institute of Banking. The Group will meet to share learning and experience of CPD, including the use of eLearning platforms and CPD compliance policies.
- The PSI's 2018 Annual Report has been published following the Minister's consent and it has been laid before the Houses of the Oireachtas. A short press release was issued on 12 June. The published report, together with the financial statements, is available in both Irish and English on the PSI website.
- A member of the PPD Department attended a pharmaceutical care committee meeting of the European Directorate on the Quality of Medicines (EDQM) in Strasbourg on the 28th and 29th May, where issues pertaining to safe pharmacy practice, and medication safety were discussed. The committee acts as an advisory committee to the European Council. The PSI is collaborating with other European pharmacy regulators on developing a pharmaceutical care resolution for presentation to the European Council.
- A presentation on "The Role of the Pharmacist; the regulator's perspective", was provided by a PSI representative at a meeting of SAGE Advocacy, whose mission is "To promote, protect and defend the rights, and dignity of vulnerable adults, older people and healthcare patients" on the 30th May.

- A meeting between senior management of the HPRA and PSI was held on 22 May where issues of mutual concern were discussed.
- The PSI's Open Data Officer attended a meeting of the National Data Infrastructure (NDI) champions, hosted by DPER's Civil Service Renewal Programme Management Office, in the Department of the Taoiseach, to discuss cross-government data sharing initiatives.
- The Head of Regulation, Head of PPD and Head of Policy met with Department of Health officials to discuss possible developments in public health policy around vaccinations.



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

- Following the audit of hospital retail pharmacy businesses undertaken late last year, a questionnaire was recently issued to hospital pharmacies to determine the level and nature of the professional services provided via each of these RPBs.
- The National Patient Safety Office (NPSO) in the Department of Health is organising a meeting with the NPSO, the DoH Medicines Unit, HIQA and PSI to discuss the proposals for the licensing of hospitals via the Patient Safety (Licensing) Bill. This meeting will discuss how hospital pharmacy departments and the existing hospital RPBs can be regulated effectively in the context of this Bill.
- New FMD safety feature requirements came into effect on 9 February. During this time, the system in Ireland has been in ‘use and learn’ phase to ensure the continuity of safe supply of medicines to patients while all parties gained a better understanding of the new system. 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) has been closely monitoring progress since go live on 9 February. Taking all factors into account, the group has decided that the use and learn period will be further extended until 9 September 2019 to allow additional time for the system to stabilise. Key facts to date:
 - Significant progress has been made on several fronts since 9 February:
 - All **pharmacies** have registered with IMVO.
 - Between **50,000 and 60,000 thousand scans** are taking place daily in Irish pharmacies, hospitals and wholesalers and this number is growing week on week.
 - Barcode data for over **100 million packs** has been uploaded to the national system by manufacturers. The number of packs bearing 2D barcodes in pharmacies will increase over the coming weeks and months as these packs work their way through the supply chain.
 - Extensive analysis of alerts is taking place across Europe, resulting in greater understanding of their root causes and the rollout of initiatives to reduce the number of alerts being generated.

- The National Patient Safety Office in the DoH invited the PSI to provide observations on General Scheme of Patient Safety Bill. This Bill provides a legislative framework for several important patient safety issues including open disclosure of serious patient safety issues and mandatory external notification of those same patient safety issues to relevant regulatory bodies. The PSI welcomed the publication of the Bill and the value that such reporting has in creating a patient safety culture that is committed to quality improvement and learning from adverse events. The PSI recommended that Retail Pharmacy Businesses be included in such a notifications scheme and that serious patient safety incidents within a community pharmacy be reportable to PSI.
- Expressions of interest were sought from members of the public, and the pharmacy profession, for appointment to a Disciplinary Committee Panel. The Panel will be drawn upon as vacancies arise on any one of the PSI's three Disciplinary Committees, up to December 2021. A total of 159 applications were received. These consisted of 133 non-pharmacist applications and 26 pharmacist applications. Applicants from a wide range of professions and backgrounds participated in the process. Following an assessment process, a total of 27 applicants are being recommended to the Council for appointment to the Panel.
- The Preliminary Proceedings Committee has prepared an Annual Report identifying a number of issues following the Committee's consideration of complaints throughout 2018.



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 PSI's submission document to EFQM is being finalised for submission in the week of 17 June 2019. An assessment visit has been scheduled for the 25/25 July next, when assessors from the EFQM office will attend PSI House to carry out an evaluation visit.
- Progress continued with implementation of the PSI's HR Strategy 2018-2020 with the following key actions taking place:
 - The Engagement Survey Action Group was established in May with staff appointed following a call for expressions of interest and terms of reference agreed by the leadership team. The primary objective of this new staff-led group is to steer, prioritise and implement, in collaboration with the ELT, the initiatives it will propose as an action plan derived from the Staff Engagement Survey and the follow-up staff workshop held in April. The group has held three meetings since its establishment.
 - Learning & Development Framework - evaluation of the first round of applications in 2019 under the Learning and Development Policy for partial / full academic study support and paid study leave).
 - New Staff Handbook: 11 draft policies are about to issue to staff for consultation. A further 30 draft policies are at various stages of development.
- Expressions of interest were sought for external (non-Council) members for the Audit and Risk Committee. The notice had been published on the State Boards website and the PSI website. The Special Purposes Committee will convene, to make a recommendation for appointment, at its next meeting in August.
- The first governance meeting of 2019 between the PSI and officials of the Department of Health was held on 6 June.
- The Business Transformation Programme procurement process is in train (as per Competitive Dialogue Procedures), see procurement update below. The second round of dialogue meetings have concluded, and the procurement has moved into the tender phase. A more detailed update will be provided by the Programme Board at the Council meeting.

- **ICT Security:**
 - The PSI ICT Security User Manual - approved by ELT on 1 April – roll-out in train
 - New ICT Security User Manual in development for Council and Committees to mirror staff requirements and obligations
 - New mandatory online ICT security user awareness training approved by ELT on 28 May
- MyPSI intranet site, “MyPSI” was launched on 31 May. This is the first PSI intranet and is a central repository for key organisation documents, diary notices and events for staff.
- As part of ongoing ICT improvements for Council, the ICT team will be collecting all Council iPads at the end of the 20 June Council meeting. Essential upgrades and security measures will be implemented. As part of this process a PSI email address with access to Microsoft Outlook on PSI iPads will be provided to all Council members.
- The ICT team is currently evaluating the Council and PPC Committee members’ current board application, Acronis Access, with a view to replacing it with an affordable application and hardware that better suits the PSI’s requirements. We are currently in the early stages of this project with any possible changes being rolled out in 2020.
- Update on current procurement activity for contract values in excess of €25k:

Service/goods to be procured	Current status
Digital transformation services	Competitive Dialogue Procedure utilised. Pre-Qualification Questionnaire phase concluded in March followed by two rounds of the dialogue process in April/May with shortlisted vendors. ITT is currently in development for publication in June.
Merchant services	Concluded. Service changeover to take place in June.
Specialist surveyors	Restricted Procedure utilised. Pre-Qualification Questionnaire phase completed. ITT to be published in June.
PCs/laptops/tablet devices	Procurement concluded (OGP Framework drawdown) – at contract stage.
Facilities management	The Pre-Qualification Questionnaire (PQQ) closed phase closed end May. Evaluation in train to be followed by ITT phase.

Appendix 1 –Statistical Summary

Fitness to Practise (figures as at 7 June 2019)

Fitness to Practise Concerns

Total concerns received in 2019	58
New concerns received since last report date (5 April 2019)	21
Concerns reviewed since last report date (5 April 2019)	16
Open concerns FTP	18

Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received in 2019	36
New complaints received since last report date (5 April 2019)	16
Open complaints	39*
Complaints considered by PPC since last report date (5 April 2019)	12**

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

** 92% 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	4*
Heard since last report (5 April 2019)	2
Cases being investigated/prepared for hearing	17**

* 75% of which met KPI for the Inquiry to be held within 2 years from when the complaint was received. A further Inquiry (Inquiry number 5) opened since the last report date and was adjourned for a second day.

** (14 – PCC & 3 - Health Committee)

Mediation

Heard year to date	1
Heard since last report date (5 April 2019)	0
Cases being prepared for mediation	0

Sanction Hearings/ Undertakings/Dismissals before Council*

Heard year to date: sanction hearings	2**
Sanction hearings/undertakings being prepared for Council	5

* 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	1
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	2
Since last report (5 April 2019)	1
Section 44 Applications (Withdrawals)	1

Prosecutions

Heard year to date	1*
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* Proceedings were commenced in 2018 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 7 June 2019)

- 1 alert has 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.
- 10 EPCs for establishment of service have been received (new European route of entry to recognition and registration) – 9 EPCs have been granted, and 1 is in process.
- 28 Certificates of Current Professional Status have been issued to date.
- 12 Restoration applications have been processed to date.
- 61 Voluntary Cancellation applications and 19 Involuntary Cancellations have been processed since 1st January 2019.
- 5 EU/TCQR Registration meetings held to date this year.
- 11 Third Country Qualification Recognition applications received to date this year, with an additional 72 applications in process.
- 0 TCQR registration applications processed to date this year.
- 73 EU recognition/registration applications processed to date this year.
- 4 National route applications processed to date this year

Regulation of Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses (as at 7 June 2019)	
Number of Registered Retail Pharmacy Businesses	1948
Number of Retail Pharmacy Businesses Registered in 2019	72
Number of Retail Pharmacy Businesses Cancelled in 2019	69
Number of Changes in Supervising and Superintendent Pharmacists in 2019	253

Internet Supply (as at 7 June 2019)	
Number of Pharmacies on Part A	46
Number of Non-Pharmacies on Part B	75

Inspection Activity 2019 (year to date, as at 7 June 2019)	
Total number of Inspections	104
Number of Registration-related Inspections (Section 19)	50
Number of pharmacy inspections (Section 67)	54
<ul style="list-style-type: none"> - Systems - Risk-based Inspections - Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d) 	<div style="text-align: right;"> 4 38 12 </div>

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
20	0	3
Investigation Fieldwork Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		0